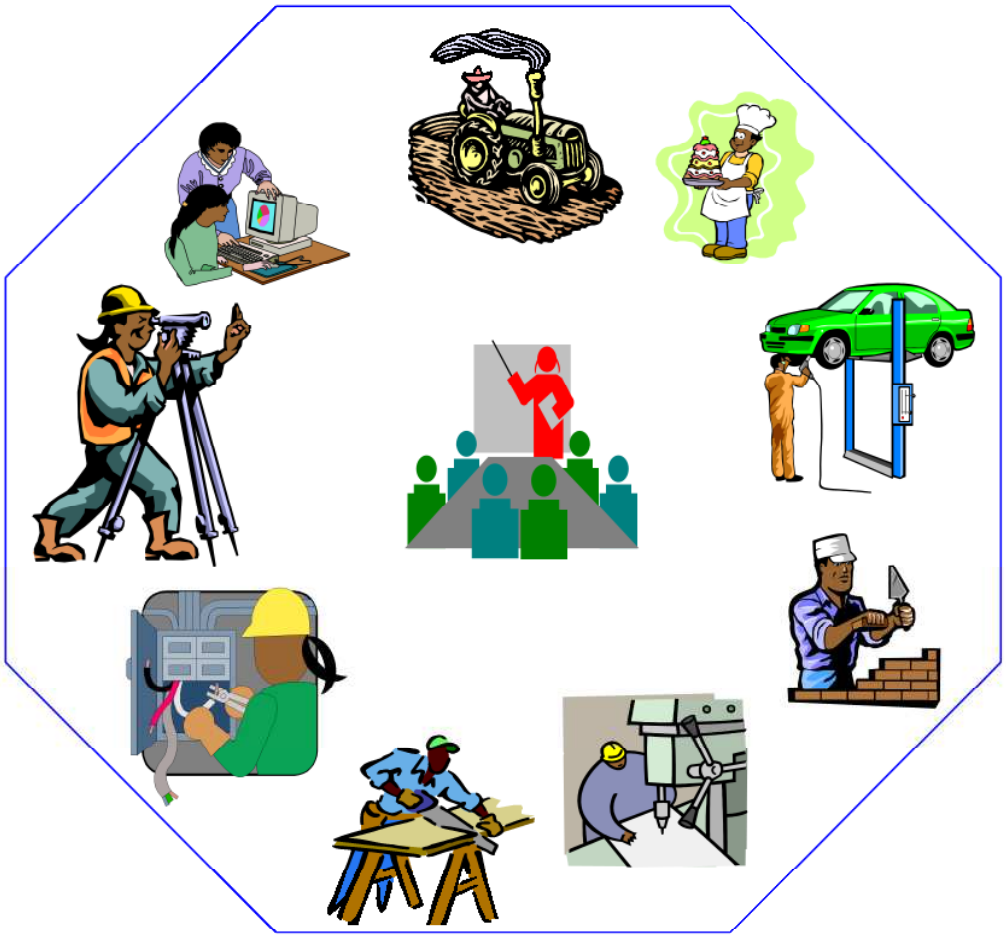
Federal Democratic Republic of Ethiopia

OCCUPATIONAL STANDARD

PHARMACEUTICALS MANUFACTURING

NTQF Level II and III



Ministry of Education
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Introduction

Ethiopia has embarked on a process of reforming its TVET-System. Within the policies and strategies of the Ethiopian Government, technology transformation – by using international standards and international best practices as the basis, and, adopting, adapting and verifying them in the Ethiopian context – is a pivotal element. TVET is given an important role with regard to technology transfer. The new paradigm in the outcome-based TVET system is the orientation at the current and anticipated future demand of the economy and the labour market.

The Ethiopia Occupational Standards (EOS) is the core element of the Ethiopian National TVET-Strategy and an important factor within the context of the National TVET-Qualification Framework (NTQF). They are national Ethiopian standards, which define the occupational requirements and expected outcome related to a specific occupation without taking TVET delivery into account.

This document details the mandatory format, sequencing, wording and layout for the Ethiopia Occupational Standard which comprised of Units of Competence.

A Unit of Competence describes a distinct work activity. It is documented in a standard format that comprises:

- Occupational title and NTQF level
- Unit title
- Unit code
- Unit descriptor
- Elements and Performance criteria
- Variables and Range statement
- Evidence guide

Together all the parts of a Unit of Competence guide the assessor in determining whether the candidate is competence.

The ensuing sections of this EOS document comprise a description of the occupation with all the key components of a Unit of Competence:

- Chart with an overview of all Units of Competence for the respective level (Unit of Competence Chart) including the Unit Codes and Unit Titles
- Contents of each Unit of Competence (competence standard)
- Occupational map providing the Technical and Vocational Education and Training (TVET) providers with information and important requirements to consider when designing training programs for this standards and for the individual, a career path

UNIT OF COMPETENCE CHART

Occupational Standard: Pharmaceuticals Manufacturing

Occupational Code: **IND PHR**

NTQF Level II

IND PHR2 01 0613 Apply Good Manufacturing Practice procedures	IND PHR2 02 0613 Operate a Water Purification Process	IND PHR2 03 0613 Operate a Compressing Process
IND PHR2 04 0613 Use Product Knowledge to Complete Work Operations	IND PHR2 05 0613 Dispense Pharmaceutical Raw Materials	IND PHR2 06 0613 Operate a Granulation Process
IND PHR2 07 0613 Operate a Drying Process	IND PHR2 08 0613 Operate a Mixing or Blending Process	IND PHR2 09 0613 Operate a Reduction Process
IND PHR2 10 0613 Apply Sampling Procedures	IND PHR2 11 0613 Use Numerical Applications in the Workplace	IND PHR2 12 0613 Operate a Tablet Coating Process
IND PHR2 13 0613 Coordinate a Label Store	IND PHR2 14 0613 Operate a Liquid Manufacturing Process	IND PHR2 15 0613 Operate a Filtration Process
IND PHR2 16 0613 Operate a Washing and Drying Process	IND PHR2 17 0613 Operate an Aseptic Fill and Seal Process	IND PHR2 18 0613 Inspect and Sort Materials and Product
IND PHR2 19 0613 Operate an Encapsulation Process	IND PHR2 20 0613 Operate a Process Control Interface	IND PHR2 21 0613 Apply Principles of Statistical Process Control
IND PHR2 22 0613 Operate a Packaging Process	IND PHR2 23 0613 Conduct Routine Maintenance	IND PHR2 24 0613 Clean and Sanitize Equipment

IND PHR2 25 0613 Operate a Boiler,– Basic	IND PHR2 26 0613 Operate an Homogenising Process	IND PHR2 27 0613 Handle Dangerous Goods/Hazardous Substances
IND PHR2 28 0613 Participate in Workplace Communication	IND PHR2 29 0613 Work in Team Environment	IND PHR2 30 0613 Develop Business Practice
IND PHR2 31 0613 Standardize and Sustain 3S		

NTQF Level III

IND PHR3 01 0613 Set up a Production or Packaging Line for Operation	IND PHR3 02 0613 Participate in Development and Adjustment of Production Schedule	IND PHR3 03 0613 Operate Processes in a Production System
IND PHR3 04 0613 Operate Interrelated Processes in a Production System	IND PHR3 05 0613 Monitor and Maintain the Implementation of Good Manufacturing Practice Procedures	IND PHR3 06 0613 Apply Raw Materials, Ingredient and Process Knowledge to Production Problems
IND PHR3 07 0613 Contribute to Development of Plant Documentation	IND PHR3 08 0613 Participate in Assessment Validation	IND PHR3 09 0613 Operate Interrelated Processes in a Packaging System
IND PHR3 10 0613 Identify Equipment Faults	IND PHR3 11 0613 Use Structured Problem Solving Tools	IND PHR3 12 0613 Monitor Storage Facilities
IND PHR3 13 0613 Monitor and Operate Trade Waste	IND PHR3 14 0613 Apply First Aid	IND PHR3 15 0613 Monitor the Implementation of Occupational Health and Safety Policies and Procedures
IND PHR3 16 0613 Apply Quality Control	IND PHR3 17 0613 Lead Workplace Communication	IND PHR3 18 0613 Lead Small Teams
IND PHR3 19 0613 Improve Business Practice	IND PHR3 20 0613 Prevent and Eliminate MUDA	

NTQF Level II

Occupational Standard: Pharmaceuticals Manufacturing Level II	
Unit Title	**Apply Good Manufacturing Practice procedures**
Unit Code	**IND PHR2 01 0613**
Unit Descriptor	This unit of competency covers the skills and knowledge required to comply with relevant Good Manufacturing Practice (GMP) codes through the implementation of workplace GMP and quality procedures. This unit applies to all production and packaging operators working in the pharmaceutical sector.

Elements	Performance Criteria
1. Identify requirements of GMP related to own work	1.1 Sources of information on GMP requirements are located. 1.2 GMP requirements and responsibilities related to own work are identified.
2. Ensure that personal hygiene and conduct meets GMP requirements	2.1 Personal hygiene meets GMP requirements. 2.2 Clothing is prepared, used, stored and disposed of according to GMP and workplace procedures. 2.3 Personal movement around the workplace is complied with area entry and exit procedures.
3. Implement GMP requirements when carrying out work activities	3.1 Work area, materials, equipment and product are routinely monitored to ensure compliance with GMP requirements. 3.2 Raw materials, packaging components and product are handled/ stored according to GMP and workplace procedures. 3.3 Workplace procedures to control resource allocation are followed to meet GMP requirements. 3.4 Common forms of contamination are identified and appropriate control measures are followed according to GMP requirements. 3.5 The workplace is maintained in a clean and tidy order to meet GMP housekeeping standards. 3.6 Work is conducted in accordance with workplace environmental guidelines. 3.7 Out-of-specification or contaminated materials, packaging components/consumables and product, waste and recyclable materials are handled and disposed of according to GMP requirements and workplace procedures. 3.8 Signs of ***unacceptable plant or equipment condition*** are identified and reported.

4. Participate in improving GMP	4.1 Processes, practices or conditions which could result in non-compliance with GMP are identified and reported according to workplace reporting requirements. 4.2 Corrective action is implemented within level of responsibility. 4.3 GMP issues are raised with designated personnel.
5. Complete workplace documentation to support GMP	5.1 Documentation and recording requirements are identified. 5.2 Information is recorded according to workplace reporting procedures to meet GMP requirements.

Variable	**Range**
Unacceptable plant or equipment condition	May include: • damage to plant or equipment • failure of cleaning regime • signs of pest infestation
Legislative requirements	to this industry includes: • relevant GMP codes • the Therapeutic Goods Act • other legislation and codes relevant to product and market • legislation relating to environmental management, Occupational Health and Safety (OHS), anti-discrimination and equal opportunity
Policies and procedures	Work activities are carried out according to company policies and procedures, FMHACA regulatory and licensing requirements, legislative requirements and industrial awards and agreements

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills in: • GMP is an ongoing and routine aspect of work responsibilities. Assessors should collect sufficient evidence to ensure that the skills and knowledge of this unit are routinely applied to the work environment. • Assessment must require the candidate to identify and demonstrate responsibilities for implementation of GMP in the workplace.
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • the role of GMP in preventing contamination, its relationship to legal requirements of pharmaceutical manufacturers and potential implications of non-compliance • GMP arrangements in the workplace, including relevant GMP codes of practice and related workplace policies and procedures to implement these responsibilities

	• the relationship between GMP and the quality system, personnel responsible for designing and managing GMP, personal role to maintain GMP, and the role of internal and external auditors as appropriate • procedures followed to investigate contamination events and performance improvement processes • personal clothing and footwear requirements for working in and/or moving between work areas • personal clothing use, storage and disposal requirements • awareness of common micro-biological, physical and chemical contaminants relevant to the work process, including the types of contamination likely to occur, such as cross-contamination, the conditions under which they occur, possible consequences and control methods to prevent occurrence • basic concepts of quality assurance, including quality specifications, operating parameters, validation procedures and control methods, and related documentation, including Standard Operating Procedures (SOPs) and/or batch instructions • control methods and procedures used in the work area to maintain GMP, including an understanding of the purpose of control, the consequence if not controlled and the method of control where relevant, as well as an understanding of the methods used to monitor process control • basic understanding of the properties, handling and storage requirements of raw materials, packaging components and final product handled and used • standards for materials, equipment and utensils used in the work area • procedures for responding to out-of-specification or unacceptable performance/outcomes • purpose of keeping records and the recording requirements of GMP, including product and materials traceability procedures • housekeeping requirements and responsibilities relating to own work, and use and storage of housekeeping/cleaning equipment where relevant • waste collection, recycling and handling procedures relevant to own work responsibilities • responsibilities for reporting and recording quality information
Underpinning Skills	Must demonstrate skills to: • locate and follow workplace information relating to GMP responsibilities • identify and report situations that do or could compromise GMP

	• participate in procedures to support GMP within level of responsibility • identify and respond to out-of-specification or unacceptable raw materials, packaging components, final or part processed product within level of responsibility • use oral communication skills/language competence to fulfil the job role as specified by the organization, including questioning, active listening, asking for clarification and seeking advice from supervisor • work cooperatively within a culturally diverse workforce
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competency may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competency may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level II	
Unit Title	**Operate a Water Purification Process**
Unit Code	**IND PHR2 02 0613**
Unit Descriptor	This unit of competency covers the skills and knowledge required to set up, operate, adjust and shut down a water purification process to produce water to meet production requirements.

Elements	Performance Criteria
1. Prepare the water purification equipment and process for operation	1.1 Materials are confirmed and available to meet operating requirements. 1.2 Cleaning and sanitising requirements and status are identified and confirmed. 1.3 Batch records or process documentation is completed. 1.4 Processing/operating parameters are entered and/or confirmed as required to meet safety and production requirements. 1.5 Equipment performance is checked and adjusted as required. 1.6 Pre-start checks are carried out as required by workplace requirements.
2. Operate and monitor the water purification process	2.1 ***Purification process*** is started and operated according to workplace procedures. 2.2 ***Water purification equipment*** is monitored to identify variation in operating conditions from those indicated in workplace documents or standard operating procedures. 2.3 Variation in ***equipment operation*** is identified and maintenance requirements are reported according to workplace reporting requirements. 2.4 The process is monitored to confirm that purified ***water*** is produced to specification. 2.5 Out-of-specification process outcomes are identified, rectified and/or reported to maintain the process within specification. 2.6 The work area is maintained according to housekeeping standards. 2.7 Work is conducted in accordance with workplace environmental guidelines. 2.8 Workplace records are maintained according to workplace recording requirements.

3. Shut down the water purification process	3.1 The appropriate shut down procedure is identified. 3.2 The process is shut down according to workplace procedures. 3.3 Workplace and/or batch documentation is completed. 3.4 Maintenance requirements are identified and reported according to workplace reporting requirements.

Variable	**Range**
Purification processes	Are typically continuous processes
Water purification equipment	May include: • dosing equipment • storage tanks • pumps • valves • distillation systems • reverse osmosis systems • UV light • deionization plants • softeners • carbon tanks and filters
Operation of equipment and processes	Typically requires: • the use of process control panels and systems
Water produced	May Include, but is not limited to: • purified water • deionised water • Reverse Osmosis (RO) • distilled water • Water For Injection (WFI)
Legislative requirements	Legislation relevant to this industry includes: • General procedures, including labeling, weights and measures legislation • legislation covering pharmaceuticals process includes, environmental management, OHS, anti-discrimination and equal opportunity
Workplace information	May include: • Standard Operating Procedures (SOPs) • specifications • production schedules and instructions • manufacturers' advice • standard forms and reports
Policies and procedures	Work is carried out according to company policies and procedures, regulatory and licensing requirements, legislative requirements, and industrial awards and agreements

Evidence Guide	
Critical Aspects of Competence	Must demonstrate skills and knowledge to: • conduct pre-start checks on machinery used for water purification • start, operate, monitor and adjust process equipment to achieve required quality outcomes • take corrective action in response to typical faults and inconsistencies • complete workplace records as required • apply safe work practices and identify OHS hazards and controls • safely shut down equipment
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • purpose and basic principles of the water purification process, including methods used to purify water appropriate to workplace requirements • basic operating principles of equipment, such as main equipment components, status and purpose of guards, equipment operating capacities and applications, and the purpose and location of sensors and related feedback instrumentation • services required and action to take if services are not available • the flow of the water purification process and the effect of outputs on downstream processes • quality characteristics to be achieved by the water purification process • quality requirements of inputs to the purification process and the effect of variation on process performance • operating requirements and parameters and corrective action required where operation is outside specified operating parameters • typical equipment faults and related causes, including following troubleshooting and problem solving guidelines, and recognizing signs and symptoms of faulty equipment and early warning signs of potential problems • basic operating principles of process control as appropriate, including the relationship between control panels and systems and the physical equipment • methods used to monitor the water purification process, such as inspecting, measuring and testing as required by the process • inspection or test points (control points) in the water purification process and the related procedures and recording requirements

	• Good Manufacturing Practice (GMP)/ safety requirements (as appropriate) associated with the purification process and related control measures • common causes of variation and corrective action required • Operational Health and Safety (OHS) hazards and controls • requirements of different shutdowns as appropriate to the water purification process and workplace production requirements, including emergency and routine shutdowns • isolation, lock out and tag out procedures and responsibilities • cleaning and sanitation procedures • procedures and responsibility for reporting production and performance information • environmental issues and controls relevant to the water purification process • sampling and testing associated with water purification process monitoring and control where relevant • routine maintenance procedures where relevant
Underpinning Skills	Must demonstrate skills to: • access workplace information to identify water purification process requirements • select, fit and use personal protective clothing and/or equipment • respond appropriately to hazards, including chemical spills • confirm supply of necessary materials and services • conduct pre-start checks, such as inspecting equipment condition to identify any signs of wear, selecting appropriate settings and/or related parameters, cancelling isolation or lockouts as required, confirming that equipment is clean and correctly configured for water purification process requirements, positioning sensors and controls correctly, ensuring any scheduled maintenance has been carried out, and confirming that all safety guards are in place and operational • start, operate, monitor and adjust water purification process equipment to achieve required outcomes, including monitoring control points and conducting inspections as required to confirm process remains within specification, such as: ➢ flow rates ➢ pressure ➢ operation of dosing equipment (where relevant) ➢ alarms ➢ monitor supply and flow of materials to and from the water purification process

	➢ take corrective action in response to out-of-specification results ➢ maintain a purification system free of physical, chemical and biological contaminants ➢ respond to and/or report equipment failure within level of responsibility ➢ locate emergency stop functions on equipment ➢ follow isolation and lock out/tag out procedures as required to take water purification process and related equipment off-line in preparation for cleaning/back flushing and/or maintenance within level of responsibility ➢ carry out cleaning, sanitizing, regenerating and back-flushing as required ➢ complete workplace records as required ➢ maintain work area to meet housekeeping standards ➢ collect samples and conduct tests according to enterprise procedures ➢ conduct routine maintenance according to enterprise procedures ➢ use oral communication skills/language competence to fulfill the job role as specified by the organization, including questioning, active listening, asking for clarification and seeking advice from supervisor ➢ work cooperatively within a culturally diverse workforce
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competency may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competency may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level II	
Unit Title	**Operate a Compressing Process**
Unit Code	**IND PHR2 03 0613**
Unit Descriptor	This unit of competency covers the skills and knowledge required to set up, operate, adjust and shut down the compressing process

Elements	Performance Criteria
1. Prepare the compressing process for operation	1.1 Materials are confirmed and available to meet operating requirements. 1.2 Cleaning and maintenance requirements and status are identified and confirmed according to ***workplace information***. 1.3 Machine components and related attachments are fitted and adjusted to meet operating requirements. 1.4 Processing/operating parameters are entered as required to meet safety and production requirements. 1.5 Equipment performance is checked and adjusted as required. 1.6 Pre-start checks are carried out as required by workplace requirements.
2. Operate and monitor the compressing process	2.1 The ***compressing process*** is started and operated according to workplace procedures. 2.2 Equipment is monitored to identify variation in operating conditions. 2.3 Variation in ***equipment operation*** is identified and maintenance requirements are reported according to workplace reporting requirements. 2.4 The process is monitored to confirm that tablet product meets specifications. 2.5 Out-of-specification product/process outcomes are identified, rectified and/or reported to maintain the process within specification. 2.6 The work area is maintained according to housekeeping standards. 2.7 Work is conducted according to environmental standards. 2.8 Spillages are reported and removed according to standard operating procedures. 2.9 Workplace records are maintained according to workplace recording requirements.

3. Shut down the compressing process	3.1 End-of-batch procedures are completed in accordance with batch instructions and Standard Operating Procedures (SOPs). 3.2 The process is shut down according to workplace procedures. 3.3 Maintenance requirements are identified and reported according to workplace reporting requirements.

Variable	**Range**
Workplace information	May include: • SOPs • specifications • production schedules and instructions • manufacturers' advice • standard forms and reports
Compressing equipment and accessories	May include: • single punch compressors • rotary compressors • punches and dies
Operation of equipment and processes	May require: • the use of process control panels and systems
Stock for the process	Is supplied from the granulation process and the dispensing process
Raw materials**/**ingredients	Which are added to the granulated product may include: • diluents • adhesives/binders • disintegrates • gladiants • lubricants • fillers • colorants • flavoring agents
In-process tests	May include: • appearance • hardness • friability • disintegration • weight and dimensions
Work	May involve exposure to dangerous and hazardous substances
Shutdown procedures	may include cleaning (in some cases cleaning may be carried out by a dedicated cleaning crew)
Services	May need to be confirmed. These depend on the nature of the process. Typical examples include: • power

	• steam • water • vacuum • gases, compressed and instrumentation air
Legislative requirements relevant to this industry includes:	• relevant Good Manufacturing Practice (GMP) codes, • the Therapeutic Goods Act and/or other relevant legislation, and • legislation covering environmental management, OHS, anti-discrimination and equal opportunity
Policies and procedures	Work is carried out according to company policies and procedures, regulatory and licensing requirements, legislative requirements, and industrial awards and agreements

Evidence Guide	
Critical Aspects of Competence	• conduct pre-start checks on equipment used for compressing • start, operate, monitor and adjust process equipment to achieve required quality outcomes • take corrective action in response to typical faults and inconsistencies • complete workplace records as required • apply safe work practices and identify OHS hazards and controls • safely shut down equipment • apply standard procedures to work practices.
Underpinning Knowledge and Attitudes	• purpose and basic principles of the compressing process • basic operating principles of equipment, such as main equipment components, status and purpose of guards, equipment operating capacities and applications, and the purpose and location of sensors and related feedback instrumentation • services required and action to take if services are not available • purpose and characteristics of ingredients/raw materials used and their role in the tablet • types of raw materials used in the encapsulation process and related handling/segregation requirements, including handling hazardous goods • stages and changes which occur during compression • quality characteristics and legal requirements to be achieved by the compressed tablet • the flow of the compressing process and the effect of outputs on downstream pharmaceutical processes • operating requirements and parameters and corrective action required where operation is outside specified operating parameters

	• typical equipment faults and related causes, including signs and symptoms of faulty equipment and early warning signs of potential problems • methods used to monitor the compressing process, such as inspecting, measuring and testing as required by the process • inspection or test points (control points) in the process and the related procedures and recording requirements • Good Manufacturing Practice (GMP) requirements associated with the compressing process and related control measures • common causes of variation and corrective action required • product/process changeover procedures and responsibilities • Occupational Health and Safety (OHS) hazards and controls, including the limitations of protective clothing and equipment relevant to the work process • end-of-batch procedures, including procedures for calculating yield, materials reconciliation and action required if yield/reconciliation are not within prescribed limits, and product labeling responsibilities and procedures • requirements of different shutdowns as appropriate to the compressing process and workplace production requirements, including emergency and routine shutdowns and procedures to follow in the event of a power outage • line clearance, cleaning and sanitation procedures • isolation, lock out and tag out procedures and responsibilities • procedures and responsibility for reporting production and performance information • environmental issues and controls relevant to the compressing process, including waste collection and handling procedures related to the process • basic operating principles of process control, where relevant, including the relationship between control panels and systems and the physical equipment • sampling and testing associated with process monitoring and control where relevant • routine maintenance procedures where relevant
Underpinning Skills	Must demonstrate skills to start, operate, and adjust process equipment to achieve required outcomes
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competency may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competency may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level II	
Unit Title	**Use Product Knowledge to Complete Work Operations**
Unit Code	**IND PHR2 04 0613**
Unit Descriptor	This unit involves the skills and knowledge required to use product knowledge to complete work operations in accordance with the relevant regulations and workplace requirements including identifying products in a subsection of a warehouse or other storage area, examining quality and reporting on products, and using inventory and labelling systems to identify and locate products. It involves the application of product knowledge and an understanding of relevant regulatory requirements to the handling and storage of various types of products/stock as part of work activities in the warehousing, distribution and/or storage industries.

Elements	Performance Criteria
1. Identify products in a subsection of a warehouse or other storage area	1.1 ***Products*** are identified against specified criteria in accordance with workplace procedures. 1.2 Storage and handling characteristics are identified and applied consistently. 1.3 Products are described to internal ***customers*** identifying features which may affect location, safety or storage requirements.
2. Examine quality and report on products	2.1 Products are inspected in accordance with workplace quality assurance procedures. 2.2 Workplace procedures are followed to replace, return or dispose of ***stock/products*** which are not useable. 2.3 Non-conforming products are recorded/reported in accordance with workplace procedures.
3. Use inventory and labelling systems to identify and locate products	3.1 ***Inventory and labeling systems*** are used to locate products within the workplace. 3.2 ***Goods*** are physically located and identified.

Variable	Range
Distinguishing identification criteria for products	May include: • shape • size • color • distinguishing features • codes and product identification/serial numbers • labels

	• signs or other documentation • locations
Customers	May be: • internal or external
Categories or groups of products/stock	May include: • small parts • overseas export • dangerous goods • refrigerated products • temperature controlled stock • fragile goods
The characteristics of products/stock	May include: • small parts • toxicity • flammability • form • weight • size • state • fragility • security risk
Inventory systems	May be: • automated • manual • paper-based • computerised • microfiche
Labelling systems	May include: • batch code • bar code • identification numbering systems • serial numbers • symbols for safe handling
Goods	May involve: • special handling, location, storage and/or packaging requirements, including temperature controlled goods and dangerous goods
Work	May be conducted: • in a range of work environments • by day or night May be conducted in: • limited or restricted spaces • exposed conditions • controlled or open environments

Communication in the work area	May include: • phone • Electronic Data Interchange (EDI) • fax • email • internet • RF systems • oral, aural or signed communications
Workplace procedures	May include: • company procedures • enterprise procedures • organizational procedures • established procedures
Personal protective equipment	May include: • gloves • safety headwear and footwear • safety glasses • two-way radios and high visibility clothing
Consultative processes	May involve: • other employees and supervisors • suppliers, customers and clients • relevant authorities and institutions • management and union representatives • industrial relations and OHS specialists • other maintenance, professional or technical staff
Hazards in the work area	May include: • chemicals • dangerous or hazardous substances • movements of equipment, goods and materials • oil or water on floor • a fire or explosion • damaged packaging or pallets • debris on floor • faulty racking • poorly stacked pallets and faulty equipment
Information/ documents	May include: • goods identification numbers and codes • manifests, picking slips, merchandise transfers, stock requisitions and bar codes • codes of practice and regulations relevant to the identification, handling and stacking of goods • international regulations and codes of practice for the handling, stacking and transport of dangerous goods and hazardous substances

	• operations manuals, job specifications and induction documentation • manufacturers specifications for equipment • workplace procedures and policies • supplier and/or client instructions • dangerous goods declarations and material safety data sheets (where applicable) • award, enterprise bargaining agreement, other industrial arrangements • quality assurance procedures • emergency procedures
Applicable regulations and legislation	May include: • relevant codes and regulations for the packaging of goods • international regulations and codes of practice for the handling and transport of dangerous goods and hazardous substances, including: • Ethiopian and International Dangerous Goods Codes • Ethiopian and International Explosives Codes • license, patent or copyright arrangements • water and road use and license arrangements • export/import/quarantine/bond requirements • marine orders • relevant state/territory OHS and environmental protection legislation • workplace relations regulations • workers compensation regulations

Evidence Guide	
Critical Aspects of Competence	Demonstration of applying: • the underpinning knowledge and skills • relevant legislation and workplace procedures • other relevant aspects of the range statement
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • Ethiopian regulations relevant to the products being identified, handled, transported, stacked and/or stored as part of work operations • Relevant OHS and environmental protection procedures and guidelines • Workplace procedures and policies for the identification, handling, stacking and storage of particular categories of products • Focus of operation of work systems, equipment, management and site operating systems for the packaging of goods • Categories or groups of products and the special handling, stacking and storage requirements for each

	• Purpose and use of cataloguing and labeling systems • Strategies to seek out sources of knowledge of products and use this information to inform work • Types of equipment and storage areas appropriate for different types of goods including fragile, dangerous, composition/state goods • Documentation requirements including reports and records concerning damaged or contaminated goods • Housekeeping standards procedures required in the workplace • Site layout and obstacles
Underpinning Skills	Must demonstrate skills to: • Communicate effectively with others when handling, transporting and storing products and providing information on products and services • Read and comprehend simple statements in English • Read and interpret instructions, procedures, information and signs relevant to the handling, transporting and storing of products and the provision of information on products and services • Identify containers and goods coding, markings and where applicable emergency information panels • Complete documentation related to work activities • Adapt appropriately to cultural differences in the workplace, including modes of behavior and interactions with others • Adapt to differences in products and services in accordance with standard operating procedures • Select and use required personal protective equipment conforming to industry and OHS standards • Select and use relevant communications, computing and load handling equipment • Estimate the size, shape and special requirements of goods and loads
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competency may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competency may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level II	
Unit Title	**Dispense Pharmaceutical Raw Materials**
Unit Code	**IND PHR2 05 0613**
Unit Descriptor	This unit of competency covers the skills and knowledge required to weigh, measure and label non-bulk ingredients to meet batch requirements. This unit applies to production operators working in the pharmaceutical sector. This person would typically work within defined Good Manufacturing Practice (GMP) programs and procedures. This unit typically targets the production worker responsible for applying basic operating principles to the operation and monitoring of measuring and dispensing equipment.

Elements	Performance Criteria
1. Prepare to dispense raw materials	1.1 ***Raw materials*** are inspected to confirm type, quality clearance, quantities and identify any obvious contamination or non-compliance. 1.2 Measuring and weighing equipment is selected appropriate to dispensing requirements and checked to confirm readiness for use. 1.3 Containers/bags and labels are available as required. 1.4 Pre-start checks are carried out as required by workplace requirements.
2. Measure and/or weigh raw materials	2.1 Non-bulk ingredients and additives are weighed/measured to meet production requirements. 2.2 Dispensed ingredients are labeled according to workplace procedure. 2.3 Accuracy of ***measuring/dispensing equipment*** is monitored to identify variation in operating conditions. 2.4 Variation in ***equipment operation*** is identified and maintenance requirements are reported according to workplace reporting requirements. 2.5 The work area is maintained according to housekeeping standards. 2.6 Work is conducted in accordance with workplace environmental guidelines.
3. Shut down the dispensing process	3.1 Dispensing equipment is cleaned according to workplace procedure. 3.2 Unacceptable equipment/utensil condition is identified and reported. 3.3 Dispensed materials are recorded and reconciled. 3.4 Maintenance requirements are identified and reported.

Variable	Range
Raw materials	May include: • drugs of addiction
Dispensing equipment	May include: • scales • pipettes • calibrated measuring containers • fume cabinets • labels/printers and related dispensary instrumentation
Operation of equipment and processes	May require: • the use of process control panels and systems
Legislative requirements	Are typically reflected in procedures and specifications. Legislation relevant to this industry includes: • relevant Good Manufacturing Practice (GMP) codes • the Therapeutic Goods Act and/or other relevant legislation • legislation covering environmental management, OHS, anti-discrimination and equal opportunity
Workplace information	May include: • Standard Operating Procedures (SOPs) • specifications • production/dispensing schedules and instructions • batch/recipe instructions • manufacturers' advice • standard forms and reports
Policies and procedures	Work is carried out according to company policies and procedures, regulatory and licensing requirements, legislative requirements, and industrial awards and agreements

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • weigh and measure materials to achieve required quantities • start, operate, monitor and adjust dispensing equipment to achieve required quality outcomes • take corrective action in response to typical faults and inconsistencies • complete workplace records as required • apply safe work practices and identify OHS hazards and controls
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • purpose and basic principles of the dispensing process, including the characteristics of raw materials and related handling requirements • dangerous goods handling requirements and procedures

	• relevant legislative responsibilities and workplace systems for recording information on dispensed pharmaceutical materials and related workplace coding and labeling systems and purpose • the relationship between the dispensing process and related operations, including an understanding of accuracy/tolerance and consequence of error • purpose, measuring/accuracy capacity of instrumentation and related equipment calibration responsibilities and procedures • control points in the dispensing process • procedures for calculating assay and adjusting potency • raw materials reconciliation purpose and procedures, such as reconciliation of drug addiction materials • GMP requirements associated with the dispensing process and related control measures • procedures for requisitioning, receiving and returning ingredients from stores • typical equipment faults and related causes, including signs and symptoms of faulty equipment and early warning signs of potential problems • OHS hazards and controls, including the limitations of protective clothing and equipment relevant to the work process • cleaning, care and storage of equipment and instrumentation used • procedures and responsibility for reporting production and performance information • environmental issues and controls relevant to the dispensing process, including waste/rework collection and handling procedures related to the process • sampling and testing associated with process monitoring and control where relevant
Underpinning Skills	Must demonstrate skills to: • access workplace information to identify dispensing requirements • select, fit and use personal protective clothing and/or equipment, such as breathing apparatus and fume cabinets as required • confirm supply of necessary raw materials, such as checking raw material labels and codes, quantity and quality clearance • conduct pre-start checks on equipment, such as inspecting the condition and cleanliness of equipment and utensils, taring scales and carrying out any related procedures to confirm that equipment is accurately calibrated and fit for use • measure materials and additives within specified accuracy range to meet batch requirements

	• calculate assay/potency adjustment • verify accuracy of raw materials dispensed with raw materials records • take corrective action in response to out-of-specification results • pace dispensing to meet production requirements • pack and label dispensed materials as required • follow labelling procedures • reconcile and record materials dispensed against materials released and return unused materials to storage as required • stack dispensed materials for transfer to designated location ensuring required material segregation • handle containers according to workplace procedures to maintain integrity of materials • clean dispensing equipment and utensils according to workplace procedures • respond to and/or report equipment failure within level of responsibility • complete dispensing records as required by workplace recording system • maintain work area to meet housekeeping standards • collect samples and conduct test according to enterprise procedures • use oral communication skills/language competence to fulfil the job role as specified by the organisation, including questioning, active listening, asking for clarification and seeking advice from supervisor • work cooperatively within a culturally diverse workforce
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competency may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competency may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level II	
Unit Title	**Operate a Granulation Process**
Unit Code	**IND PHR2 06 0613**
Unit Descriptor	This unit of competency covers the skills and knowledge required to set up, operate, adjust and shut down the granulation process. This unit has application in a pharmaceutical manufacturing environment. It typically targets the production worker responsible for applying basic operating principles to the operation and monitoring of a granulation process and equipment.

Elements	Performance Criteria
1. Prepare the granulation process for operation	1.1 Materials are confirmed and available to meet operating requirements. 1.2 Cleaning and maintenance requirements and status are identified and confirmed according to ***workplace information***. 1.3 Machine components and related attachments are fitted and adjusted to meet operating requirements. 1.4 Processing/operating parameters are entered as required to meet safety and production requirements. 1.5 Equipment performance is checked and adjusted as required. 1.6 Pre-start checks are carried out as required by workplace requirements.
2. Operate and monitor the granulation process	2.1 The ***granulation process*** is started up and operated according to workplace specifications. 2.2 ***Granulation equipment*** is monitored to identify variation in operating conditions. 2.3 Variation in ***equipment operation*** is identified and maintenance requirements are reported according to workplace reporting requirements. 2.4 The process is monitored to confirm that granulated product meets specifications. 2.5 Out-of-specification product/process outcomes are identified, rectified and/or reported to maintain the process within specification. 2.6 The work area is maintained according to housekeeping standards. 2.7 Work is conducted according to environmental standards. 2.8 Spillages are reported and removed according to Standard Operating Procedures (SOPs). 2.9 Workplace records are maintained according to workplace recording requirements.

3. Shut down the granulation process	3.1 End-of-batch procedures are completed in accordance with batch instructions and SOPs. 3.2 The process is ***shut down*** according to workplace procedures. 3.3 Maintenance requirements are identified and reported according to workplace reporting requirements.

Variable	**Range**
Workplace information	May include: • SOPs • specifications • production schedules and instructions • manufacturers' advice • standard forms and reports
Granulation process	May be: • a dry or wet process or a combination
Granulation equipment	May include: • granulators • mixers • blenders • dryers • oscillators • mills • sieves • Fluidized Bed Dryer (FBD)
Operation of equipment and processes	May require: • the use of process control panels and systems
Shutdown procedures	May include cleaning (in some cases cleaning may be carried out by a dedicated cleaning crew)
Stock	• for the granulation process is supplied from the dispensing process and from bulk containers
Services	May need to be confirmed. These depend on the nature of the process. Typical examples include: • power • steam • water • compressed and instrumentation air
Policies and procedures	Work is carried out according to company policies and procedures, regulatory and licensing requirements, legislative requirements, and industrial awards and agreements
Legislative requirements	relevant to this industry includes: • relevant Good Manufacturing Practice (GMP) codes • the Therapeutic Goods Act and/or other relevant legislation

	• legislation covering environmental management, OHS, anti-discrimination and equal opportunity

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge skills to: • conduct pre-start checks on equipment used for granulation • start, operate, monitor and adjust process equipment to achieve required quality outcomes • take corrective action in response to typical faults and inconsistencies • complete workplace records as required • apply safe work practices and identify OHS hazards and controls • safely shut down equipment
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • purpose and basic principles of the granulation process • basic operating principles of equipment, such as main equipment components, status and purpose of guards, equipment operating capacities and applications, and the purpose and location of sensors and related feedback instrumentation • services required and action to take if services are not available • types of raw materials used in the granulation process and related handling/segregation requirements, such as handling hazardous goods • stages and changes which occur during granulation • quality characteristics and legal requirements to be achieved by the granulation process • the flow of the granulation process and the effect of outputs on downstream pharmaceutical processes • operating requirements and parameters and corrective action required where operation is outside specified operating parameters • typical equipment faults and related causes, including signs and symptoms of faulty equipment and early warning signs of potential problems • methods used to monitor the granulation process, such as inspecting, measuring and testing as required by the process • inspection or test points (control points) in the granulation process and the related procedures and recording requirements • Good Manufacturing Practice (GMP) requirements associated with the granulation process and related control measures • common causes of variation and corrective action required

	• product/process changeover procedures and responsibilities • Occupational Health and Safety (OHS) hazards and controls, including the limitations of protective clothing and equipment relevant to the work process • end-of-batch procedures, including procedures for calculating yield, materials reconciliation and action required if yield/reconciliation is not within prescribed limits, and product labelling responsibilities and procedures • requirements of different shutdowns as appropriate to the granulation process and workplace production requirements, including emergency and routine shutdowns and procedures to follow in the event of a power outage • line clearance, cleaning and sanitation procedures • isolation, lock out and tag out procedures and responsibilities • procedures and responsibility for reporting production and performance information • environmental issues and controls relevant to the granulation process, including waste collection and handling procedures related to the process • basic operating principles of process control, where relevant, including the relationship between control panels and systems and the physical equipment • sampling and testing associated with process monitoring and control where relevant • routine maintenance procedures where relevant
Underpinning Skills	• access workplace information to identify production requirements for the granulation process • select, fit and use personal protective clothing and/or equipment • confirm supply of necessary materials and services • conduct pre-start checks, such as inspecting equipment condition to identify any signs of wear, selecting appropriate settings and/or related parameters, cancelling isolation or lock outs as required, confirming line clearance and cleaning status, ensuring equipment is correctly configured for processing requirements, positioning sensors and controls correctly, ensuring any scheduled maintenance has been carried out, and confirming that all safety guards are in place and operational • verify raw materials with batch instructions • start, operate, monitor and adjust granulation process equipment to achieve required outcomes, including interpreting and implementing batch instructions, labelling product, calculating yield, monitoring control points and conducting inspections as required to confirm process remains within specification, such as:

	➢ granule size ➢ moisture content • take corrective action in response to out-of-specification results • monitor supply and flow of materials to and from the granulation process • respond to and/or report equipment failure within level of responsibility • locate emergency stop functions on equipment • follow isolation and lock out/tag out procedures as required to take granulation process and related equipment off-line in preparation for cleaning and/or maintenance within level of responsibility • demonstrate batch/product changeovers • follow end-of-batch procedures including line clearance and cleaning, yield calculation, materials reconciliation and product labelling • complete workplace records as required • maintain work area to meet housekeeping standards • use process control systems according to enterprise procedures • collect samples and conduct tests according to enterprise procedures • conduct routine maintenance according to enterprise procedures • use oral communication skills/language competence to fulfill the job role as specified by the organization, including questioning, active listening, asking for clarification and seeking advice from supervisor • work cooperatively within a culturally diverse workforce
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competency may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competency may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level II	
Unit Title	**Operate a Drying Process**
Unit Code	**IND PHR2 07 0613**
Unit Descriptor	This unit of competency covers the skills and knowledge required to set up, operate, adjust and shut down a drying process.

Elements	Performance Criteria
1. Prepare the drying process for operation	1.1 ***Materials*** are confirmed and available to meet operating requirements. 1.2 Cleaning and maintenance requirements and status are identified and confirmed according to ***workplace information***. 1.3 Processing and operating parameters are entered as required to meet safety and production requirements. 1.4 Equipment performance is checked and adjusted as required. 1.5 Pre-start checks are carried out as required by workplace requirements.
2. Operate and monitor the drying process	2.1 The process is started and operated according to workplace procedures. 2.2 ***Drying equipment*** is monitored to identify variation in operating conditions. 2.3 Variation in ***equipment operation*** is identified and maintenance requirements are reported according to workplace reporting requirements. 2.4 The process is monitored to confirm that specifications are met. 2.5 Out-of-specification product/process outcomes are identified, rectified and/or reported to maintain the process within specification. 2.6 The work area is maintained according to housekeeping standards. 2.7 Work is conducted in accordance with workplace environmental guidelines. 2.8 Workplace records are maintained according to workplace recording requirements.
3. Shut down the drying process	3.1 The appropriate ***shut down procedure*** is identified. 3.2 The process is shut down according to workplace procedures.

	3.3 Maintenance requirements are identified and reported according to workplace reporting requirements.

Variable	Range
Materials	May include product to be dried and additives or drying agents as required, consistent with the provisions as per standard procedures.
Workplace information	May include: • Standard Operating Procedures (SOPs) • specifications • production schedules and instructions • manufacturers' advice • standard forms and reports
Drying equipment	May include: • drying chambers • atomisers • heaters • coolers • air filters • fans • recovery cyclones • conveyors
Operation of equipment and processes	May require: • the use of process control panels and systems
Shutdown procedures	May include cleaning, (in some cases cleaning may be carried out by a dedicated cleaning crew)
Services	Typical examples include: • power • fuel • steam • water • compressed and instrumentation air
Policies and procedures	Work is carried out according to company policies and procedures, regulatory and licensing requirements, legislative requirements, and industrial awards and agreements
Legislative requirements	relevant to this industry includes: • general Standards, including labeling, weights and measures legislation • legislation covering pharmaceuticals processing, environmental management, OHS, anti-discrimination and equal opportunity

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • conduct pre-start checks on machinery used for drying

	• start, operate, monitor and adjust process equipment to achieve required quality outcomes • take corrective action in response to typical faults and inconsistencies • complete workplace records as required • apply safe work practices and identify OHS hazards and controls • safely shut down equipment
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • purpose and basic principles of the drying process, including the stages that occur during the drying process and the effect on product structure of each stage • basic operating principles of equipment, including main equipment components, status and purpose of guards, equipment operating capacities and applications, and the purpose and location of sensors and related feedback instrumentation • services required and action to take if services are not available • quality characteristics to be achieved by the process • materials preparation requirements and effect of variation on the process • the flow of the drying process and the effect of outputs on downstream processes • operating requirements and parameters and corrective action required where operation is outside specified operating parameters • typical equipment faults and related causes, including signs and symptoms of faulty equipment and early warning signs of potential problems • methods used to monitor the drying process, such as inspecting, measuring and testing as required by the process • inspection or test points (control points) in the process and the related procedures and recording requirements • contamination risks associated with the process and related control measures • common causes of variation, such as air temperature, air velocity, humidity and pressure, and corrective actions required if these are out-of-specification • OHS hazards and controls, including limitations of protective clothing and equipment relevant to the work process • requirements of different shutdowns as appropriate to the process and workplace production requirements, including emergency and routine shutdowns and procedures to follow in the event of a power outage

	• isolation, lock out and tag out procedures and responsibilities • procedures and responsibility for reporting production and performance information • environmental issues and controls relevant to the drying process, including waste/rework collection and handling procedures related to the process • basic operating principles of process control where relevant, including the relationship between control panels and systems and the physical equipment • product/process changeover procedures and responsibilities where relevant • routine maintenance procedures where relevant • sampling and testing associated with process monitoring and control where relevant • cleaning and sanitation procedures where relevant
Underpinning Skills	Must demonstrate skills to: • access workplace information to identify processing requirements • select, fit and use personal protective clothing and/or equipment • confirm supply of necessary materials and services • prepare materials as required • conduct pre-start checks, such as inspecting equipment condition (e.g. checking belts, chains, screens, seals and valves, and filters) to identify any signs of wear, selecting appropriate settings and/or related parameters, cancelling isolation or lockouts as required, confirming that equipment is clean and correctly configured for processing requirements, positioning sensors and controls correctly, ensuring any scheduled maintenance has been carried out, and confirming that all safety guards are in place and operational • start, operate, monitor and adjust process equipment to achieve required outcomes, including monitoring control points and conducting inspections as required to confirm process remains within specification, such as: ➢ temperatures ➢ moisture content ➢ air flow ➢ throughput ➢ time/speed ➢ pressure/vacuum and product characteristics • monitor supply and flow of materials to and from the process • take corrective action in response to out-of-specification results or non-compliance

	• respond to and/or report equipment failure within level of responsibility • report and/or record corrective action as required • locate emergency stop functions on equipment • follow isolation and lock out/tag out procedures as required to take process and related equipment off-line in preparation for cleaning and/or maintenance within level of responsibility • prepare equipment for cleaning • complete workplace records as required • maintain work area to meet housekeeping standards • use process control systems according to enterprise procedures • demonstrate product/batch changeovers (may not apply to some continuous operations) according to enterprise procedures • conduct routine maintenance according to enterprise procedures • clean and sanitize equipment according to enterprise procedures • collect samples and conduct tests according to enterprise procedures • use oral communication skills/language competence to fulfil the job role as specified by the organization, including questioning, active listening, asking for clarification and seeking advice from supervisor • work cooperatively within a culturally diverse workforce
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competency may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competency may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level II	
Unit Title	**Operate a Mixing or Blending Process**
Unit Code	**IND PHR2 08 0613**
Unit Descriptor	This unit of competency covers the skills and knowledge required to combine ingredients and additives in the correct quantities and sequence and to operate and shut down mixing and blending equipment to achieve the required mix characteristics.

Elements	Performance Criteria
1. Prepare the mixing or blending equipment and process for operation	1.1 Materials are confirmed and available to meet production requirements. 1.2 Pre-mixes are prepared according to ***workplace information***. 1.3 Cleaning and maintenance requirements and status are identified and confirmed according to workplace guide lines. 1.4 Machine components and related attachments are fitted and adjusted to meet operating requirements. 1.5 Processing or operating parameters are entered as required to meet production requirements. 1.6 Equipment performance is checked and adjusted as required. 1.7 Pre-start checks are carried out as required by workplace requirements.
2. Operate and monitor the mixing or blending process	2.1 ***Ingredients and additives*** are delivered to the mixer in the required quantities and sequence to meet recipe specifications. 2.2 The ***mixing or blending process*** is started and operated according to workplace procedures. 2.3 Equipment is monitored to identify variation in operating conditions. 2.4 Variation in ***equipment operation*** is identified and maintenance requirements are reported according to workplace reporting requirements. 2.5 The ***mixing process*** is monitored to confirm that specifications are met. 2.6 Out-of-specification product or process outcomes are identified, rectified and/or reported to maintain the process within specification.

	2.7 ***Mix*** is transferred to required production or storage location. 2.8 The work area is maintained according to housekeeping standards. 2.9 Work is conducted in accordance with workplace environmental guidelines. 2.10 Workplace records are maintained according to workplace recording requirements.
3. Shut down the mixing or blending process	3.1 The appropriate ***shutdown procedure*** is identified. 3.2 The process is shut down according to workplace procedures. 3.3 Maintenance requirements are identified and reported.

Variable	**Range**
Workplace information	May include: • Standard Operating Procedures (SOPs) • specifications • production schedules and instructions • manufacturers' advice • consignment notes • verification procedures • standard forms and reports
Ingredient addition	May involve operation of: • automatic materials transfer equipment • dosing equipment and/or be manually loaded
Mixing or blending equipment	Typically includes: • measuring and weighing equipment, such as scales, load cells • dosing equipment • mixers • pumps • in-line homogenizers • conveyors • bulk materials transfer and materials handling equipment • storage facilities • Common mixer types include: • ribbon and vertical screw mixers/conveyors
Operation of equipment and processes	May require: • the use of process control panels and systems
Mixes	Typically includes: • concentrated pre-mixes • pastes

	• bulk mixes/blends • powders • Materials may include: • bulk and non-bulk ingredients and additives
Processes	may include: • extruding • stamping • pedal mixing • homogenizing and agitator
Shutdown procedures	May include cleaning (in some cases cleaning may be carried out by a dedicated cleaning crew)
Services	Typical examples include: • power • steam • vacuum • compressed and instrumentation air
Policies and procedures	Work is carried out according to company policies and procedures, regulatory and licensing requirements, legislative requirements, and industrial awards and agreements
Legislative requirements	relevant to this industry includes: • the Standards Code, including labeling, weights and measures legislation • legislation covering pharmaceuticals manufacturing safety, environmental management, OHS, anti-discrimination and equal opportunity to the pharmaceutical industry, current Good Manufacturing Practice (cGMP) code is applied

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • prepare premixes for mixing or blending • conduct pre-start checks on machinery used for mixing or blending • start, operate, monitor and adjust process equipment to achieve required quality outcomes • take corrective action in response to typical faults and inconsistencies • complete workplace records as required • apply safe work practices and identify OHS hazards and controls • safely shut down equipment
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • purpose and basic principles of preparing mixes and blends, including the characteristics and basic function of ingredients and additives used, method and sequence of ingredient addition required to achieve required blend

	characteristics, and where relevant, the purpose of conditioning, maturation or holding stages required prior to further processing of the mix • basic understanding of specific gravity and bulk density as appropriate for ingredients used • basic operating principles of mixing/blending equipment, including main equipment components, status and purpose of guards, equipment operating capacities and applications, the purpose and location of sensors and related feedback instrumentation, and awareness of calibration schedules for scales and related weighing/measuring equipment • services required and action to take if services are not available • the flow of the mixing process and the effect of mix preparation on downstream processes • procedures for requisitioning, receiving and returning ingredients from stores • ingredient handling requirements and shelf-life or coding • quality characteristics required of ingredients and additives and their effect on mixing process performance, including methods used to condition or prepare ingredients prior to addition • methods used to monitor the blending or mixing process, including inspecting, measuring, and testing as required by the process • inspection or test points (control points) in the process and the related procedures and recording requirements, such as: ➢ flow rates ➢ ingredient/additive addition sequence ➢ times/temperatures and agitator speeds ➢ required characteristics of blend, such as viscosity, appearance and temperature ➢ required attributes of the mixed or blended output, such as chemical, texture and flavour profiles as required ➢ the effect of the mixing or blending parameters, such as temperature and length of mix time on mixing outcome ➢ contamination and risks associated with the process and related control measures, including product compatibility and cross contamination risks and associated cleaning requirements, as well as common allergens used in mixes prepared • operating requirements and parameters and corrective action required where operation is outside specified operating parameters • typical equipment faults and related causes, including signs and symptoms of faulty equipment and early warning signs

	of potential problems • common causes of variation and corrective action required • Occupational Health and Safety (OHS) hazards and controls • requirements of different shutdowns as appropriate to the blending or mixing process and workplace production requirements, including emergency and routine shutdowns and procedures to follow in the event of a power outage • product or process changeover procedures and responsibilities • isolation, lock out and tag out procedures and responsibilities • procedures and responsibility for reporting production and performance information • environmental issues and controls relevant to the mixing or blending process, including waste or rework collection and handling procedures related to the process • basic operating principles of process control, where relevant, including the relationship between control panels and systems and the physical equipment • characteristics of solutions, suspensions and emulsions where relevant • sampling and testing associated with process monitoring and control where relevant • product labelling and storage requirements where relevant • routine maintenance procedures where relevant • cleaning and sanitation procedures where relevant
Underpinning Skills	Must demonstrate skills to: • access workplace information to identify mixing/blending requirements • select, fit and use personal protective clothing and/or equipment • confirm supply of necessary materials and services • conduct pre-start checks, such as inspecting equipment condition to identify any signs of wear, selecting appropriate settings and/or related parameters, cancelling isolation or lockouts as required, confirming that equipment is clean and correctly configured for processing requirements, positioning sensors and controls correctly, ensuring any scheduled maintenance has been carried out, and confirming that all safety guards are in place and operational • add/load materials in correct quantities and sequence, such as monitoring automatic ingredient addition and/or manual addition • start, monitor and adjust mixing or blending process equipment to achieve required outcomes, including monitoring flow rates/quantity, time or temperature and

	mix/blending settings • monitor control points and conduct inspections as required to confirm process remains within specification • monitor supply and flow of ingredients and additives to and from the mixing or blending process • pace mixing/blending to meet production requirements • take corrective action in response to out-of-specification results • respond to and/or report equipment failure within level of responsibility • locate emergency stop functions on equipment • follow isolation and lock out or tag out procedures as required to take process and related equipment off-line in preparation for cleaning and/or maintenance within level of responsibility • complete workplace records as required • demonstrate batch or product changeovers • maintain work area to meet housekeeping standards • use process control systems according to enterprise procedures • collect samples and conduct tests according to enterprise procedures • label and store pre-mixes and/or mixes according to enterprise procedures • conduct routine maintenance according to enterprise procedures • clean and sanitize equipment according to enterprise procedures • use oral communication skills/language competence to fulfil the job role as specified by the organization, including questioning, active listening, asking for clarification and seeking advice from supervisor • work cooperatively within a culturally diverse workforce
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competency may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competency may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level II	
Unit Title	**Operate a Reduction Process**
Unit Code	**IND PHR2 09 0613**
Unit Descriptor	This unit of competency covers the skills and knowledge required to set up, operate, adjust and shut down a reduction process to mill and sift particles to gradually reduce particle size to meet specifications

Elements	Performance Criteria
1. Prepare the reduction equipment and process for operation	1.1 Materials are confirmed and available to meet operating requirements. 1.2 Cleaning and maintenance requirements and status are identified and confirmed according to ***workplace information***. 1.3 Machine components and related attachments are fitted and adjusted to meet operating requirements. 1.4 Processing/operating parameters are entered as required to meet safety and production requirements. 1.5 Equipment performance is checked and adjusted as required. 1.6 Pre-start checks are carried out as required by workplace requirements.
2. Operate and monitor the reduction process	2.1 The process is started and operated according to workplace procedures. 2.2 ***Reduction equipment*** is monitored to identify variation in operating conditions. 2.3 Variation in ***equipment operation*** is identified and maintenance requirements are reported according to workplace reporting requirements. 2.4 The process is monitored to confirm that particle size and flour extraction rates meet production specifications. 2.5 Out-of-specification product/process outcomes are identified, rectified and/or reported to maintain the process within specification. 2.6 By-product generated from the reduction process is segregated and transferred to designated storage area according to safety requirements. 2.7 The work area is maintained according to housekeeping standards.

	2.8 Work is conducted in accordance with workplace environmental guidelines. 2.9 Workplace records are maintained according to workplace recording requirements.
3. Shut down the reduction process	3.1 The appropriate ***shutdown procedure*** is as per the operating manual. 3.2 The process is shut down according to workplace procedures. 3.3 Maintenance requirements are identified and reported according to workplace reporting requirements .

Variable	**Range**
Workplace information	May include: • Standard Operating Procedures (SOPs) • specifications • production schedules and instructions • manufacturers' advice • standard forms and reports
Reduction equipment	May include: • reduction rolls • plain sifters • miller
Operation of equipment and processes	May require: • the use of process control panels and systems • SOP for operation of equipment
Shutdown procedures	May include: • cleaning (in some cases cleaning may be carried out by a dedicated cleaning crew
Services	May need to be confirmed. These depend on the nature of the process. Typical examples include: • power • vacuum • compressed and instrumentation air
Policies and procedures	Work is carried out according to company policies and procedures, regulatory and licensing requirements, legislative requirements, and industrial awards and agreements
Legislative requirements	Are typically reflected in procedures and specifications. Legislation relevant to this industry includes: • the Standards Code, including labeling, weights and measures legislation • legislation covering safety, environmental management, OHS, anti-discrimination and equal opportunity

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • Prepare the reduction equipment and process for operation • Operate and monitor the reduction process • Shut down the reduction process
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • purpose and basic principles of the reduction process • basic operating principles of equipment, such as main equipment components, status and purpose of guards, equipment operating capacities and applications, and the purpose and location of sensors and related feedback instrumentation • services required and action to take if services are not available • the flow of the reduction process and the effect of outputs on downstream flour milling processes • quality characteristics to be achieved by the reduction process • quality requirements of materials and effect of variation on reduction process performance • operating requirements and parameters and corrective action required where operation is outside specified operating parameters • typical equipment faults and related causes, including signs and symptoms of faulty equipment and early warning signs of potential problems • methods used to monitor the reduction process, such as inspecting, measuring and testing as required by the process • inspection or test points (control points) in the reduction process and the related procedures and recording requirements • contamination/food safety risks associated with the reduction process and related control measures • common causes of variation and corrective action required • Operational Health and Safety (OHS) hazards and controls, including limitations of protective clothing and equipment relevant to the work process • requirements of different shutdowns as appropriate to the reduction process and workplace production requirements, including emergency and routine shutdowns and procedures to follow in the event of a power outage • isolation, lock out and tag out procedures and responsibilities • product/process changeover procedures and responsibilities • procedures and responsibility for reporting production and performance information

	• environmental issues and controls relevant to the reduction process, including waste/rework collection and handling procedures related to the process • basic operating principles of process control, where relevant, including the relationship between control panels and systems and the physical equipment • sampling and testing associated with process monitoring and control where relevant • routine maintenance procedures where relevant • cleaning and sanitation procedures where relevant
Underpinning Skills	Must demonstrates skills to: • access workplace information to identify reduction process requirements • select, fit and use personal protective clothing and/or equipment • confirm supply of necessary materials and services • conduct pre-start checks, such as inspecting equipment condition to identify any signs of wear, selecting appropriate settings and/or related parameters, cancelling isolation or lockouts as required, confirming that related equipment is clean and correctly configured for reduction process requirements, positioning sensors and controls correctly, ensuring any scheduled maintenance has been carried out, and confirming that all safety guards are in place and operational • start, operate, monitor and adjust reduction process equipment to achieve required outcomes, including monitoring control points and conducting inspections as required to confirm process remains within specification, such as: ➢ correct product type/quantity ➢ roll releases ➢ even spread of feed across rolls ➢ mill balance ➢ even grind/correct particle size • monitor supply and flow of materials to and from the reduction process • take corrective action in response to out-of-specification results • respond to and/or report equipment failure within level of responsibility • locate emergency stop functions on equipment • follow isolation and lock out/tag out procedures as required to take reduction process and related equipment off-line in preparation for cleaning and/or maintenance within level of responsibility

	• demonstrate batch/product changeovers • complete workplace records as required • maintain work area to meet housekeeping standards • use process control systems according to enterprise procedures • collect samples and conduct tests according to enterprise procedures • conduct routine maintenance according to enterprise procedures • clean and sanitize equipment according to enterprise procedures • use oral communication skills/language competence to fulfil the job role as specified by the organization, including questioning, active listening, asking for clarification and seeking advice from supervisor • work cooperatively within a culturally diverse workforce
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competency may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competency may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level II	
Unit Title	**Apply Sampling Procedures**
Unit Code	**IND PHR2 10 0613**
Unit Descriptor	This unit of competency covers the skills and knowledge required to understand the requirements of sampling plans, and to collect and transfer samples on process of production to retain sample integrity.

Elements	Performance Criteria
1. Prepare for sampling	1.1 ***Sampling requirements*** are identified in accordance with the sampling plan. 1.2 Sampling equipment, containers and labels are prepared in accordance with ***workplace information***.
2. Collect samples	2.1 ***Samples*** are collected according to sampling procedures and the requirements of the sampling plan. 2.2 Samples are handled and prepared to preserve ***sample and source integrity***. 2.3 Defects or abnormalities in source material and/or sample are identified and reported. 2.4 ***Sample information*** is recorded according to workplace sample recording requirements. 2.5 The work area is maintained according to housekeeping standards. 2.6 Work is conducted in accordance with workplace GMP guidelines.

Variable	Range
Sampling requirements	May include: • sampling under standard conditions • sampling after processes are adjusted in response to variation or non-conformance
Workplace information	May include: • Standard Operating Procedures (SOPs) • specifications • production schedules and instructions • manufacturers' advice • sampling plans
Sampling	typically occurs at a number of points and using a range of techniques
The scope of sampling	May include to follow weight variation, check volume and for inspection in production process

Maintenance of sample integrity	may be achieved by: • use of appropriate personal protective clothing • use of clean sampling tools and containers (sterilized tools/containers for aseptic sampling) • temperature control • addition of preservatives as required
Sampling tools	May include: • Scoop, sampling hose, sampling container, bottle, beakers and gloves
Sampling techniques	• are carried out according SOPs sampling procedures
Policies and procedures	• Work is carried out according to company policies and procedures, regulatory and licensing requirements, legislative requirements and industrial awards and agreements

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • conduct pre-start checks on equipment used for collecting and handling samples • collect, handle and store samples according to sampling requirements and standards • take corrective action in response to typical defects and inconsistencies • complete workplace records as required • apply safe work practices and identify OHS hazards and control
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • basic sampling principles, including the importance of following the sampling plan to obtain representative sampling reflecting characteristics of source material, the sample characteristics and related preservation, handling and storage requirements, and the labelling system purpose and requirements • tests to be conducted on samples and related handling and preparation requirements and responsibilities • characteristics of materials sampled and common contaminants and related conditions under which contamination is likely to occur • sampling techniques relevant to samples collected, such as sterilization methods and procedures • the relationship between sampling, testing and production processes, including different sampling regimes that may apply in response to non-standard conditions or after corrective action is taken to adjust production outputs

	• procedures and responsibility for reporting and recording sampling information, such as legislative requirements • procedures for preparing samples where relevant
Underpinning Skills	Must demonstrate skills to: • access and interpret sampling plan to identify sampling requirements • select, fit and use personal protective clothing and/or equipment • prepare for sampling to ensure required tools, containers and labels are available • follow sampling procedures and the sampling plan to collect samples from the points, in the quantities and at the times specified • identify atypical source materials and/or samples and take corrective action, such as reporting abnormalities, repeating sample collection and/or following intensive sampling schedules as required • complete sample records according to workplace requirements, such as labeling samples as required • transfer samples for testing • maintain work area to meet housekeeping standards • prepare samples according to standard procedures • use oral communication skills/language competence to fulfill the job role as specified by the organization, including questioning, active listening, asking for clarification and seeking advice from supervisor • work cooperatively within a culturally diverse workforce
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competency may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competency may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level II	
Unit Title	**Use Numerical Applications in the Workplace**
Unit Code	**IND PHR2 11 0613**
Unit Descriptor	This is unit of competency covers the skills and knowledge required to apply basic mathematical functions of addition, subtraction, multiplication and division to undertake workplace calculations or to estimate approximate answers when exact calculations are not required. This unit has application in a production environment where basic mathematics may be required to undertake or support work processes. Typical applications of mathematical concepts in the workplace include but are not limited to measuring or estimating product characteristics, such as weight, capacity, time and temperature; measuring and estimating material usage, quantities and ratios; measuring equipment and processing parameters, such as speed/throughput; and calculating entitlements, such as pay, leave entitlements, and shift allowances.

Elements	Performance Criteria
1. Apply basic mathematical concepts to calculate workplace information	1.1 Calculation requirements are identified and appropriate method is selected. 1.2 Data is obtained from relevant sources and interpreted correctly. 1.3 ***Calculations*** are undertaken using addition, subtraction, multiplication and division to support work role.
2. Apply basic mathematical concepts to estimate workplace information	2.1 Estimation requirements are identified and appropriate estimation method is selected. 2.2 Data is obtained from relevant sources and interpreted correctly. 2.3 ***Estimations*** are made to meet work requirements.

Variable	Range
Calculations	may be made manually or using calculators and other measuring instruments as appropriate to the task
Estimations	can be made from: • observations of other amounts or measurements • supplied data, such as volume or weight information on packaging of raw materials
Conversion charts	are those in common use in the workplace
Results	may or may not be recorded depending on workplace requirements
Numerical information	may be presented in forms simple run charts and graphs

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • identify calculation or estimation requirements • carry out calculations involving basic addition, subtraction, division and multiplication where estimations are used, estimated amounts must be consistent with process or product specification and demonstrate knowledge of measurement units used in the workplace • use estimation techniques to check calculated results and workplace data.
Underpinning Knowledge and Attitudes	• mathematical processes, including addition, subtraction, multiplication and division • application of calculation and estimation techniques to meet work requirements • units of measurement used in the workplace, including whole numbers, fractions and decimals (to one decimal point) (this may include use of conversion charts) • representation of numerical information relevant to work requirements, such as charts, graphs and tables • recording requirements and responsibilities where relevant
Underpinning Skills	• identify whether a calculation or estimation is required to meet workplace requirements • carry out calculations involving basic addition, subtraction, division and multiplication to support work role (this may involve use of a calculator and conversion tables where required) • use estimation techniques to check quantities, ratios, speed and other required data estimates • use estimation techniques to check calculated results and workplace data • record calculations and measurement information accurately according to enterprise procedures • use oral communication skills/language competence to fulfil the job role as specified by the organisation, including questioning, active listening, asking for clarification and seeking advice from supervisor • work cooperatively within a culturally diverse workforce
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competency may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competency may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level II	
Unit Title	**Operate a Tablet Coating Process**
Unit Code	**IND PHR2 12 0613**
Unit Descriptor	This unit of competency covers the skills and knowledge required to set up, operate and shut down the tablet coating process. This unit has application in a pharmaceutical manufacturing environment. It typically targets the production worker responsible for applying basic operating principles to the operation and monitoring of a tablet coating process.

Elements	Performance Criteria
1.Prepare the tablet coating process for operation	1.1 Tablets and coating materials are confirmed and available to meet operating requirements. 1.2 Cleaning and maintenance requirements and status are identified and confirmed in accordance to ***workplace information***. 1.3 Machine components and related attachments are fitted and adjusted to meet operating requirements. 1.4 Processing/operating parameters are entered as required to meet safety and production requirements. 1.5 Equipment performance is checked and adjusted as required. 1.6 Pre-start checks are carried out as required by workplace requirements.
2. Operate and monitor the tablet coating process	2.1 ***Tablet coating process*** is started and operated according to workplace procedures. 2.2 ***Tablet coating equipment*** is monitored to identify variation in operating conditions. 2.3 Variation in ***equipment operation*** is identified and maintenance requirements are reported according to workplace reporting requirements. 2.4 The process is monitored to confirm that coated tablets meet specifications. 2.5 Spillages are reported and removed according to Standard Operating Procedures (SOPs). 2.6 Out-of-specification product/process outcomes are identified, rectified and/or reported to maintain the process within specification. 2.7 The work area is maintained according to housekeeping standards.

	2.8 Work is conducted according to environmental standards. 2.9 Workplace records are maintained according to workplace recording requirements.
3. Shut down the tablet coating process	3.1 End-of-batch procedures are completed in accordance with batch instructions and SOPs. 3.2 The process is shut down according to workplace procedures. 3.3 Maintenance requirements are identified and reported according to workplace reporting requirements.

Variable	**Range**
Workplace information	May include: • SOPs • specifications • production schedules and instructions • manufacturers' advice • standard forms and reports
Tablet coating processes	May include: • sugar coating • film coating
Tablet coating equipment	May include: • coating preparation (homogenisers, blenders and mixers) • heat exchangers • pumps • jacketed spray guns/heads • coating pans • polishing pans • holding tanks
Operation of equipment and processes	May require: • the use of process control panels and systems
Materials used in the sugar coating process	May include: • purified water • cellulose derivatives • polyvinal • gums • sugar • Materials used in film coating include: • purified water • cellulose derivatives • methleyene chloride • colorants • isopropyl alcohol

Shutdown procedures	May include: • cleaning (in some cases cleaning may be carried out by a dedicated cleaning crew)
Services	May need to be confirmed. These depend on the nature of the process. Typical examples include: • power • steam • water • vacuum • gases • compressed and instrumentation air
Policies and procedures	Work is carried out according to company policies and procedures, regulatory and licensing requirements, legislative requirements, and industrial awards and agreements
Legislative requirements relevant to this industry includes:	• relevant Good Manufacturing Practice (GMP) codes • the Therapeutic Goods Act and/or other relevant legislation • legislation covering environmental management, OHS, anti-discrimination and equal opportunity

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • conduct pre-start checks on machinery used for coating tablets • start, operate, monitor and adjust process equipment to achieve required quality outcomes • take corrective action in response to typical faults and inconsistencies • complete workplace records as required • apply safe work practices and identify OHS hazards and controls • safely shut down equipment
Underpinning knowledge	Must demonstrate knowledge of: • purpose and basic principles of the tablet coating process, such as tablet preparation/conditioning procedures and requirements, coating preparation and the stages in the coating process • basic operating principles of equipment, such as main equipment components, status and purpose of guards, equipment operating capacities and applications, and the purpose and location of sensors and related feedback instrumentation • services required and action to take if services are not available • the flow of the tablet coating process and the effect of outputs on downstream pharmaceutical processes

	• stages and changes which occur during tablet coating • types of materials used in preparation of coatings and related handling/segregation requirements • quality characteristics and legal requirements to be achieved by the tablet coating process • effect of tablet coating process on the end product • quality requirements of materials and effect of variation on tablet coating process performance • operating requirements and parameters and corrective action required where operation is outside specified operating parameters • typical equipment faults and related causes, including signs and symptoms of faulty equipment and early warning signs of potential problems • methods used to monitor the tablet coating process, such as inspecting, measuring and testing as required by the process • inspection or test points (control points) in the tablet coating process and the related procedures and recording requirements • Good Manufacturing Practice (GMP) requirements associated with the tablet coating process and related control measures • common causes of variation and corrective action required • product/process changeover procedures and responsibilities • Occupational Health and Safety (OHS) hazards and controls, including the limitations of protective clothing and equipment relevant to the work process • end-of-batch procedures, including procedures for calculating yield, materials reconciliation and action required if yield/reconciliation is not within prescribed limits, and product labelling responsibilities and procedures • requirements of different shutdowns as appropriate to the process and workplace production requirements, including emergency and routine shutdowns and procedures to follow in the event of a power outage • line clearance, cleaning and sanitation procedures • isolation, lock out and tag out procedures and responsibilities • procedures and responsibility for reporting production and performance information • environmental issues and controls relevant to the tablet coating process, including waste collection and handling procedures related to the process

	• basic operating principles of process control, where relevant, including the relationship between control panels and systems and the physical equipment • sampling and testing associated with process monitoring and control where relevant • routine maintenance procedures where relevant
Underpinning Skills	Must demonstrate skills to: • access workplace information to identify tablet coating process requirements • select, fit and use personal protective clothing and/or equipment • confirm supply of necessary tablets, coating materials and services to the tablet coating process • prepare coating materials according to specification • conduct pre-start checks on coating application equipment, such as inspecting equipment condition to identify any signs of wear, selecting appropriate settings and/or related parameters, cancelling isolation or lock outs as required, confirming line clearance and cleaning status, ensuring equipment is correctly configured for processing requirements, positioning sensors and controls correctly, ensuring any scheduled maintenance has been carried out, and confirming that all safety guards are in place and operational • start, operate, monitor and adjust the tablet coating process equipment to achieve required outcomes, including monitoring control points and conducting inspections as required to confirm process remains within specification, such as: ➢ pan preparation/coating ➢ coating addition rate ➢ addition/dosing of materials ➢ drying air temperature and flow ➢ addition of polishing agent/gum as required • take corrective action in response to out-of-specification results • monitor supply and flow of materials to and from the tablet coating process • respond to and/or report equipment failure within level of responsibility • locate emergency stop functions on equipment • follow isolation and lock out/tag out procedures as required to take the tablet coating process and related equipment off-line in preparation for cleaning and/or maintenance within level of responsibility • demonstrate batch/product changeovers

	• follow end-of-batch procedures, including line clearance and cleaning, yield calculation, materials reconciliation and product labelling • complete workplace records as required • maintain work area to meet housekeeping standards • use process control systems according to enterprise procedures • collect samples and conduct tests according to enterprise procedures • conduct routine maintenance according to enterprise procedures • use oral communication skills/language competence to fulfil the job role as specified by the organisation, including questioning, active listening, asking for clarification and seeking advice from supervisor • work cooperatively within a culturally diverse workforce
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competency may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competency may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level II	
Unit Title	**Coordinate a Label Store**
Unit Code	**IND PHR2 13 0613**
Unit Descriptor	This unit of competency covers the skills and knowledge required to manage a label store in a pharmaceutical workplace to meet workplace and legislative requirements

Elements	Performance Criteria
1. Receive labels	1.1 Label details are identified and verified. 1.2 The quantity of labels received is counted and reconciled against receivals documentation. 1.3 Discrepancies are identified, investigated and reported.
2. Issue and reconcile labels	2.1 Labels are located/created to meet batch requirements. 2.2 Labels are issued in correct quantities to meet batch requirements. 2.3 Labels returned to store are received, reconciled and recorded according to verification and reconciliation procedures. 2.4 Records are maintained to meet workplace and legislative requirements. 2.5 Work is conducted in accordance with ***workplace information***.

Variable	Range
Workplace information may include:	• Standard Operating Procedures (SOPs) • labels and related documentation • production schedules and instructions • standard forms and reports
Policies and procedures	Work is carried out according to company policies and procedures, regulatory and licensing requirements, legislative requirements, and industrial awards and agreements
Legislative requirements relevant to this industry includes	• relevant Good Manufacturing Practice (GMP) codes • the Therapeutic Goods Act and/or other relevant legislation • legislation covering environmental management, OHS, anti-discrimination and equal opportunity

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • receive and verify labels • issue labels according to batch requirements

	• take corrective action in response to typical faults and discrepancies • complete workplace records as required • apply safe work practices and identify OHS hazards and controls
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • system of label control, including the purpose and procedures for receiving, issuing, reconciling and verifying label management • legislative responsibilities relating to label management • purpose and requirements of security procedures and responsibilities • types of labels received and issued and significance of codes • consequences of issuing incorrect labels • procedures for setting up, testing and operating label store equipment, including label counting equipment • corrective action required if a discrepancy is identified • Occupational Health and Safety (OHS) hazards associated with the work role • procedures and responsibility for recording and reporting information • operating procedures for label coding and printing equipment where relevant
Underpinning Skills	Must demonstrate skills to: • follow receivals procedures to receive, count and store labels • access production schedule to identify label requirements • carry out procedures to test accuracy of label counting select documentation • demonstrate and issue labels to meet batch requirements and • procedures to receive labels issued and returned from production • conduct reconciliations of labels received and issued and conduct backup verification as required • maintain security of label store • maintain work area to meet housekeeping standards • operate label coding and printing equipment according to enterprise procedures • use oral communication skills/language competence to fulfil the job role as specified by the organization, including questioning, active listening, asking for clarification and seeking advice from supervisor • work cooperatively machines and record results

	• verify that label information meets batch type, including setting up and using label counting equipment • demonstrate the procedure for removing and accounting for damaged or other non-conforming labels • within a culturally diverse workforce
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competency may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competency may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level II	
Unit Title	**Operate a Liquid Manufacturing Process**
Unit Code	**IND PHR2 14 0613**
Unit Descriptor	This unit of competency covers the skills and knowledge required to set up, operate, adjust and shut down the liquid manufacturing process. This unit applies to production operators working in the pharmaceutical sector. This person would typically work within defined Good Manufacturing Practice (GMP) programs and procedures.

Elements	Performance Criteria
1. Prepare the liquid manufacturing process for operation	1.1 Materials are confirmed and available to meet operating requirements. 1.2 Cleaning and maintenance requirements and status are identified and confirmed in accordance to ***workplace information***. 1.3 Machine components and related attachments are fitted and adjusted to meet operating requirements. 1.4 Processing/operating parameters are entered as required to meet safety and production requirements. 1.5 Equipment performance is checked and adjusted as required. 1.6 Pre-start checks are carried out as required by workplace requirements.
2. Operate and monitor the liquid manufacturing process	2.1 Raw materials are delivered to the process in the required quantities and sequence to meet recipe specifications. 2.2 ***Liquid manufacturing process*** is started and operated according to workplace procedures. 2.3 ***Liquid manufacturing equipment*** is monitored to identify variation in operating conditions. 2.4 Variation in ***equipment operation*** is identified and maintenance requirements are reported according to workplace reporting requirements. 2.5 Liquid manufacturing process is monitored to confirm that specifications are met. 2.6 Out-of-specification product/process outcomes are identified, rectified and/or reported to maintain the process within specification. 2.7 The liquid mix is transferred to the required production or storage location.

	2.8 Spillages are reported and removed according to standard operating procedures. 2.9 The work area is maintained according to housekeeping and environmental standards. 2.10 Workplace records are maintained according to workplace recording requirements.
3. Shut down the liquid manufacturing process	3.1 End-of-batch procedures are completed in accordance with batch instructions and Standard Operating Procedures (SOPs). 3.2 The process is shut down according to workplace procedures. 3.3 Maintenance requirements are identified and reported according to workplace reporting requirements.

Variable	**Range**
Workplace information	May include: • SOPs • specifications • production schedules and instructions • manufacturers' advice • standard forms and reports
Stock for the liquid manufacturing process	is supplied from the dispensing process and from bulk containers
Liquid manufacturing equipment	May include: • tanks • mixers • homogenisers • thermal jackets • mills • filters • vacuum systems • pumps • stirrers and impellers • purified water systems • materials handling equipment
Operation of equipment and processes	May require: • the use of process control panels and systems
Work	May include exposure to dangerous and hazardous substances
Shutdown procedures	May include: • cleaning (in some cases cleaning may be carried out by a dedicated cleaning crew)

Services	Typical examples include: • power • steam • water • vacuum • gases • compressed and instrumentation air
Policies and procedures	Work is carried out according to company policies and procedures, regulatory and licensing requirements, legislative requirements, and industrial awards and agreements
Legislative requirements	relevant to this industry includes: • relevant Good Manufacturing Practice (GMP) codes • the Therapeutic Goods Act and/or other relevant legislation • legislation covering environmental management, OHS, anti-discrimination and equal opportunity

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • conduct pre-start checks on equipment used for liquid manufacturing process • start, operate, monitor and adjust process equipment to achieve required quality outcomes • take corrective action in response to typical faults and inconsistencies • complete workplace records as required • apply safe work practices and identify OHS hazards and controls • safely shut down equipment • apply food safety procedures to work practices.
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • purpose and basic principles of the liquid manufacturing process, including the characteristics and basic function of raw materials used, and method and sequence of addition required to achieve required mix characteristics, and where required, the characteristics of solutions, suspensions and emulsions • basic understanding of specific gravity and bulk density as appropriate for ingredients used • basic operating principles of liquid manufacturing equipment, such as main equipment components, status and purpose of guards, equipment operating capacities and applications, the purpose and location of sensors and related feedback instrumentation, and awareness of calibration schedules for scales and related weighing/measuring equipment

	• services required and action to take if services are not available • stages and changes which occur during liquid manufacturing • quality characteristics and legal requirements to be achieved by the liquid manufacturing process • the flow of the liquid manufacturing process and the effect of outputs on downstream pharmaceutical processes • operating requirements and parameters and corrective action required where operation is outside specified operating parameters • typical equipment faults and related causes, including signs and symptoms of faulty equipment and early warning signs of potential problems • methods used to monitor the liquid manufacturing process, such as inspecting, measuring and testing as required by the process • inspection or test points (control points) in the liquid manufacturing process and the related procedures and recording requirements, including monitoring: ➢ flow rates ➢ materials addition sequence ➢ times/temperatures and agitator speeds ➢ required characteristics of manufactured liquid • GMP requirements associated with the liquid manufacturing process and related control measures • common causes of variation and corrective action required • product/process changeover procedures and responsibilities • Occupational Health and Safety (OHS) hazards and controls, including the limitations of protective clothing and equipment relevant to the work process • end-of-batch procedures, including procedures for calculating yield, materials reconciliation and action required if yield/reconciliation is not within prescribed limits, and product labelling responsibilities and procedures • requirements of different shutdowns as appropriate to the liquid manufacturing process and workplace production requirements, including emergency and routine shutdowns and procedures to follow in the event of a power outage • line clearance, cleaning and sanitation procedures • isolation, lock out and tag out procedures and responsibilities • procedures and responsibility for reporting production and performance information

	• environmental issues and controls relevant to the liquid manufacturing process, including waste collection and handling procedures related to the process • basic operating principles of process control, where relevant, including the relationship between control panels and systems and the physical equipment • sampling and testing associated with process monitoring and control where relevant • routine maintenance procedures where relevant
Underpinning Skills	Must demonstrate skills to: • access workplace information to identify liquid manufacturing process requirements • select, fit and use personal protective clothing and/or equipment • confirm supply of necessary materials and services to the liquid manufacturing process • conduct pre-start checks, such as inspecting equipment condition to identify any signs of wear, selecting appropriate settings and/or related parameters, cancelling isolation or lockouts as required, confirming line clearance and cleaning status, • ensuring equipment is correctly configured for processing requirements, positioning sensors and controls correctly, ensuring any scheduled maintenance has been carried out, and confirming that all safety guards are in place and operational • add/load materials in correct quantities and sequence, such as monitoring automatic ingredient addition and/or manual addition • start, operate, monitor and adjust liquid manufacturing process equipment to achieve required outcomes, including monitoring control points and conducting inspections as required to confirm process remains within specification • take corrective action in response to out-of-specification results • monitor supply and flow of materials to and from the liquid manufacturing process • pace the liquid manufacturing process to meet production requirements • respond to and/or report equipment failure within level of responsibility • locate eemergency stop functions on equipment • follow isolation and lock out/tag out procedures as required to take liquid manufacturing process and related equipment off-line in preparation for cleaning and/or maintenance within level of responsibility

	• demonstrate batch/product changeovers • follow end-of-batch procedures, including line clearance and cleaning, yield calculation, materials reconciliation and product labelling • complete workplace records as required • maintain work area to meet housekeeping standards • use process control systems according to enterprise procedures • collect samples and conduct tests according to enterprise procedures • conduct routine maintenance according to enterprise procedures • use oral communication skills/language competence to fulfil the job role as specified by the organization, including questioning, active listening, asking for clarification and seeking advice from supervisor • work cooperatively within a culturally diverse workforce
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competency may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competency may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level II	
Unit Title	**Operate a Filtration Process**
Unit Code	**IND PHR2 15 0613**
Unit Descriptor	This is a specialist unit. It covers the skills and knowledge required to set up, operate, adjust and shut down filtration equipment used to Separate course particles from solutions. Operate a separation process and Operate a membrane process for separation of fine particle sizes.

Elements	Performance Criteria
1. Prepare the filtration equipment and process for operation	1.1 Materials are confirmed and available to meet operating requirements. 1.2 Cleaning and maintenance requirements and status are identified and confirmed in accordance with ***workplace information***. 1.3 Machine components and related attachments are fitted and adjusted to meet operating requirements. 1.4 Processing/operating parameters are entered as required to meet safety and production requirements. 1.5 Equipment performance is checked and adjusted as required. 1.6 Pre-start checks are carried out as required by workplace requirements.
2. Operate and monitor the filtration process	2.1 Filtration process is started and operated according to workplace procedures. 2.2 ***Filtration equipment*** is monitored to identify variation in operating conditions. 2.3 Variation in ***equipment operation*** is identified and maintenance requirements are reported according to workplace reporting requirements. 2.4 The process is monitored to confirm that specifications are met. 2.5 Out-of-specification product/process outcomes are identified, rectified and/or reported to maintain the process within specification. 2.6 The workplace meets housekeeping standards. 2.7 Workplace records are maintained according to workplace recording requirements.
3. Shut down the filtration process	3.1 The appropriate ***shut down procedure*** is identified. 3.2 The process is shutdown according to workplace procedures.

	3.3 Maintenance requirements are identified and reported according to workplace reporting requirements.

Variable	Range
Workplace information	May include • Standard Operating Procedures (SOPs), specifications, production schedules • and instructions, manufacturers' advice, standard forms and reports
Filtration equipment	May include: • Vibratory, rotary, membrane filter, Sieves, screens, and drum filters. • The filtration process may consist of multiple in-line filters
Operation of equipment and processes	May require: • the use of process control panels and systems
Operators	Carry out changeovers within workplace • Arrangements and the relevant changeover procedures should be used to customize the details of this unit. • Where more detailed changeovers are carried out, Conduct routine maintenance
Shutdown procedures	May include: • Cleaning In some cases cleaning may be carried out by a dedicated cleaning crew
Services	• Are appropriate to the process to be operated. • Typical examples include power, steam, water, vacuum, • and compressed and instrumentation air
Work	is carried out according to company policies and procedures, regulatory and licensing requirements, legislative requirements, and industrial awards and agreements
Legislative requirements	Are typically reflected in: • Procedures and specifications. Legislation relevant to this • industry includes the Standards Code including • labeling, weights and measures legislation; and • legislation covering pharmaceuticals manufacturing safety, environmental • management, occupational health and safety, • anti-discrimination and equal opportunity. • to the pharmaceutical industry, current GMP codes is applied.

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • Prepare the filtration equipment and process for operation • Operate and monitor the filtration process • Shut down the filtration process

Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • Purpose and basic principles of filtration. This includes stages and changes that occur during filtration • Basic operating principles of filtration equipment. This includes an operational understanding of main equipment components; status and purpose of guards; equipment operating capacities and applications including relevant screens and sieves as required by filtration equipment; the purpose and location of sensors and related feedback instrumentation; and services required for operation of filtration equipment used in the workplace • The flow of the filtration process and the effect of product output on downstream processes • Effect of raw material characteristics on filtration performance • Quality characteristics required of filtration process output • Test methods used to monitor solids in infeed and outfeed streams • Operating requirements and parameters and corrective action required where operation is outside specified operating parameters • Typical equipment faults and related causes. This includes recognition of signs and symptoms of faulty equipment and early warning signs of potential problems such as screen or sieve damage • Common causes of variation and corrective action required • Spoilage and other safety risks associated with filtration • OHS hazards and controls. This includes awareness of the limitations of protective clothing and equipment relevant to the work process • Requirements of different shutdowns as appropriate to the filtration process and workplace production requirements. This may include emergency and routine shutdowns and procedures to follow in the event of a power outage • Cleaning procedures appropriate for the range of filtration components used • Isolation, lock out and tag out procedures and responsibilities • Product/batch changeover procedures • Cleaning and sanitizing methods and procedures • Procedures and responsibility for reporting production and performance information • Environmental issues and controls relevant to filtration. • This includes handling of effluent

Underpinning Skills	Must demonstrate skills to: • Access workplace information to identify filtration processing requirements • Select, fit and use personal protective clothing and/or equipment • Confirm supply of necessary materials and services • Conduct pre-start checks. This may involve inspecting equipment condition to identify any signs of wear; selecting and fitting appropriate screens and equipment components; selecting settings and/or related parameters; cancelling isolation or lockouts as required; confirming that sensors and controls are correctly positioned; any scheduled maintenance has been carried out, and that all safety guards are in place and operational • Start, operate, monitor and adjust filtration process and equipment to achieve required outcomes. This may include monitoring: ➢ flow rates ➢ residence time ➢ solids for in-feeds and out-feeds. This is typically done by conducting a spin test • Monitor supply and flow of materials to and from the filtration process • Take corrective action in response to out-of-specification results. This may include identifying and responding to sieve or screen blockages or tears • Identify and correct or report equipment faults. This may include confirming condition screens and sieves and replacing damaged components within level of responsibility • Locate emergency stop functions on equipment • Follow isolation and lock out/tag out procedures as required to take filtration and related equipment off-line in preparation for cleaning and/or maintenance within level of responsibility • Clean and sanitize filtration equipment • Conduct product/batch changeover • Complete workplace records as required • Maintain work area to meet housekeeping standards
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competency may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competency may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level II	
Unit Title	**Operate a Washing and Drying Process**
Unit Code	**IND PHR2 16 0613**
Unit Descriptor	This unit of competency covers the skills and knowledge required to set up, operate, adjust and shut down a washing and drying process.

Elements	Performance Criteria
1. Prepare the equipment and process for operation	1.1 Raw materials are confirmed and available to meet production requirements. 1.2 Cleaning and maintenance requirements and status are identified and confirmed according to ***workplace information***. 1.3 Machine components and related attachments are fitted and adjusted to meet operating requirements. 1.4 Equipment performance is checked and adjusted as required. 1.5 Pre-start checks are carried out as required by workplace requirements.
2. Operate and monitor the washing and drying process	2.1 ***Washing and drying process*** is started and operated according to workplace procedures. 2.2 Raw materials are inspected and washed to meet workplace specifications. 2.3 Washed materials are transferred to drying stage. 2.4 Materials are dried to specification. 2.5 Variation in ***equipment operation*** is identified and maintenance requirements are reported according to workplace reporting requirements. 2.6 Out-of-specification product/process outcomes are identified, rectified and/or reported to maintain the process within specification. 2.7 The work area is maintained according to housekeeping standards. 2.8 Work is conducted in accordance with workplace environmental guidelines. 2.9 Workplace records are maintained according to workplace recording requirements.
3. Shut down the washing and drying process	3.1 The appropriate ***shutdown procedure*** is identified. 3.2 The process is shut down according to workplace procedures. 3.3 Maintenance requirements are identified and reported according to workplace reporting requirements.

Variable	Range
Workplace information	May include: • Standard Operating Procedures (SOPs) • specifications • production schedules and instructions • manufacturers' advice • standard forms and reports
Washing and drying equipment	May include: • wash baths/tanks/flumes • pumps • drying equipment, such as centrifuges • conveyors • materials handling equipment
Operation of equipment and processes	May require: • the use of process control panels and systems
Shutdown procedures	May include cleaning (in some cases cleaning may be carried out by a dedicated cleaning crew)
Services	May need to be confirmed. These depend on the nature of the process. Typical examples include: • power • water • compressed/instrumentation air
Policies and procedures	May include: • Work is carried out according to company policies and procedures, regulatory and licensing requirements, legislative requirements, and industrial awards and agreements
Legislative requirements	Are typically reflected in procedures and specifications. Legislation relevant to this industry includes: • The Standards Code, including labeling, weights and measures legislation • legislation covering pharmaceuticals manufacturing safety, environmental management, OHS, anti-discrimination and equal opportunity

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • conduct pre-start checks on machinery used for washing and drying product • start, operate, monitor and adjust process equipment to achieve required quality outcomes • take corrective action in response to typical faults and inconsistencies • complete workplace records as required

	• apply safe work practices and identify OHS hazards and controls • safely shut down equipment
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • purpose and basic principles of the washing and drying process, including water quality, the role of sanitizers in the washing process, and of drying technology, such as the use of centrifugal force in a drying process • basic operating principles of equipment, such as main equipment components, status and purpose of guards, equipment operating capacities and applications, and the purpose and location of sensors and related feedback instrumentation • services (principally water) required and action to take if services are not available • the flow of this process and the effect of outputs on downstream processes • quality characteristics to be achieved by both the washing and drying stages, including consequence of out-of-specification moisture levels on further processing and final product • quality requirements of raw materials and effect of variation on process performance, including how variation in microbial load can affect the washing and drying process • operating requirements, parameters and corrective action required where operation is outside specified operating parameters • typical equipment faults and related causes, including signs and symptoms of faulty equipment and early warning signs of potential problems • methods used to monitor the washing and drying process, such as inspecting, measuring and testing as required by the process • inspection or test points (control points) in the process and the related procedures and recording requirements • contamination risks associated with the process and related control measures • common causes of variation and corrective action required • Operational Health and Safety (OHS) hazards and controls • requirements of different shutdowns as appropriate to the process and workplace production requirements, including emergency and routine shutdowns and procedures to follow in the event of a power outage • isolation, lock out and tag out procedures and responsibilities • product/process changeover procedures and responsibilities • procedures and responsibility for reporting production and performance information

	• environmental issues and controls relevant to the process, including waste/rework collection and handling procedures related to the process • basic operating principles of process control, where relevant, including the relationship between control panels and systems and the physical equipment • sampling and testing associated with process monitoring and control where relevant • routine maintenance procedures where relevant • cleaning and sanitation procedures where relevant
Underpinning Skills	Must demonstrate skills to: • access workplace information to identify production requirements • select, fit and use personal protective clothing and/or equipment • confirm supply of necessary raw materials and services • conduct pre-start checks, such as inspecting equipment condition to identify any signs of wear, selecting appropriate settings and/or related parameters, cancelling isolation or lockouts as required, confirming that equipment is clean and correctly configured for processing requirements, positioning sensors and controls correctly, ensuring any scheduled maintenance has been carried out, and confirming that all safety guards are in place and operational • start, operate, monitor and adjust washing and drying equipment to achieve required outcomes, including monitoring control points and conducting inspections to confirm process remains within specification, such as: ➢ operation of dosing equipment ➢ tank/bath or flume water levels ➢ related equipment operation (such as pumps/conveyors) ➢ immersion of raw materials ➢ temperatures ➢ water quality ➢ flow rates ➢ drying times and weight (before and after drying) • monitor supply and flow of raw materials to the wash process and from the drying process • take corrective action in response to out-of-specification results • respond to and/or report equipment failure within level of responsibility • locate emergency stop functions on equipment • follow isolation and lock out/tag out procedures as required to take process and related equipment off-line in preparation for cleaning and/or maintenance within level of responsibility

	• demonstrate batch/product changeovers • complete workplace records as required • maintain work area to meet housekeeping standards • use process control systems according to enterprise procedures • collect samples and conduct tests according to enterprise procedures • conduct routine maintenance according to enterprise procedures • clean and sanitize equipment according to enterprise procedures • use oral communication skills/language competence to fulfil the job role as specified by the organization, including questioning, active listening, asking for clarification and seeking advice from supervisor • work cooperatively within a culturally diverse workforce
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competency may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competency may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level II	
Unit Title	**Operate an Aseptic Fill and Seal Process**
Unit Code	**IND PHR2 17 0613**
Unit Descriptor	This unit of competency covers the skills and knowledge required to set up, operate, adjust and shut down an aseptic fill and seal process. This is a primary packaging process to fill product into packaging.

Elements	Performance Criteria
1. Prepare the filling and sealing equipment and process for operation	1.1 Materials and packaging components/consumables are confirmed and available to meet operating requirements. 1.2 Cleaning and maintenance requirements and status are identified and confirmed in accordance with ***workplace information***. 1.3 Machine components and related attachments are fitted and adjusted to meet operating requirements. 1.4 Operating parameters are entered as required to meet safety and production requirements. 1.5 Equipment performance is checked and adjusted as required. 1.6 Pre-start checks are carried out as required by workplace requirements.
2. Operate and monitor the filling and sealing process	2.1 Filling and Sealing process is started and operated according to workplace procedures. 2.2 ***Filling and sealing equipment*** is monitored to identify variation in operating conditions. 2.3 Variation in ***equipment operation*** is identified and maintenance requirements are reported according to workplace reporting requirements. 2.4 Packaging quality and seal integrity are monitored to confirm that specifications are met. 2.5 Out-of-specification process outcomes are identified, rectified and/or reported to maintain the process within specification. 2.6 The work is maintained according to housekeeping standards. 2.7 Work is conducted in accordance with workplace environmental guidelines.

	2.8 Spillages are reported and removed according to standard operating procedures. 2.9 Workplace records are maintained according to workplace recording requirements.
3. Shut down the filling and sealing process	3.1 End-of-batch procedures are completed in accordance with batch instructions and Standard Operating Procedures (SOPs). 3.2 The process is ***shut down*** according to workplace procedures. 3.3 Maintenance requirements are identified and reported according to workplace reporting requirements.

Variable	**Range**
Workplace information	may include: • SOPs • specifications • production schedules and instructions • manufacturers' advice • standard forms and reports
Filling and sealing equipment	may include: • pumps • aseptic fillers • hermetic sealers • aseptic packaging
Operation of equipment and processes	may require: • the use of process control panels and systems
Shutdown procedures	may include: • cleaning (in some cases cleaning may be carried out by a dedicated cleaning crew)
Sterilization methods used	may include: • use of heat (dry and steam) • chemicals (gases and liquids) • gamma irradiation • filtration
Services	are appropriate to the process to be operated. Typical examples include: • power • steam • water • vacuum • compressed and instrumentation air
Policies and procedures	Work is carried out according to company policies and procedures, regulatory and licensing requirements, legislative requirements, and industrial awards and agreements

Legislative requirements	relevant to this manufacturing includes: • relevant Good Manufacturing Practice (GMP) codes • the Therapeutic Goods Act and/or other relevant legislation • legislation covering environmental management, OHS, anti-discrimination and equal opportunity

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • conduct pre-start checks on equipment used for filling and sealing • start, operate, monitor and adjust process equipment to achieve required quality outcomes • take corrective action in response to typical faults and inconsistencies • complete workplace records as required • apply safe work practices and identify OHS hazards and controls • safely shut down equipment • apply GMP principles and procedures to work practices • maintain standards of a clean room work environment.
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • purpose and basic principles of filling and sealing, including properties of packaging materials used, the principles of heat sterilization and its effect on microbiological characteristics of the product and packaging materials, and the filling process (methods may require exclusion of air using inert gas, such as nitrogen and filling under vacuum) • aseptic container preparation, handling and loading • basic operating principles of aseptic filling and sealing equipment, such as main equipment components, status and purpose of guards, equipment operating capacities and applications, the purpose and location of sensors and related feedback instrumentation, and services required for operation of filling equipment used in the workplace • quality characteristics and legal requirements to be achieved by the filling and sealing process, such as quality requirements of packaging components/consumables, sterilization requirements and procedures, filling (fill levels and weights), requirements of seal formation and integrity, and where relevant, understanding integrity testing procedures • the flow of processes supplying the filling and sealing process and the effect of outputs on downstream processes • operating requirements and parameters and corrective action required where operation is outside specified operating parameters

	• typical equipment faults and related causes, including signs and symptoms of faulty equipment and early warning signs of potential problems • methods used to monitor the process, such as inspecting, measuring and testing as required by the process • inspection or test points (control points) in the process and the related procedures and recording requirements • Good Manufacturing Practice (GMP) requirements associated with the liquid manufacturing process and related control measures • common causes of variation and corrective action required, including the effect of variation in both product and packaging components/consumables on filling and sealing performance, e.g. it may include an understanding of the effect of temperature variation on the filling process • product/packaging changeover procedures • Occupational Health and Safety (OHS) hazards and controls, including the limitations of protective clothing and equipment relevant to the work process • end-of-batch procedures, including procedures for calculating yield, materials reconciliation and action required if yield/reconciliation is not within prescribed limits, and product labeling responsibilities and procedures • requirements of different shutdowns as appropriate to the process and workplace production requirements, including emergency and routine shutdowns and procedures to follow in the event of a power outage • line clearance, cleaning and sanitation procedures • isolation, lock out and tag out procedures and responsibilities • procedures and responsibility for reporting production and performance information • environmental issues and controls relevant to the filling and sealing process, including waste/rework collection and handling procedures related to the process • basic operating principles of process control, where relevant, including the relationship between control panels and systems and the physical equipment • sampling and testing procedures where relevant • routine maintenance procedures where relevant
Underpinning Skills	Must demonstrate skills to: • access workplace information to identify processing requirements • select, fit and use personal protective clothing and/or equipment, including gowning up, following required work area entry and exit procedures and moving around the work area to minimize risk of contamination

	• confirm supply of necessary packaging components/consumables and product • conduct pre-start checks, such as inspecting equipment condition to identify any signs of wear, disinfecting and sterilizing equipment and surfaces, selecting appropriate settings and/or related parameters, cancelling isolation or lock outs as required, confirming that equipment is clean and correctly configured for packaging requirements, ensuring packaging components/consumables are loaded, positioning sensors and controls correctly, ensuring any scheduled maintenance has been carried out, and confirming that all safety guards are in place and operational • start, operate, monitor and adjust the filling and sealing process equipment to achieve required outcomes, including monitoring control points and conducting inspections as required to confirm process remains within specification, such as: ➢ flow rates ➢ weights and volumes ➢ fill levels ➢ temperature, including materials and sealing temperatures ➢ supply of packaging components/consumables ➢ packaging quality and seal integrity, and where required, testing packaging integrity • take corrective action in response to out-of-specification results • monitor supply and flow of materials to and from the process • respond to and/or report equipment failure within level of responsibility • locate emergency stop functions on equipment • follow isolation and lock out/tag out procedures as required to take filling and sealing process and related equipment off-line in preparation for cleaning and/or maintenance within level of responsibility • demonstrate product/process changeovers • follow end of batch procedures including line clearance and cleaning, yield calculation, materials reconciliation and product labeling • complete workplace records as required • maintain work area to meet housekeeping standards • use process control systems according to standard procedures • collect samples and conduct tests according to standard procedures

	• use oral communication skills/language competence to fulfil the job role as specified by the organisation, including questioning, active listening, asking for clarification and seeking advice from supervisor • work cooperatively within a culturally diverse workforce
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competency may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competency may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level II	
Unit Title	**Inspect and Sort Materials and Product**
Unit Code	**IND PHR2 18 0613**
Unit Descriptor	This unit of competency covers the skills and knowledge required to inspect and sort product and incoming materials ready for processing.

Elements	Performance Criteria
1. Inspect materials to confirm fitness for use	1.1 Type and quality requirements of materials are confirmed as per ***work information***. 1.2 ***Materials are transferred*** to required locations.
2. Sort materials	2.1 Materials are inspected to confirm quality requirements are met. 2.2 Materials are sorted as required to meet production requirements. 2.3 Unacceptable quality is identified and reported according to workplace reporting requirements. 2.4 The work area is maintained according to housekeeping standards. 2.5 Work is conducted in accordance with workplace environmental guidelines.

Variable	Range
Workplace information	May include: • work instructions • Standard Operating Procedures (SOPs) • specifications • production schedules • labels and codes • safety signs and symbols • photos or other visual representations of acceptable quality • standard forms • verbal messages • requests or instructions
Materials transfer equipment	May be mechanical or pneumatic, and may include: • conveyors and flumes pumped systems
Product inspection and sorting	May include: • sizing • quality inspection • sorting/grading • Aspects of these processes may be automated or done using equipment, such as sieves

	• Related processes may include trimming or removal of unacceptable product
Related processes	May include washing/cleaning product
Policies and procedures	Work is carried out according to company policies and procedures, regulatory and licensing requirements, legislative requirements, and industrial awards and agreements

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • recognize and act on materials or product that does not comply with quality standards • apply safe work practices and identify OHS hazards and controls
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • purpose and standards to be met by the inspection and sorting process, including criteria and specifications as they apply to inspection and sorting requirements • the relationship between visual inspection and sorting and other inspection procedures, such as those that may be conducted by a laboratory or at subsequent processing stages • typical causes of unacceptable or out-of-specification product, including causes of product damage that can occur prior to arrival at the plant and as part of the handling process • the stages that occur in the inspection and sorting process and their effect on product, such as in-line cleaning or conditioning and product or materials transfer stages • typical equipment faults and related causes, including signs and symptoms of faulty equipment and early warning signs of potential problems • contamination risks associated with the sorting process and related control measures • Occupational Health and Safety (OHS) hazards and controls, including the limitations of protective clothing and equipment relevant to the work process • procedures and responsibility for reporting production and performance information • environmental issues and controls relevant to equipment operation, including waste collection and handling procedures related to the process • basic operating principles of equipment used, where relevant, including main equipment components, status and purpose of guards, emergency stop, isolation and lockout controls, equipment operating capacities and applications • services required and action to take if services are not available • recording procedures and responsibilities where relevant

	• washing/cleaning requirements and standards where relevant
Underpinning Skills	Must demonstrate skills to: • access workplace information on materials specification/quality requirements • select, fit and use personal protective clothing and/or equipment • inspect quality of materials to confirm compliance with quality specifications, such as: ➢ product type and quantity ➢ product condition, such as identifying any bruising, discolouration or other damage, confirming product is clean, and checking size and weight • identify out-of-specification or non-conforming product and follow procedures to separate unacceptable product • respond to and/or report equipment failure within level of responsibility • maintain work area to meet housekeeping standards • complete workplace records as required according to enterprise procedures • demonstrate procedures for operating materials transfer equipment as required according to enterprise procedures • wash/clean raw materials or product according to enterprise procedures • use oral communication skills/language competence to fulfil the job role as specified by the organization, including questioning, active listening, asking for clarification and seeking advice from supervisor • work cooperatively within a culturally diverse workforce
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competency may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competency may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level II	
Unit Title	**Operate an Encapsulation Process**
Unit Code	**IND PHR2 19 0613**
Unit Descriptor	This unit of competency covers the skills and knowledge required to set up, operate, adjust and shut down the encapsulation process. This unit has application in a pharmaceutical manufacturing environment. It typically targets the production worker responsible for applying basic operating principles to the operation and monitoring of an encapsulation process and equipment. This person would typically work within defined Good Manufacturing Practice (GMP) programs and procedures.

Elements	Performance Criteria
1. Prepare the encapsulation process for operation	1.1 Materials are confirmed and available to meet operating requirements. 1.2 Cleaning and maintenance requirements and status are identified and confirmed in accordance to ***workplace information***. 1.3 Machine components and related attachments are fitted and adjusted to meet operating requirements. 1.4 Processing/operating parameters are entered as required to meet safety and production requirements. 1.5 Equipment performance is checked and adjusted as required. 1.6 Pre-start checks are carried out as required by workplace requirements.
2. Operate and monitor the encapsulation process	2.1 The ***encapsulation process*** is started and operated according to workplace procedures. 2.2 Equipment is monitored to identify variation in operating conditions. 2.3 Variation in equipment operation is identified and maintenance requirements are reported according to workplace reporting requirements. 2.4 The process is monitored to confirm that capsules meet specifications. 2.5 Out-of-specification product/process outcomes are identified, rectified and/or reported to maintain the process within specification. 2.6 The work area is maintained according to housekeeping standards.

	2.7 Work is conducted according to environmental standards. 2.8 Spillages are reported and removed according to standard operating procedures. 2.9 Workplace records are maintained according to workplace recording requirements.
3. Shut down the encapsulation process	3.1 End-of-batch procedures are completed in accordance with batch instructions and Standard Operating Procedures (SOPs). 3.2 The process is shut down according to workplace procedures. 3.3 Maintenance requirements are identified and reported according to workplace reporting requirements.

Variable	**Range**
Workplace information	May include: • SOPs • specifications • production schedules and instructions • manufacturers' advice • standard forms and reports
Stock for the encapsulation process	• is supplied from the granulation process and ingredients/raw materials from the dispensing process
Encapsulation equipment and accessories	May include: • semi-automatic filling machines • intermittent filling machines • continuous filling machines • augers • stirrers • hoppers • post-ejection accessories
Encapsulation filling methods	May include: • powder filling • pellet filling • solid filling • liquid filling
Capsule defects	May include: • short body • short cap • rough cut, • collect pinches • punched ends • long body or cap • split

	• wrinkles • specks • star ends • dirt • strings • bubbles • print errors/defects
Operation of equipment and processes	May require: • the use of process control panels and systems
Shutdown procedures	May include cleaning (in some cases cleaning may be carried out by a dedicated cleaning crew)
Services	Typical examples include: • power • steam • water • vacuum • gases • compressed and instrumentation air
Policies and procedures	Work is carried out according to company policies and procedures, regulatory and licensing requirements, legislative requirements, and industrial awards and agreements
Legislative requirements	relevant to this industry includes: • relevant Good Manufacturing Practice (GMP) codes • the Therapeutic Goods Act and/or other relevant legislation • legislation covering environmental management, OHS, anti-discrimination and equal opportunity

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • conduct pre-start checks on equipment used for encapsulation • start, operate, monitor and adjust process equipment to achieve required quality outcomes • take corrective action in response to typical faults and inconsistencies • complete workplace records as required • apply safe work practices and identify OHS hazards and controls • safely shut down equipment
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • purpose and basic principles of the encapsulation process • basic operating principles of equipment, such as main equipment components, status and purpose of guards, equipment operating capacities and applications, and the purpose and location of sensors and related feedback instrumentation

	• services required and action to take if services are not available • types of raw materials used in the encapsulation process and related handling/segregation requirements, such as handling hazardous goods • stages and changes which occur during encapsulation • quality characteristics and legal requirements to be achieved by the encapsulation process • the flow of the encapsulation process and the effect of outputs on downstream pharmaceutical processes • operating requirements and parameters and corrective action required where operation is outside specified operating parameters • typical equipment faults and related causes, including signs and symptoms of faulty equipment and early warning signs of potential problems • methods used to monitor the encapsulation process, such as inspecting, measuring and testing as required by the process • inspection or test points (control points) in the encapsulation process and the related procedures and recording requirements • GMP requirements associated with the encapsulation process and related control measures • common causes of variation and corrective action required • product/process changeover procedures and responsibilities • OHS hazards and controls, including the limitations of protective clothing and equipment relevant to the work process • end-of-batch procedures including procedures for calculating yield, materials reconciliation and action required if yield/reconciliation is not within prescribed limits, and product labeling responsibilities and procedures • requirements of different shutdowns as appropriate to the encapsulation process and workplace production requirements, including emergency and routine shutdowns and procedures to follow in the event of a power outage • line clearance, cleaning and sanitation procedures • isolation, lock out and tag out procedures and responsibilities • procedures and responsibility for reporting production and performance information • environmental issues and controls relevant to the encapsulation process, including waste collection and handling procedures related to the process • basic operating principles of process control, where relevant, including the relationship between control panels and

	systems and the physical equipment • sampling and testing associated with process monitoring and control where relevant • routine maintenance procedures where relevant
Underpinning Skills	Must demonstrate skills to: • access workplace information to identify production requirements for the encapsulation process • select, fit and use personal protective clothing and/or equipment • confirm supply of necessary materials and services to the encapsulation process • conduct pre-start checks, such as inspecting equipment condition to identify any signs of wear, selecting appropriate settings and/or related parameters, cancelling isolation or lock outs as required, confirming line clearance and cleaning status and that equipment is correctly configured for processing requirements, positioning sensors and controls correctly, ensuring any scheduled maintenance has been carried out, and confirming that all safety guards are in place and operational • verify raw materials with batch instructions • start, operate, monitor and adjust encapsulation process equipment to achieve required outcomes, including monitoring control points and conducting inspections as required to confirm process remains within specification, such as: ➢ flow rates/quantity ➢ product quality • take corrective action in response to out-of-specification results, such as adjusting the flow rates • monitor supply and flow of materials to and from the encapsulation process • respond to and/or report equipment failure within level of responsibility • locate emergency stop functions on equipment • follow isolation and lock out/tag out procedures as required to take encapsulation process and related equipment off-line in preparation for cleaning and/or maintenance within level of responsibility • demonstrate batch/product changeovers • follow end-of-batch procedures, including line clearance and cleaning, yield calculation, materials reconciliation and product labelling • complete workplace records as required • maintain work area to meet housekeeping standards • use process control systems according to enterprise procedures

	• collect samples and conduct tests according to enterprise procedures • conduct routine maintenance according to enterprise procedures • use oral communication skills/language competence to fulfil the job role as specified by the organization, including questioning, active listening, asking for clarification and seeking advice from supervisor • work cooperatively within a culturally diverse workforce
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competency may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competency may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level II	
Unit Title	**Operate a Process Control Interface**
Unit Code	**IND PHR2 20 0613**
Unit Descriptor	This unit of competency covers the skills and knowledge required to operate a computer-based interface to modify and/or interrogate a control system. This unit typically targets skills required by a production worker to operate equipment using process control interface. Work may require the ability to work within a team environment

Elements	Performance Criteria
1. Navigate the process control interface	1.1 The readiness of the control interface and related components for operation are confirmed. 1.2 Hardware provided is used to operate the interface. 1.3 Page links are used to move between screens. 1.4 Messages and alarms are acknowledged. 1.5 Required information is accessed from screen displays. 1.6 Interface system malfunctions are recorded and reported in accordance with workplace procedures.
2. Use interface system to operate and maintain a process within required parameters	2.1 Individual items of equipment and/or processes are started, monitored and shutdown using the control interface. 2.2 Equipment is selected, status altered and settings entered to meet operating requirements. 2.3 Sequences are activated to initiate process operation. 2.4 Equipment giving a bad signal or bad measurements is recognized and responsive action taken.
3. Analyse data to predict and control performance	3.1 Trends are selected and analyzed to identify performance patterns. 3.2 Causes of abnormal or unacceptable performance are identified and corrective action taken. 3.3 Information is recorded as required.

Variable	Range
Information accessed	May include: • graphics, trends • parameter settings • alarms and individual plant item status
Computer-based interface	May consist of: • computer processor • monitor • keyboards

	• track ball • mouse • storage devices • printers • (It is linked to the process control system)
Policies and procedures	Work is carried out in accordance with company policies and procedures, manufacturers' recommendations, legislative requirements, codes of practice and industrial awards and agreements
Workplace information	May include: • Standard Operating Procedures (SOPs) • manufacturers' specifications

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • operate and navigate interface to access, retrieve, enter and store work data • start, operate, monitor and shut down process equipment • control and adjust equipment using control interface to achieve production requirements • recognize faults and inconsistencies and take corrective action • complete workplace records as required • Apply safe work practices and identify OHS hazards and controls.
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • processes and equipment being controlled, including required processing sequences • operating principles of process control and interface system, including the relationship between control panels, systems and the physical equipment, and where relevant understanding of the operating conditions required for accurate information input from sensors and related instrumentation • action required to respond to error messages and alarms • typical faults that can occur when operating a process control interface and corrective action required • performance data collected by the control interface system and its application to troubleshoot performance, including the ability to identify and investigate related trend data to track cause and effect • recording requirements and responsibilities
Underpinning Skills	Must demonstrate skills to: • use all hardware components to operate the control interface • navigate the system to locate and use information required, including moving between screens and locating relevant performance data

	• operate the control system using the interface, including start up and shut down equipment components and change set points as required • locate sensors and instrumentation providing input signals to the control system and confirm operating order within level of responsibility • recognize and respond to error messages and alarms as required • access relevant performance data using the control system, including locating and interpreting performance trend information • record log information using the interface system according to enterprise procedures • use oral communication skills/language competence to fulfil the job role as specified by the organization, including questioning, active listening, asking for clarification and seeking advice from supervisor • work cooperatively within a culturally diverse workforce
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competency may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competency may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level II	
Unit Title	**Apply Principles of Statistical Process Control**
Unit Code	**IND PHR2 21 0613**
Unit Descriptor	This unit of competency covers the skills and knowledge required to collect statistical information and analyse and interpret data in order to inform work processes.

Elements	Performance Criteria
1. Collect statistical information	1.1 Data requirements are identified from ***BMR.***
	1.2 ***Data is collected*** to meet requirements.
2. Analyse and interpret data	2.1 ***Data is analysed*** to identify variation.
	2.2 Trends in data are identified.
	2.3 Corrective action requirements are determined based on data.

Variable	Range
BMR	Is Batch Manufacturing Record which contains the history of that specific product
Data collection	• may be based on a sampling regime followed by an operator or collected automatically. Data collection may include: • collecting samples and taking measurements
Data analysis	typically involves use of computer programs but may also be carried out manually

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • identify data for collection requirements for ensuring accuracy • interpret data • document data on charts, graphs or required workplace format • identify need for corrective action.
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • data sampling method, including the nature of the sample on which data is based and the reasons for different sampling requirements that may apply in a given situation • concept of variation, including the difference between common and special causes of variation and consequent options for reducing variation and remaining within a given range • the purpose and process of establishing targets and limits • concept of standard distribution/standard deviation • methods used to analyze statistical data, including methods to determine the average, median and mean, and what these measures indicate

Underpinning Skills	Must demonstrate skills to: • identify and collect required data • retrieve/access data, which may require use of computer programs to access and analyze data, and the ability to locate the relevant information or screens to collect and analyze the data • apply basic statistical analysis techniques to meet work requirements, such as plotting data on charts (e.g. run or control charts) and identify variation according to given limits • interpret data to identify trends (manually or using a computer program) • determine when corrective action is required, such as identifying upper and lower control limits (and warning limits where relevant)
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competency may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competency may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level II	
Unit Title	**Operate a Packaging Process**
Unit Code	**IND PHR2 22 0613**
Unit Descriptor	This unit of competency covers the skills and knowledge required to set up, operate, adjust and shut down a packaging process or sub-system. This unit has application in a pharmaceuticals process packing environment. It typically targets the worker responsible for applying basic operating principles to the operation and monitoring of a packing process and associated equipment. This unit is generic and should be customized for a given process. It should only be selected where no specific packaging unit is available.

Elements	Performance Criteria
1. Prepare the equipment and process for operation	1.1 ***Packaging*** components/consumables, materials and items to be packaged are confirmed and available to meet operating requirements. 1.2 Cleaning and maintenance requirements and status are identified and confirmed. 1.3 Machine components and related attachments are fitted and adjusted to meet operating requirements. 1.4 Operating parameters are entered as required to meet safety and production requirements. 1.5 Materials, product and packaging components/ consumables are loaded or positioned as required to meet packaging requirements. 1.6 Equipment performance is checked and adjusted as per the ***workplace information***. 1.7 Pre-start checks are carried out as required by workplace requirements.
2. Operate and monitor the process	2.1 The process is started and operated according to workplace procedures. 2.2 Equipment is monitored to identify variation in operating conditions. 2.3 Variation in ***equipment operation*** is identified and maintenance requirements are reported according to workplace reporting requirements. 2.4 The process is monitored to confirm that specifications are met. 2.5 Out-of-specification process outcomes are identified, rectified and/or reported to maintain the process within specification.

	2.6 The work area is maintained according to housekeeping standards. 2.7 Work is conducted in accordance with workplace guidelines. 2.8 Workplace records are maintained according to workplace recording requirements.
3. Shut down the process	3.1 The appropriate ***shutdown procedure*** is identified. 3.2 The process is shut down according to workplace procedures. 3.3 Maintenance requirements are identified and reported according to workplace reporting requirements.

Variable	**Range**
A packaging process	may relate to primary and/or secondary packaging activities. It typically requires the operation of a series of related items of equipment to achieve the required outcome.
Packaging	May include: • vacuum packing • Modified Atmosphere Packaging (MAP) • blister packaging or over wrapping • sachet
Workplace information may include:	• Standard Operating Procedures (SOPs) • specifications • equipment manual • production schedules and instructions • manufacturers' advice • standard forms and reports
Typical equipment that may form a packaging sub-system may include:	• conveyor systems • filling • sealing • wrapping • thermo-form equipment • case packers • bundlers • ink jet coders • labellers • palletisers • shrink wrappers and stripers
Policies and procedures	Work is carried out according to company policies and procedures, regulatory and licensing requirements, legislative requirements, and industrial awards and agreements
Legislative requirements	relevant to this industry includes: • general Standards Code, including labelling, weights and measures legislation' • legislation covering manufacturing safety, environmental management, OHS, anti-discrimination and equal opportunity

	• to the pharmaceutical industry, current Good Manufacturing Practice (cGMP) codes is applied .
Operation of equipment and processes	may require: • the use of process control panels and systems
Shutdown procedures	May include cleaning (in some cases cleaning may be carried out by a dedicated cleaning crew)

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • conduct pre-start checks on machinery used for packing • start, operate, monitor and adjust process equipment to achieve required quality outcomes • take corrective action in response to typical faults and inconsistencies • complete workplace records as required • apply safe work practices and identify OHS hazards and controls • safely shut down equipment
Underpinning Knowledge and Attitude	Must demonstrate knowledge of: • purpose and basic principles of the packaging process, including the purpose and characteristics required of packaging materials used and the principles of the packaging process used (where methods involve vacuum or map packaging, it includes an understanding of the effect of modified atmosphere on product shelf-life) • product and packaging coding requirements and related legal requirements, including product weight • basic operating principles of equipment, such as main equipment components, status and purpose of guards, equipment operating capacities and applications, and the purpose and location of sensors and related feedback instrumentation • services required and action to take if services are not available • the flow of processes supplying the packaging process and the effect of outputs on downstream processes • quality characteristics required of the packaging process, such as seal integrity requirements • effect of variation in inputs, such as packaging components/consumables, materials and/or services, on process performance • operating requirements and parameters and corrective action required where operation is outside specified operating parameters, including restart procedures following a crash or jam up

	• typical equipment faults and related causes, including signs and symptoms of faulty equipment and early warning signs of potential problems • methods used to monitor the packaging process, such as visual inspecting, and measuring and testing as required by the process • inspection or test points (control points) in the process and the related procedures and recording requirements • contamination risks related to stages in the packaging process and related control measures • common causes of variation and corrective action required • Occupational Health and Safety (OHS) hazards and controls • requirements of different shutdowns as appropriate to the packaging process, including emergency and routine shutdowns and procedures to follow in the event of a power outage, and conducting basic equipment referencing where required • product/packaging changeover procedures and • responsibilities • isolation, lock out and tag out procedures and responsibilities • procedures and responsibility for reporting production and performance information • environmental issues and controls relevant to the process, including waste/rework collection and handling procedures related to the process • basic operating principles of process control, where relevant, including the relationship between control panels and systems and the physical equipment • routine maintenance procedures where relevant • packaging integrity testing where relevant • cleaning and sanitation procedures where relevant
Underpinning Skills	Must demonstrate skills to: • access workplace information to identify packaging requirements • select, fit and use personal protective clothing and/or equipment • confirm supply of necessary packaging components/consumables, materials and services • conduct pre-start checks, such as inspecting equipment condition to identify any signs of wear, setting coders and printers, selecting appropriate equipment settings and/or related parameters, cancelling isolation or lockouts as required, confirming that equipment is clean and correctly configured for packaging requirements, positioning sensors and controls correctly, ensuring any scheduled maintenance has been completed, and confirming that all safety guards are in place and operational

	• start, operate, monitor and adjust packaging equipment to achieve required outcomes., such as packaging components/consumables and/or product, and monitoring control points (e.g. weights, codes, placement, glue temperatures, alignment and appearance, configuration and seal integrity) as required to confirm process remains within specification • monitor supply and flow of materials to and from the process • take corrective action in response to out-of-specification results • respond to and/or report equipment failure within level of responsibility • locate emergency stop functions on equipment • follow isolation and lock out/tag out procedures as required to take packaging equipment off-line in preparation for cleaning and/or maintenance within level of responsibility • demonstrate batch/process changeovers • complete workplace records as required • maintain work area to meet housekeeping standards • use process control systems according to enterprise procedures • integrity testing of packaging according to enterprise procedures • carry out routine maintenance according to enterprise procedures • clean and sanitize equipment according to enterprise procedures • use oral communication skills/language competence to fulfil the job role as specified by the organization, including questioning, active listening, asking for clarification and seeking advice from supervisor • work cooperatively within a culturally diverse workforce
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competency may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competency may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level II	
Unit Title	**Conduct Routine Maintenance**
Unit Code	**IND PHR2 23 0613**
Unit Descriptor	This unit of competency covers the skills and knowledge required to inspect equipment and carry out routine maintenance and/or adjustment using a limited range of hand tools.

Elements	Performance Criteria
1. Conduct routine inspection of plant and equipment	1.1 ***Equipment is inspected*** to identify signs of wear. 1.2 Nature of maintenance requirement is assessed.
2. Prepare to conduct routine maintenance	2.1 ***Maintenance task*** is assessed to determine tools and services required. 2.2 Equipment is prepared for maintenance. 2.3 Hand tools are selected according to task requirements. 2.4 Tools are checked before use and unsafe and/or faulty items are reported within standard procedures. 2.5 Maintenance is planned and scheduled in consultation with affected work areas to minimise disruption to production.
3. Carry out routine maintenance	3.1 ***Routine maintenance*** on equipment is carried out according to workplace procedures. 3.2 Maintenance activities are reported according to workplace reporting requirements.
4. Complete maintenance tasks	4.1 Equipment is returned to operating order. 4.2 ***Tools and materials*** are stored according to workplace procedure. 4.3 Relevant personnel are notified of maintenance completion. 4.4 Housekeeping standards are maintained. 4.5 Work is conducted in accordance with workplace guidelines.

Variable	Range
Inspections of equipment	May be carried out informally or as part of a structured program associated with proactive maintenance
Typical routine maintenance tasks may include:	• replacement of consumable components, such as O-rings, hoses, filters and other 'bolt-on/bolt-off' equipment parts • lubrication of equipment and maintenance of fluid levels • simple adjustment, alignment or attachment of equipment components, parts, guides and sensors • clearing blocked nozzles, such as glue nozzles • positioning/attaching equipment components

Routine maintenance	• is carried out according to company policies and procedures, licensing requirements, legislative requirements and industrial awards and agreements
Tools and materials	May: • depend on the maintenance function and may include: • a limited range of hand tools, such as spanners and screwdrivers, grease guns, Allen keys and measuring and alignment equipment Materials may include: ➢ lubricants ,oil
Workplace information	May include: • Standard Operating Procedures (SOPs) • specifications • log books • Operating manual • routine maintenance schedules • manufacturers' advice • condition monitoring information

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • identify routine maintenance tasks for machine or equipment • monitor operation and identify need for maintenance tasks • schedule maintenance tasks and communicate requirements with affected personnel • select and use appropriate hand tools to undertake routine maintenance • assess readiness for returning machine or equipment to operation or referring for further attention • complete maintenance documentation • Apply safe work practices and identify OHS hazards and controls.
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • system in place to manage maintenance of plant and equipment in the workplace, including programs, such as responsive, preventative and proactive maintenance as appropriate • responsibilities for participating in the maintenance program, including scope of operator responsibilities, roles of others involved in plant and equipment maintenance and procedures for raising maintenance orders where requirements are outside operator role • basic operating principles of equipment to be maintained • signs and symptoms of faulty equipment and early warning signs of potential problems • basic checks used to confirm the nature of maintenance requirements, including distinguishing between mechanical and electrical faults and identifying probable causes or

	conditions that may increase maintenance requirements of equipment used • procedures for issuing, maintaining and storing tools used • safe use of hand tools and measuring instrumentation relevant to maintenance responsibilities • safe work procedures, including appropriate signage of maintenance activities as required, use of appropriate personal protective clothing and equipment, and awareness of safety hazards and controls relating to maintenance tasks • methods used to render equipment safe to work on or clean including lock out/tag out and isolation procedures (in some cases this may involve liaising with other maintenance operators) • procedures and inspections to be carried out to confirm that equipment is in operating order and all parts are accounted for risks arising from poor personal hygiene, cleaning and housekeeping practices and procedures associated with routine maintenance • maintenance planning, scheduling and recording procedures
Underpinning Skills	Must demonstrate skills to: • access workplace information such as the equipment history, faults or difficulties • select, fit and use personal protective clothing and/or equipment • inspect equipment for signs of wear, such as visual inspections to detect leaks, listening for unusual noises and/or vibrations • identify and describe maintenance requirements, including the ability to assess the urgency of the maintenance issue, recognize common types of maintenance requirements and run basic checks according to workplace procedures to confirm the need for and type of maintenance support required • take action to address maintenance requirements, such as carrying out routine maintenance within level of skill and responsibility and/or reporting outstanding maintenance to appropriate personnel using the required forms or request system • plan and schedule maintenance within level of responsibility, such as consulting affected personnel and/or work areas on timing and notifying of maintenance progress • prepare equipment and work area for routine maintenance, including cleaning equipment prior to carrying out maintenance and confirming that equipment is safe to work on, and simple isolation or tag out of equipment as required by workplace procedure • select and use hand tools as required to carry out maintenance task

	• select relevant parts and materials as required to carry out maintenance task • carry out routine maintenance tasks according to workplace procedures • on completion of maintenance tasks, return equipment to operational order, including confirming that all equipment parts, nuts and bolts are accounted for and correctly tightened, and where required, cleaning and sanitizing equipment • store tools in designated location, including basic tool maintenance, such as oiling • complete records of maintenance as required • maintain work area to meet housekeeping standards • use oral communication skills/language competence to fulfil the job role as specified by the organization, including questioning, active listening, asking for clarification and seeking advice from supervisor • work cooperatively within a culturally diverse workforce
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competency may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competency may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level II	
Unit Title	**Clean and Sanitize Equipment**
Unit Code	**IND PHR2 24 0613**
Unit Descriptor	This unit of competency covers cleaning, sanitation and related procedures for pharmaceutical manufacturing process of production equipment.

Elements	Performance Criteria
1. Prepare for cleaning	1.1 ***Cleaning/sanitising agents and services*** are available and ready for use ***workplace information***. 1.2 Equipment is cleared of product and/or packaging consumables in preparation for cleaning. 1.3 Equipment is rendered safe to clean according to workplace procedure.
2. Clean and sanitise equipment to meet workplace requirements	2.1 ***Equipment is cleaned and sanitised*** according to workplace procedure and requirements. 2.2 Equipment is inspected to confirm operating condition and cleanliness. 2.3 Unacceptable equipment condition is identified and reported according to workplace procedures. 2.4 ***Cleaning equipment and chemicals*** are stored according to workplace procedure. 2.5 Waste from cleaning process is disposed of according to workplace procedures. 2.6 Work is conducted in accordance with workplace information. 2.7 Equipment is restored to operating order.

Variable	Range
Cleaning and sanitizing chemicals	• may be pre-mixed or manually mixed
Workplace information may include:	• Standard Operating Procedures (SOPs) • specifications • production and cleaning schedules • labels and codes • safety signs and symbols • Materials Safety Data Sheets (MSDS) • standard forms and written or verbal instruction
Preparing/restoring equipment to operating order	May involve: • simple dismantling and reassembling of equipment parts • basic isolation • covering of motors and instrumentation

Chemicals used	Alcohols(70%), disinfectant, antiseptics etc
Services	May include: • power • water • steam • compressed and instrumentation air
Inspecting cleaning effectiveness	typically involves carrying out a visual inspection
Policies and procedures	Work is carried out in accordance with company procedures, licensing requirements, legislative requirements, and industrial awards and agreements. to the pharmaceutical industry, current Good Manufacturing Practice (GMP) code is applied

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • prepare equipment for cleaning • prepare and use chemicals according to safe work requirements • clean and sanitize equipment to meet work standards • monitor cleaning and report or address any non-compliances • dispose of waste according to environmental guidelines • complete required documentation • apply safe work practices and identify OHS hazards and controls
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • the purpose of cleaning and sanitation and importance in maintaining standard safety • functions of cleaners, sanitizers and related equipment • safe work procedures, including appropriate signage of cleaning activities, safe handling and storage of cleaners and sanitizers used, safety when using cleaning methods, such as hot water and steam hoses, and status and purpose of safety guards • purpose and limitations of protective clothing and equipment • cleaning and sanitation requirements relating to work responsibilities, including the need for different levels of cleaning where relevant • procedures for preparing cleaners and sanitizers as required • cleaning method/s to be followed relating to work responsibilities • other work areas/operators who need to be consulted/advised on timing of cleaning • methods used to render equipment safe to clean, including understanding the status and purpose of equipment guards, relevant lock out/tagout and isolation procedures and related equipment settings for both cleaning and operating as required

	• procedures for conducting cleaning and sanitizing • types of waste generated by the cleaning process and related collection, treatment and disposal requirements • potential environmental impact of incorrect waste handling • inspection, cleaning and storage requirements of cleaning equipment used • inspection points and methods for confirming the effectiveness of cleaning and sanitation, including visual inspection, and where required, recording of cleaning conducted • inspection requirements to confirm equipment condition, including acceptable equipment condition, ability to identify faulty or unacceptable equipment and take required corrective action • recording requirements and responsibilities • routine maintenance procedures where relevant • sampling methods and test procedures where relevant
Underpinning Skills	Must demonstrate skills to: • access workplace information, such as the cleaning schedule to identify cleaning requirements • select, fit and use personal protective clothing and/or equipment • confirm supply of necessary cleaning and sanitizing equipment and services • select and prepare cleaners and sanitizers as required according to workplace procedures • prepare equipment for cleaning, such as rendering equipment safe to clean, clearing product and waste materials, covering motors and instrumentation where steam or water hoses are used, and simple dismantling of equipment parts • advise any affected work areas/operators of cleaning progress to coordinate timely completion with minimal disruption to production • clean and sanitize equipment as required according to workplace procedures and cleaning schedule • return equipment to operating order (this may involve basic assembly of equipment parts) • inspect equipment to identify equipment condition and cleanliness • locate emergency stop functions on equipment • report and/or correct unacceptable equipment condition • maintain housekeeping standards • prepare cleaners and sanitizers as required • store cleaners, sanitizers and related equipment as required • carry out relevant checks and inspections • maintain work area to meet housekeeping standards • conduct routine maintenance according to standards procedures

	• take samples and conduct tests according to enterprise procedures • record cleaning and sanitation information according to enterprise procedures • use oral communication skills/language competence to fulfil the job role as specified by the organization, including questioning, active listening, asking for clarification and seeking advice from supervisor • work cooperatively within a culturally diverse workforce
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competency may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competency may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level II	
Unit Title	**Operate a Boiler, – Basic**
Unit Code	**IND PHR2 25 0613**
Unit Descriptor	This unit describes the outcomes required for continuous and short term operation of a basic boiler and for start-up and shut down after a prolonged break.

Elements	Performance Criteria
1. Prepare the boiler for operation	1.1 Health and safety ***hazards*** / maintenance requirements are identified and reported to appropriate personnel according to workplace reporting procedures. 1.2 The boiler is purged according to workplace procedure. 1.3 Services are confirmed and available in accordance with ***workplace information.*** 1.4 Pre-operational checks are conducted to confirm operational status of ***boiler and related equipment***.
2. Start and monitor boiler operation	2.1 The boiler is started and brought on line safely according to workplace procedures and manufacturer's specifications. 2.2 Plant is operated within limits of manufacturer's specifications to meet workplace requirements. 2.3 Equipment is monitored to confirm operating condition. 2.4 Water quality is tested and adjusted as required. 2.5 Sluice water is circulated to remove ash from boiler according to duty requirements. 2.6 The workplace meets housekeeping standards.
3. Analyse and respond to abnormal performance	3.1 Operating data and plant operating conditions are analysed to identify causes of abnormal performance. 3.2 Corrective action is taken in accordance with workplace procedures in response to hazards, out-of-specification test results and/or plant performance. 3.3 Emergency procedures are implemented as required according to workplace procedures and manufacturer's recommendations.
4. Handover boiler operations	4.1 Workplace records are maintained in accordance with statutory requirements and workplace procedures. 4.2 Handover is carried out according to workplace procedure. 4.3 Boiler operators are aware of boiler status and related equipment at completion of handover.
5. Carry out an operational shutdown	5.1 The boiler is shut down according to workplace procedures and manufacturer's recommendations. 5.2 Maintenance requirements are identified and reported according to workplace reporting procedure.

6. Shutdown the boiler and prepare for an internal inspection	6.1 The boiler is shut down according to workplace procedures and manufacturer's recommendations. 6.2 The boiler is cleaned internally and externally according to workplace procedures and manufacturer's recommendations. 6.3 Valves and fittings are removed in preparation for maintenance.
7. Store boiler in shutdown mode	7.1 The boiler is stored in the appropriate storage mode according to workplace procedures and manufacturer's recommendations.
8. Record information	8.1 Workplace information is recorded according to workplace recording requirements.

Variable	**Range**
Hazards	Typically include: • working around hot surfaces • manual handling • Steam, hot gasses and fuel leaks
Workplace information	May include: • Standard Operating Procedures (SOPs) • Manufacturer’s specifications
Boilers [basic] and related equipment	May be fully or partly attended, and include: • single fixed combustion air supply • non-modulating single heat source • Fixed firing rate. • Operation and monitoring of equipment and processes typically requires the use of control panels and systems
Equipment status	May include: • conducting relevant pre-start checks • confirming that cleaning standards are met • all safety guards and manholes are in place • Equipment is operational.
Services	May include: • fuel supply of bagasse, • coal, • gas, • oil or other fuel types, • steam, • mill and instrumentation air, • cooling water, • general mill water supply and cooling water
Internal cleaning	Is carried out in accordance with statutory requirements regarding confined space entry and does not typically include chemical cleaning.
Teamwork	May require the ability to work within a team environment.

Information systems	May be print or screen based.
Policies and procedures	Work is carried out in accordance with company policies and procedures, licensing requirements, manufacturer's recommendations, legislative requirements, codes of practice and industrial awards and agreements.
Codes of Practice	Include the pharmaceutical Industry Code of Practice.

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • confirm status of boiler and related equipment including the fuel supply system, ash removal and services • demonstrate purge procedure • conduct pre-start checks • liaise with other work areas to advise of boiler status • demonstrate set up and start up procedures in both manual and automatic modes • conduct water quality test • take corrective action in response to out-of-specification results • report and/or record corrective action • Demonstrate emergency procedures and related re-start.
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • relevant state OHS legislation, standards and codes of practice relating to work responsibilities • safe work procedures including awareness of health and safety hazards related to boiler operation and associated control measures • purpose and limitations of protective clothing and equipment • hierarchy of hazard control measures • duty of care of the boiler operator • purpose and basic principles of combustion and boiler operation including principles of heat transfer and properties of steam • boiler system layout and steam cycle • the purpose of purging a boiler • the effect of fuel quality on boiler operation • impact of ash removal on efficient boiler operation and impact of sluice water flow • relationship to other processes including an understanding of the impact of sudden load changes on boiler pressure and plant operation • purpose and limitations of protective clothing and equipment • methods used to render equipment safe to inspect, maintain and/or clean including lock-out, tag-out and isolation procedures • water quality test procedures

	• typical causes of water/condensate contamination and corrective action required • equipment purpose and basic operating principles including high pressure feed pumps, fuel supply system and dual fuel systems as required by boiler type • operating requirements and parameters • procedures for responding to emergency situations including safe shutdown procedure • handover and long term shut down and storage procedures • cleaning procedures and grate dumping • environmental issues and controls including an understanding of sluice water usage • requirements to liaise/advise related work areas • housekeeping standards for the work area • reporting and recording systems including both statutory and workplace requirements relevant state OHS legislation, standards and codes of practice relating to work responsibilities • safe work procedures including awareness of health and safety hazards related to boiler operation and associated control measures • purpose and limitations of protective clothing and equipment • hierarchy of hazard control measures • duty of care of the boiler operator • purpose and basic principles of combustion and boiler operation including principles of heat transfer and properties of steam • boiler system layout and steam cycle • the purpose of purging a boiler • the effect of fuel quality on boiler operation • impact of ash removal on efficient boiler operation and impact of sluice water flow • relationship to other processes including an understanding of the impact of sudden load changes on boiler pressure and plant operation • purpose and limitations of protective clothing and equipment • methods used to render equipment safe to inspect, maintain and/or clean including lock-out, tag-out and isolation procedures • water quality test procedures • typical causes of water/condensate contamination and corrective action required • equipment purpose and basic operating principles including high pressure feed pumps, fuel supply system and dual fuel systems as required by boiler type • operating requirements and parameters

	• procedures for responding to emergency situations including safe shutdown procedure • handover and long term shut down and storage procedures • cleaning procedures and grate dumping • environmental issues and controls including an understanding of sluice water usage • requirements to liaise/advise related work areas • housekeeping standards for the work area • reporting and recording systems including both statutory and workplace requirements
Underpinning Skills	Must demonstrate skills to: • access workplace information on combustion and operating requirements • select, fit and use personal protective clothing and/or equipment • identify and report hazards and potential hazards in the work area • confirm status of boiler and related equipment including the fuel supply system, ash removal and services • demonstrate purge procedure • conduct pre-start checks including checking: ➢ feed water supply and system ➢ fuel supply system ➢ fans and dampers ➢ inspection doors ➢ boiler valves - operation and position ➢ combustion air supply system ➢ boiler water level • liaise with other work areas to advise of boiler status • demonstrate set-up and start-up procedures in both manual and automatic modes • monitor boiler operation including monitoring: ➢ steam reticulation line pressure ➢ boiler steam pressure ➢ steam supply/usage ➢ condensate tank level ➢ bagasse levels ➢ feed water levels and pressure ➢ fuel levels ➢ boiler load ➢ water quality ➢ furnace pressure ➢ ash pit level and removal system ➢ balance draft system ➢ super heater temperature ➢ drum levels ➢ equipment condition • conduct water quality test

	• take corrective action in response to out-of-specification results • report and/or record corrective action as required • demonstrate shift handover procedure and confirm that replacement operators are aware of all relevant issues prior to completing handover • demonstrate procedure to take boiler off line • demonstrate procedure to shut-down and clean the boiler • demonstrate removal of valves and fittings to prepare the boiler for inspection • demonstrate procedure to store boiler • demonstrate emergency procedures and related re-start including the use of emergency fuel supply • maintain workplace records • maintain work area to meet housekeeping standards
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competency may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competency may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level II	
Unit Title	**Operate an Homogenising Process**
Unit Code	**IND PHR2 26 0613**
Unit Descriptor	This unit of competency covers the skills and knowledge required to set up, operate, adjust and shut down homogenising equipment.

Elements	Performance Criteria
1. Prepare homogenising process for operation	1.1 Materials are confirmed and available to meet operating requirements. 1.2 Cleaning and maintenance requirements and status are identified and confirmed in accordance to ***workplace information***. 1.3 Machine components and related attachments are fitted and adjusted to meet operating requirements. 1.4 Processing/operating parameters are entered as required to meet safety and production requirements. 1.5 Equipment performance is checked and adjusted as required. 1.6 Pre-start checks are carried out as required by workplace requirements.
2. Operate and monitor the homogenising process	2.1 The process is started and operated according to workplace procedures. 2.2 Equipment is monitored to identify variation in operating conditions. 2.3 Variation in ***equipment operation*** is identified and maintenance requirements are reported according to workplace reporting requirements. 2.4 The process is monitored to confirm that specifications are met. 2.5 Out-of-specification product/process outcomes are identified, rectified and/or reported to maintain the process within specification. 2.6 The work area is maintained according to housekeeping standards. 2.7 Work is conducted in accordance with workplace environmental guidelines. 2.8 Workplace records are maintained according to workplace recording requirements.

3. Shut down homogenising equipment	3.1 The appropriate ***shutdown procedure*** is identified. 3.2 The process is shut down according to workplace procedures. 3.3 Maintenance requirements are identified and reported according to workplace reporting requirements.

Variable	**Range**
Workplace information	May include: • Standard Operating Procedures (SOPs) • specifications • production schedules and instructions • manufacturers' advice • standard forms and reports
Operation of equipment and processes	May require: • the use of process control panels and systems
Homogenizing equipment	Typically includes: • supply pump • homogenizer block • homogenizing valve • pressure gauge • back-pressure valve • pressure relief valve • pressure • micro-gap • centrifugal and ultrasonic homogenizers • Related equipment may include: • a de-aeration unit
Shutdown procedures	May include: • cleaning (in some cases cleaning may be carried out by a dedicated cleaning crew) • cleaning SOPs • equipment manual
Processes	May be batch or continuous, and apply to single or multiple product types
Services	May need to be confirmed. These depend on the nature of the process. Typical examples include: • power • steam • water • vacuum • compressed and instrumentation air
Policies and procedures	Work is carried out according to company policies and procedures, regulatory and licensing requirements, legislative requirements, and industrial awards and agreements

Legislative requirements	relevant to this industry includes: ● the Standards Code, including labelling, weights and measures legislation ● legislation covering pharmaceuticals manufacturing safety, environmental management, OHS, anti-discrimination and equal opportunity

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: ● conduct pre-start checks on machinery used for homogenizing ● start, operate, monitor and adjust process equipment to achieve required quality outcomes ● take corrective action in response to typical faults and inconsistencies ● complete workplace records as required ● apply safe work practices and identify OHS hazards and controls ● safely shut down equipment
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: ● purpose and basic principles of homogenising ● basic operating principles of equipment, including main equipment components, status and purpose of guards, equipment operating capacities and applications, and the purpose and location of sensors and related feedback instrumentation ● effect of raw materials on homogenisation, such as variables, including solids (brix), acidity, temperature, consistency and colour on process outcomes ● quality requirements to be achieved by the homogenisation process ● the flow of the homogenising process and the effect of product output on downstream processes ● operating requirements and parameters and corrective action required where operation is outside specified operating parameters ● typical equipment faults and related causes, including signs and symptoms of faulty equipment and early warning signs of potential problems ● techniques used to monitor the homogenising process, such as inspecting, measuring and testing as required by the process ● inspection or test points (control points) in the process and the related procedures and recording requirements ● common causes of variation and corrective action required ● Operational Health and Safety (OHS) hazards and controls

	• requirements of different shutdowns as appropriate to the process and workplace production requirements, including emergency and routine shutdowns and procedures to follow in the event of a power outage • isolation, lock out and tag out procedures and responsibilities • product/process changeover procedures and responsibilities • procedures and responsibility for reporting production and performance information • environmental issues and controls relevant to the homogenising process, including waste/rework collection and handling procedures related to the process • basic operating principles of process control where relevant, including the relationship between control panels and systems and the physical equipment • sampling and testing associated with process monitoring and control where relevant • routine maintenance procedures where relevant • cleaning and sanitation procedures where relevant
Underpinning Skills	Must demonstrate skills to: • access workplace information to identify processing requirements • select, fit and use personal protective clothing and/or equipment • confirm supply of necessary materials and services • conduct pre-start checks, such as inspecting equipment condition to identify any signs of wear, selecting appropriate settings and/or related parameters, cancelling isolation or lockouts as required, and confirming that equipment is clean and correctly configured for processing requirements, positioning sensors and controls correctly, ensuring any scheduled maintenance has been carried out, and confirming that all safety guards are in place and operational • start, operate, monitor and adjust process equipment to achieve required outcomes, including monitoring control points and conducting inspections as required to confirm the homogenising process remains within specification, such as: ➢ temperature ➢ pressure ➢ throughput • monitor supply and flow of materials to and from the process • take corrective action in response to out-of-specification results • respond to and/or report equipment failure within level of responsibility • locate emergency stop functions on equipment

	• follow isolation and lock out/tag out procedures as required to take process and related equipment off-line in preparation for cleaning and/or maintenance within level of responsibility • demonstrate batch/product changeovers • complete workplace records as required • maintain work area to meet housekeeping standards • use process control systems according to enterprise procedures • conduct routine maintenance according to enterprise procedures • collect samples and conduct tests according to enterprise procedures • clean and sanitise equipment according to enterprise procedures • use oral communication skills/language competence to fulfil the job role as specified by the organisation, including questioning, active listening, asking for clarification and seeking advice from supervisor • work cooperatively within a culturally diverse workforce
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competency may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competency may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level II	
Unit Title	**Handle Dangerous Goods/Hazardous Substances**
Unit Code	**IND PHR2 27 0613**
Unit Descriptor	This unit involves the skills and knowledge required to handle dangerous goods and hazardous substances, including identifying requirements for working with dangerous goods and/or hazardous substances; confirming site incident procedures; and selecting handling techniques. Licensing, legislative, regulatory or certification requirements are applicable to this unit. This unit covers anyone working in the transport, warehousing, distribution and storage industries who may handle dangerous goods and/or hazardous substances.

Elements	Performance Criteria
1. Identify requirements for working with dangerous goods and/or hazardous substances	1.1 ***Dangerous goods*** and/or hazardous substances are identified from information including class labels, manifests and other documentation. 1.2 Storage requirements for ***hazardous*** substances and/or dangerous goods are identified and applied. 1.3 Legislative requirements for hazardous substances and/or dangerous goods are known and used to plan work activities. 1.4 Handling procedures for different classes and characteristics of goods are observed. 1.5 Confirmation is sought from relevant personnel where dangerous goods or hazardous materials do not appear to be appropriately marked.
2. Confirm site incident procedures	2.1 Incident reporting processes are identified. 2.2 Emergency equipment is located and checked according to ***workplace*** procedures and statutory regulations. 2.3 Emergency procedures are identified and confirmed.
3. Select handling techniques	3.1 Load handling and shifting procedures are selected in accordance with identified requirements for particular goods. 3.2 Handling equipment is checked for conformity with workplace requirements and manufacturers guidelines. 3.3 Where relevant, suitable signage is checked for compliance with ***workplace procedures***.

Variable	Range
The dangerous goods	May be handled in a range of work environments by day or night for: • short-term storage • for long-term storage and in transit

Hazards	May include: • hazardous or dangerous materials • contamination of, or from, materials being handled • noise, light, energy sources • stationary and moving machinery, parts or components • service lines • spills, leakages, ruptures • fire or ignition • dust/vapours
Hazard management	is consistent with the principle of hierarchy of control with elimination, substitution, isolation and engineering control measures being selected before safe working practices and personal protective equipment
Information/ documents	May include: • goods identification numbers and codes • manifests, stock lists, packaging labels, bar codes, stock lists • goods and container identification • workplace procedures and policies concerning the handling of dangerous goods and hazardous substances • supplier and/or client instructions • Materials Safety Data Sheets (MSDS) • relevant legislation, codes, regulations and related documentation concerning the handling of dangerous goods and hazardous substances • award, enterprise bargaining agreement, other industrial arrangements • standards and certification requirements • quality assurance procedures • emergency procedures pertaining to dangerous goods and hazardous substances
Customers	may be internal or external
Workplace environment	May include: • movement of equipment • movement of goods • materials and vehicular traffic
Requirements for work	May include: • site restrictions and procedures • use of safety and personal protective equipment • communications equipment • specialized lifting and/or handling equipment • incident breakdown procedures • authorities and permits • hours of operations • noise restrictions • additional gear and equipment • segmentation procedures

	• emergency procedures, including response to spillage/leaks, evacuation and firefighting
Consultative processes	May involve: • other employees and supervisors • suppliers, potential customers and existing clients • representatives of regulatory authorities with jurisdiction over OHS, dangerous goods and hazardous substances • management and union representatives • industrial relations and OHS specialists • other maintenance, professional or technical staff
Personnel in the work area	May include: • workplace personnel • site visitors • contractors • official representatives
Identification of goods	May be from: • material safety data sheets • packaging labels • manifests • stock lists • HAZCHEM interpretative advice
Workplace procedures	May include: • company procedures • enterprise procedures • organizational procedures • established procedures
Personal protective equipment	May include: • gloves • safety headwear and footwear • safety glasses • mask and respirator • protective clothing • breathing apparatus
Applicable regulations and legislation	May include: • regulations relating to the handling of dangerous goods and hazardous substances • international regulations and codes of practice for the handling and transport of dangerous goods and hazardous substances, including: • International Dangerous Goods Code • IATA Dangerous Goods by Air regulations • International Explosives Codes • all relevant Standards • relevant state/territory OHS legislation • workplace relations regulations • equal employment opportunity and affirmative action legislation

	• equal opportunity legislation • relevant state/territory environmental protection legislation

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills in: • identifying dangerous goods/hazardous substances (from labels, IMDG markings, HAZCHEM signs and other relevant identification criteria) • identifying and selecting the safely requirements for handling dangerous goods/hazardous substances • maintaining workplace records and documentation • determining (any) required permits • identifying job and site hazards and planning work to minimise risks • selecting appropriate equipment and work systems including personal protection equipment • estimating weight and dimensions of load and any special requirements • identifying and assessing handling and storage precautions and requirements for dangerous goods/hazardous substances
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • All relevant regulations and codes concerning the handling of dangerous goods hazardous substances • Permit and licence requirements • Workplace procedures for handling and storing dangerous goods/hazardous substances • Problems that may arise during the handling of dangerous goods and hazardou substances and actions that should be taken to prevent or solve them • Risks when handling dangerous goods and hazardous substances and related precautions to control the risk • Equipment applications, capacities, configurations, safety hazards and control mechanisms • Housekeeping standards procedures required in the workplace
Underpinning Skills	Must demonstrate skills to: • Communicate effectively with others when handling dangerous goods and hazardous substances • Read and interpret instructions, procedures, regulations, information and signs relevant to the handling of dangerous goods and hazardous substances • Identify containers and goods coding, markings and, where applicable, emergency information panels for the mode of transport storage selected • Interpret and follow operational instructions and prioritise work • Complete documentation related to work activities • Operate electronic communication equipment to required protocol

	• Work collaboratively with others when handling dangerous goods and hazardous substances • Adapt appropriately to cultural differences in the workplace, including modes of behavior and interactions with others • Promptly report and/or rectify any identified problems, faults or malfunctions that may occur when handling dangerous goods and hazardous substances in accordance with regulatory requirements and workplace procedures • Plan own work including predicting consequences and identifying improvements • Implement contingency plans for unanticipated situations that may arise when handling dangerous goods and hazardous substances • Recognize hazards and apply precautions and required action to minimize, control or eliminate hazards that may exist during the handling of dangerous goods and hazardous substances • Monitor work activities in terms of planned schedule • Modify activities depending on differing operational contingencies, risk situations and environments • Work systematically with required attention to detail without injury to self or others, or damage to goods or equipment • Operate and adapt to differences in equipment in accordance with standard operating procedures • Select and use required personal protective equipment conforming to industry and OHS standards
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competency may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competency may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level II	
Unit Title	**Participate in Workplace Communication**
Unit Code	**IND PHR2 28 0613**
Unit Descriptor	This unit covers the knowledge, skills and attitudes required to gather, interpret and convey information in response to workplace requirements.

Elements	Performance Criteria
1. Obtain and convey workplace information	1.1 Specific and relevant information is accessed from ***appropriate sources***. 1.2 Effective questioning, active listening and speaking skills are used to gather and convey information. 1.3 Appropriate ***medium*** is used to transfer information and ideas. 1.4 Appropriate non- verbal communication is used. 1.5 Appropriate lines of communication with supervisors and colleagues are identified and followed. 1.6 Defined workplace procedures for the location and ***storage*** of information are used. 1.7 Personal interaction is carried out clearly and concisely.
2. Participate in workplace meetings and discussions	2.1 Team meetings are attended on time. 2.2 Own opinions are clearly expressed and those of others are listened to without interruption. 2.3 Meeting inputs are consistent with the meeting purpose and established ***protocols***. 2.4 ***Workplace interactions*** are conducted in a courteous manner. 2.5 Questions about simple routine workplace procedures and matters concerning working conditions of employment are asked and responded to. 2.6 Meetings outcomes are interpreted and implemented.
3. Complete relevant work related documents	3.1 Range of ***forms*** relating to conditions of employment is completed accurately and legibly. 3.2 Workplace data is recorded on standard workplace forms and documents. 3.3 Basic mathematical processes are used for routine calculations. 3.4 Errors in recording information on forms/ documents are identified and properly acted upon.

	3.5 Reporting requirements to supervisor are completed according to organizational guidelines.

Variable	Range
Appropriate sources	May include but not limited to: • Team members • Suppliers • Trade personnel • Local government • Industry bodies
Medium	May include but not limited to: • Memorandum • Circular • Notice • Information discussion • Follow-up or verbal instructions • Face to face communication
Storage	May include but not limited to: • Manual filing system • Computer-based filing system
Protocols	May include but not limited to: • Observing meeting • Compliance with meeting decisions • Obeying meeting instructions
Workplace interactions	May include but not limited to: • Face to face • Telephone • Electronic and two way radio • Written including electronic, memos, instruction and forms, non-verbal including gestures, signals, signs and diagrams
Forms	May include but not limited to: • Personnel forms, telephone message forms, safety reports

Evidence Guide	
Critical Aspects of Competency	Demonstrates skills and knowledge to: • Prepare written communication following standard format of the organization • Access information using communication equipment • Mae use of relevant terms as an aid to transfer information effectively • Convey information effectively adopting the formal or informal communication
Underpinning Knowledge and Attitudes	Demonstrate knowledge of: • Effective communication • Different modes of communication • Written communication

	• Organizational policies • Communication procedures and systems • Technology relevant to the enterprise and the individual's work responsibilities
Underpinning Skills	Demonstrate skills to: • Follow simple spoken language • Perform routine workplace duties following simple written notices • Participate in workplace meetings and discussions • Complete work related documents • Estimate, calculate and record routine workplace measures • Do basic mathematical processes of addition, subtraction, division and multiplication • relate to people of social range in the workplace • Gather and provide information in response to workplace Requirements
Resource Implications	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competence may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competence may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level II	
Unit Title	**Work in Team Environment**
Unit Code	**IND PHR2 29 0613**
Unit Descriptor	This unit covers the skills, knowledge and attitudes to identify role and responsibility as a member of a team.

Elements	Performance Criteria
1. Describe team role and scope	1.1 The ***role and objective of the team*** are identified from available ***sources of information***. 1.2 Team parameters, reporting relationships and responsibilities are identified from team discussions and appropriate external sources.
2. Identify own role and responsibility within team	2.1 Individual role and responsibilities within the team environment are identified. 2.2 Roles and responsibility of other team members are identified and recognized. 2.3 Reporting relationships within team and external to team are identified.
3. Work as a team member	3.1 Effective and appropriate forms of communications used and interactions undertaken with team members who contribute to known team activities and objectives. 3.2 Effective and appropriate contributions are made to complement team activities and objectives, based on individual skills and competencies and ***workplace context.*** 3.3 Protocols are observed in reporting using standard operating procedures. 3.4 Contribute to the development of team work plans based on an understanding of team's role and objectives and individual competencies of the members.

Variable	Range
Role and objective of team	May include but not limited to: • Work activities in a team environment with enterprise or specific sector • Limited discretion, initiative and judgment maybe demonstrated on the job, either individually or in a team environment
Sources of information	May include but not limited to: • Standard operating and/or other workplace procedures • Job procedures • Machine/equipment manufacturer's specifications and instructions • Organizational or external personnel

	• Client/supplier instructions • Quality standards • OHS and environmental standards
Workplace context	May include but not limited to: • Work procedures and practices • Conditions of work environments • Legislation and industrial agreements • Standard work practice including the storage, safe handling and disposal of chemicals • Safety, environmental, housekeeping and quality guidelines

Evidence Guide	
Critical Aspects of Competence	Demonstrates skills and knowledge to: • Operate in a team to complete workplace activity • Work effectively with others • Convey information in written or oral form • Select and use appropriate workplace language • Follow designated work plan for the job • Report outcomes
Underpinning Knowledge and Attitude	Demonstrate knowledge of: • Communication process • Team structure • Team roles • Group planning and decision making
Underpinning Skills	Demonstrate skills to: • Communicate appropriately, consistent with the culture of the workplace
Resource Implications	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competence may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competence may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level II	
Unit Title	**Develop Business Practice**
Unit Code	**IND PHR2 30 0613**
Unit Descriptor	This unit specifies the outcomes required to establish a business operation from a planned concept. It includes researching the feasibility of establishing a business operation, planning the setting up of the business, implementing the plan and reviewing operations once commenced.

Elements	Performance Criteria
1. Identify business opportunity	1.1 ***Business opportunities*** are investigated and identified. 1.2 Feasibility study is undertaken to determine likely ***business viability***. 1.3 Market research on product or service is undertaken. 1.4 Assistance with feasibility study of ***specialist and relevant parties*** is sought as required. 1.5 Impact of emerging or changing technology including e-commerce, on business operations is evaluated. 1.6 Practicability of business opportunity is assessed in line with perceived risks, returns sought and resources available. 1.7 Business plan is completed for operation.
2. Identify personal business skills	2.1 Financial and business skills available are identified and taken into account when business opportunities are researched. 2.2 ***Personal skills/attributes*** are assessed and matched against those perceived as necessary for a particular business opportunity. 2.3 ***Business risks*** are identified and assessed according to resources available and personal preferences.
3. Plan for establishment of business operation	3.1 Business structure and operations are determined and documented. 3.2 Procedures are developed and documented to guide operations. 3.3 Financial backing is secured for business operation. 3.4 Business legal and regulatory requirements are identified and complied. 3.5 ***Human and physical resources*** required to commence business operation are determined. 3.6 Recruitment strategies are developed and implemented.
4. Implement establishment plan	4.1 Marketing of business operation is undertaken. 4.2 Physical and human resources are obtained to implement business operation.

	4.3 ***Operational unit*** is established to support and coordinate business operation. 4.4 Monitoring process is developed and implemented for managing operation. 4.5 ***Legal documents*** are carefully maintained and relevant records are kept and updated to ensure validity and accessibility. 4.6 Contractual procurement rights for goods and services including ***contracts with relevant people****,* negotiated and secured as required in accordance with the business plan. 4.7 Options for leasing/ownership of business premises identified and contractual arrangements are completed in accordance with the business plan.
5. Review implementation process	5.1 Review process for implementation of business operation is developed and implemented. 5.2 Improvements in business operation and associated management process are identified. 5.3 Identified improvements are implemented and monitored for effectiveness.

Variable	Range
Business opportunities	May include but not limited to: • expected financial viability • skills of operator • amount and types of finance available • returns expected or required by owners • likely return on investment • finance required • lifestyle issues
Business viability	May include but not limited to: • opportunities available • market competition • timing/ cyclical considerations • skills available • resources available • location and/ or premises available • risk related to a particular business opportunity, especially • in regard to Occupational Health and Safety and • environmental considerations
Specialist and relevant parties	May include but not limited to: • Chamber of commerce • Financial planners and financial institution representatives, business planning specialists and marketing specialists • accountants

	• lawyers and providers of legal advice • government agencies • industry/trade associations • online gateways • business brokers/business consultants
Personal skills/attributes	May include but not limited to: • technical and/ or specialist skills • business knowledge and skills • entrepreneurship • willingness to take risks
Business risks	May include but not limited to: • occupational health and safety and environmental • considerations • relevant legislative requirements • security of investment • market competition • security of premises/ location • supply and demand • resources available
Human and physical resources	May include but not limited to: • software and hardware • office premises • communications equipment • specialist services through outsourcing, contracting and • consultancy • staff • vehicles
Operational unit	May include but not limited to: • office location staffed with required personnel and equipped to service and support business • home-based site or other location such as leased or owned property
Legal documents	May include but not limited to: • partnership agreements, constitution documents, statutory books for companies (Register of Members, Register of Directors and Minute Books), Certificate of Incorporation, Franchise Agreements and financial documentation, appropriate software for financial records • recordkeeping including personnel, financial, taxation, OHS and environmental
Contracts with relevant people	May include but not limited to: • owners, suppliers, employees, landlords, agents, distributors, customers or any person with whom the business has, or seeks to have, a performance-based relationship

Evidence Guide	
Critical Aspects of Competence	Demonstrates skills and knowledge in: • that a business operation has been planned and implemented from initial research into feasibility of the business and completion of the plan, through to implementing the plan and commencing operations • the ability to evaluate the results of research and assess the likely viability and practicability of a business opportunity, taking into account the current business/market climate and resources available
Underpinning Knowledge and Attitudes	Demonstrate knowledge of: • Federal and regional government legislative requirements affecting business operations, especially in regard to Occupational Health and Safety (OHS), Equal Employment Opportunity (EEO), industrial relations and anti-discrimination • Technical or specialist skills relevant to the business operation • Financing options • Business systems and operations • Relevant marketing, management, sales and financial concepts • Methods for researching business opportunities • Principles of risk management relevant to the business • Methods of identifying relevant specialist services to complement the business • Forms and administrative systems • Services available and charges • Planning and control systems (sales, • Advertising and promotion, distribution and logistics • Financial recording systems • Legal rights and responsibilities • Record keeping duties • Operational factors relating to the business (provision of professional services, products)
Underpinning Skills	Demonstrate skills of: • Literacy skills to interpret legal requirements, company policies and procedures and immediate, day-to-day demands • Marketing skills • Business planning skills • Entrepreneurial skills • Problem-solving skills • OHS skills • Time management skills • Belief in services and products offered by the business • Communication skills including questioning, clarifying, reporting, and giving and receiving constructive feedback • Technical and analytical skills to interpret business documents, reports and financial statements and projections

	• Ability to relate to people from a range of social, cultural and ethnic backgrounds and physical and mental abilities • Problem solving skills to develop contingency plans • Using computers and software packages to record and manage data and to produce reports • Literacy skills to enable interpretation of business information, numeracy skills for data analysis to aid research • Research skills to identify a business opportunity and to conduct a feasibility study • Analytical skills to assess personal attributes and to identify business risks • Observation skills for identifying appropriate people, resources and to monitor work
Resource Implications	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competence may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competence may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level II	
Unit Title	**Standardize and Sustain 3S**
Unit Code	**IND PHR2 31 0613**
Unit Descriptor	This unit of competence covers the knowledge, skills and attitudes required by worker to standardize and sustain 3S to his/her workplace. It covers responsibility for the day- to-day operations of the workplace and ensuring that continuous improvements of Kaizen elements are initiated and institutionalized.

Elements	Performance Criteria
1. Prepare for work.	1.1 Work instructions are used to determine job requirements, including method, material and equipment. 1.2 Job specifications are read and interpreted following working manual. 1.3 ***OHS requirements***, including dust and fume collection, breathing apparatus and eye and ear personal protection needs are observed throughout the work. 1.4 ***Safety equipment and tools*** are identified and checked for safe and effective operation. 1.5 ***Tools and equipment*** are prepared and used to implement 3S.
2. Standardize 3S.	2.1 Plan is prepared and used to standardize 3S activities. 2.2 ***Tools and techniques*** to standardize 3S are prepared and implemented based on ***relevant procedures***. 2.3 Checklists are followed for standardize activities and ***reported*** to ***relevant personnel***. 2.4 The workplace is kept to the specified standard. 2.5 Problems are avoided by standardizing activities.
3. Sustain 3S.	3.1 Plan is prepared and followed to standardize 3S activities. 3.2 ***Tools and techniques*** to sustain 3S are discussed, prepared and implemented based on relevant procedures. 3.3 Workplace is inspected regularly for compliance to specified standard and sustainability of 3S techniques. 3.4 Workplace is cleaned up after completion of job and before commencing next job or end of shift. 3.5 Situations are identified where compliance to standards is unlikely and actions specified in procedures are taken. 3.6 Improvements are recommended to lift the level of compliance in the workplace. 3.7 Checklists are followed to sustain activities and reported to relevant personnel. 3.8 Problems are avoided by sustaining activities.

Variable	Range
OHS requirements	May include but not limited to: • Are to be in accordance with legislation/ regulations/codes of practice and enterprise safety policies and procedures. This may include protective clothing and equipment, use of tooling and equipment, workplace environment and safety, handling of material, use of fire fighting equipment, enterprise first aid, hazard control and hazardous materials and substances. • Personal protective equipment is to include that prescribed under legislation/regulations/codes of practice and workplace policies and practices. • Safe operating procedures are to include, but are not limited to the conduct of operational risk assessment and treatments associated with workplace organization. • Emergency procedures related to this unit are to include but may not be limited to emergency shutdown and stopping of equipment, extinguishing fires, enterprise first aid requirements and site evacuation.
Safety equipment and tools	May include but not limited to: • dust masks / goggles • glove • working cloth • first aid • safety shoes
Tools and equipment	May include but not limited to: • paint • hook • sticker • signboard • nails • shelves • chip wood • sponge • broom • pencil • shadow board/ tools board
Tools and techniques	May include but not limited to: • 5S Job Cycle Charts • Visual 5S • The Five Minute 5S • Standardization level checklist • 5S checklist • The five Whys and one How approach(5W1H) • Suspension • Incorporation and Use Elimination

Relevant procedures	May include but not limited to: • Assign 3S responsibilities • Integrate 3S duties into regular work duties • Check on 3S maintenance level • OHS measures such as signage, symbols / coding and labeling of workplace and equipment • Creating conditions to sustain your plans • Roles in implementation
Reporting	May include but not limited to: • verbal responses • data entry into enterprise database • brief written reports using enterprise report formats
Relevant personnel	May include but not limited to: • supervisors, managers and quality managers • administrative, laboratory and production personnel • internal/external contractors, customers and suppliers
Tools and techniques	May include but not limited to: • 5S slogans • 5S posters • 5S photo exhibits and storyboards • 5S newsletter • 5S maps • 5S pocket manuals • 5S department/benchmarking tours • 5S months • 5S audit • Awarding system • Big cleaning day • Patrolling system may include: ➢ Top management Patrol ➢ 5S Committee members and Promotion office Patrol ➢ Mutual patrol ➢ Self-patrol ➢ Checklist patrol ➢ Camera patrol

Evidence Guide	
Critical Aspects of Competence	Demonstrates skills and knowledge to: • Discuss the relationship between Kaizen elements. • Standardize and sustain 3S activities by applying appropriate tools and techniques.
Underpinning Knowledge and Attitudes	Demonstrates knowledge of: • Elements of Kaizen • Ways to improve Kaizen elements • Benefits of improving kaizen elements • Relationship between Kaizen elements • The fourth pillar of 5S

	• Benefits of standardizing and sustaining 3S • Procedures for standardizing and sustaining 3S activities • Tools and techniques to sustain 3S • Relevant Occupational Health and Safety (OHS) and environment requirements • Plan and report • Method of communication
Underpinning Skills	Demonstrates skills of: • improving Kaizen elements by applying 5S • standardizing and sustaining procedures and techniques to avoid problems • technical drawing • procedures to standardizing 3S activities • analyzing and preparing shop layout of the workplace • standardizing and sustaining checklists • preparing and implementing tools and techniques to sustain 3S • working with others • reading and interpreting documents • observing situations • solving problems by applying 5S • communication skills • preparing labels, slogans, etc. • gathering evidence by using different means • using Kaizen board properly in accordance the procedure • reporting activities and results using report formats
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competence may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competence may be assessed in the work place or in a simulated work place setting.

NTQF Level III

Occupational Standard: Pharmaceuticals Manufacturing Level III	
Unit Title	**Set up a Production or Packaging Line for Operation**
Unit Code	**IND PHR3 01 0613**
Unit Descriptor	This unit of competency covers the skills and knowledge required to set up multiple production or packaging processes and/or conduct multiple process changeovers for operation by others.

Elements	Performance Criteria
1. Prepare for line setup	1.1 Materials are confirmed and available to meet production requirements. 1.2 Equipment and related accessories are confirmed, available and fit for use to meet production requirements. 1.3 Tools and equipment required for line setup are available, operational and fit for use. 1.4 Processing parameters and settings are identified to meet production or packaging requirements.
2. Set up the line for operation	2.1 ***Cleaning and*** maintenance ***requirements and status*** are identified and confirmed. 2.2 Equipment is inspected to confirm condition. 2.3 Machine settings are selected or adjusted as required to meet safety and production requirements. 2.4 Processing or packaging parameters are entered as required meeting production requirements. 2.5 Equipment performance is checked and adjusted as required. 2.6 Pre-start checks are carried out as required by workplace requirements. 2.7 Line setup is completed to match production or packaging schedule and operating requirements. 2.8 The line is ready and safe to operate and any maintenance requirements are reported according to workplace reporting requirements. 2.9 Work is conducted in accordance with workplace environmental guidelines. 2.10 Relevant personnel are notified of setup completion.

Variable	Range
Confirming cleaning requirements and status	May involve: • accessing cleaning records
Policies and procedures	Work is carried out according to company procedures, regulatory and licensing requirements, legislative requirements, and industrial awards and agreements

Legislative requirements	relevant to this industry includes: • the Standards Code, including labelling, weights and measures legislation • legislation covering pharmaceuticals manufacturing safety, environmental management, OHS, anti-discrimination and equal opportunity • to the pharmaceutical industry, relevant Good Manufacturing Practice (GMP) codes is applied .
Workplace information	May include: • Standard Operating Procedures (SOPs) • specifications • production schedules and instructions • standard forms and reports
Equipment adjustment	May include limited use of hand tools, such as Allen keys and screwdrivers, within level of responsibility

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • determine cleaning, maintenance and operation readiness • determine production parameters and requirements • set up line according to production requirements • take corrective action in response to typical faults and inconsistencies • complete workplace records and communicate line status with other personnel as required • apply safe work practices and identify OHS hazards and controls • safely shut down equipment
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • basic operating principles of equipment and related accessories, including equipment adjustment points, range and location/alignment requirements of sensors and related feedback instruments, and status and purpose of guards • operating capacities of equipment used in the work area, such as different types of equipment and/or components as required by processing operations • nature of setup/changeover requirements, such as product compatibility and related cleaning requirements, impact of variation in materials or product on setup requirements, equipment and/or attachment changeovers related to given products • typical equipment faults and related causes, including signs and symptoms of faulty equipment and early warning signs of potential problems • pre-start checks required by setup/changeover • related processes and personnel dependent on line setup, and communication responsibilities

	• isolation, lock out and tag out procedures and responsibilities • Occupational Health and Safety (OHS) hazards and controls • procedures and responsibility for reporting equipment performance information • basic operating principles of process control, where relevant, including the relationship between control panels and systems and the physical equipment • routine maintenance requirements and procedures where relevant
Underpinning Skills	Must demonstrate skills to: • access production/packing schedule and related information to identify line setup/changeover requirements, such as checking product sequencing and compatibility, confirming that the required cleaning and/or sanitation has occurred and required packaging components and consumables are available as appropriate • select, fit and use personal protective clothing and/or equipment • confirm supply of necessary equipment and related attachments, materials and services for production • confirm supply of necessary equipment and services to carry out setup operations • set and/or adjust equipment to meet production/packaging requirements, including selecting the required parameters or equipment settings, and changing processing set points as required • position safety guards and cancel isolation/lockouts ready for operation • confirm that sensors and related feedback instruments are correctly positioned and operational • operate equipment to confirm equipment setup and make final adjustments as required • time setup activities to meet production requirements • advise affected work areas/personnel of completion of setup • maintain work area to meet housekeeping standards • load and/or position materials/ingredients/product and/or packaging consumables according to enterprise procedures • use the control panel/system to set and adjust equipment components according to enterprise procedures • conduct routine maintenance according to enterprise procedures • use oral communication skills/language competence to fulfil the job role as specified by the organisation, including questioning, active listening, asking for clarification and seeking advice from supervisor • work cooperatively within a culturally diverse workforce

Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competence may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competence may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level III	
Unit Title	**Participate in Development and Adjustment of Production Schedule**
Unit Code	**IND PHR3 02 0613**
Unit Descriptor	This unit refers to the scheduling of production to meet operational requirements. It aims at ensuring that operators identify resource requirements, and document, monitor and adjust schedules in response to operational variations.

Elements	Performance Criteria
1. Identify resources to meet production requirements.	1.1 Access and verify information on orders, stocks and delivery. 1.2 Determine material requirements by quantity and type required. 1.3 Determine human resource requirements in work area. 1.4 Determine health, safety or environment issues in meeting requirements.
2. Develop schedules	2.1 Determine production priorities based on the adjusted schedule. 2.2 Identify production opportunities ('windows') 2.3 Develop production schedules in accordance with ***procedures*** taking account of safety requirements. 2.4 Communicate and distribute production schedules to appropriate personnel.
3. Monitor production schedules.	3.1 Monitor production output against schedule. 3.2 Identify variations between production and schedule. 3.3 Record operational variation and discuss with appropriate personnel. 3.4 Identify possible cause of variation.
4. Adjust schedules.	4.1 Adjust schedules in response to operational variation. 4.2 Adjust schedules in response to unexpected events. 4.3 Distribute adjusted/amended schedules to appropriate personnel. 4.4 Maintain product output in accordance with production and ***health, safety and environment requirements***.

Variable	Range
Procedures	All operations are performed in accordance with procedures. Procedures mean all relevant workplace procedures, work instructions, temporary instructions and relevant industry and government codes and standards.

Health, Safety and Environment (HSE)	All operations are subject to stringent health, safety and environment requirements, which may be imposed through State or federal legislation, and these must not be compromised at any time. Where there is an apparent conflict between Performance Criteria and HSE requirements, the scheduler needs to ensure the HSE requirements take precedence.
Context	This competency is typically performed by an experienced operator, team leader or similar. Indicative functions include: • regular planning operations • Communication with all relevant personnel, including management and administration. • Unit content areas include responses to: • immediate production needs • future production needs and reworking requirements.
Indicative information sources and resources	May include: • customer requirements • organizational plans, policies and procedures • production schedules, run plans • Resource utilization actual and targets.

Evidence Guide	
Critical Aspects of Competence	Must demonstrate skills and knowledge to: • identify resource requirements • record, monitor and adjust schedules in response to operational requirements. • Consistent performance should be demonstrated. For example, look to see that: ➢ resource requirements are correctly identified in accordance with production requirements ➢ schedules are planned for the most effective and efficient manner to meet operational requirements ➢ schedules allow for safety, health and environmental (HSE) issues and reinforce HSE priorities ➢ timelines are adhered to ➢ schedules are adjusted and resource requirements amended in response to operational variations ➢ variations to schedules are communicated and documented appropriately.
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • production objectives, priorities, targets and resource requirements • customer and quality requirements • process and plant operational requirements • hazards associated with the process • awareness of the hierarchy of control in controlling the hazards

	• impact of adjustments on process/plant efficiencies and production outcomes/targets • safety implications for schedule/schedule changes • planning, sequencing, monitoring and reviewing steps • company policies and procedures as is relevant to scheduling of production to meet operational requirements.
Underpinning Skills	Must demonstrate skills of: • ability to access and interpret a range of written, numeric and graphical data. • Writing is required to the level of interpreting orders (and forecasts) and producing schedules and related reports. • Numeracy is required to interpret numeric data and relevant statistics (such as trends and cycles) and from this calculate production and resource requirements.
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competence may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competence may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level III	
Unit Title	**Operate Processes in a Production System**
Unit Code	**IND PHR3 03 0613**
Unit Descriptor	This is a Specialist unit. It covers the skills and knowledge required to set up, operate and adjust inter-related processes in a production system. A system typically involves a series of inter-related processes that must be co-ordinate and concurrently operated to produce the required outcome. Individual processes may be directly operated, automated and/or operated by others. System operation requires higher level planning and problem solving skills applied to the series of processes than is required when operating an individual unit of equipment or multiple pieces of the same equipment.

Elements	Performance Criteria
1. Prepare the production system for operation	1.1 Equipment, materials and services are confirmed and available to meet production requirements. 1.2 Cleaning requirements and equipment status are identified and confirmed. 1.3 Machine settings are selected or adjusted as required to meet safety and production requirements. 1.4 Processing/operating parameters are entered as required to meet production requirements. 1.5 Materials, ingredients and/or product are loaded or positioned as required to meet production requirements. 1.6 Pre-start checks are carried out as required by workplace requirements. 1.7 Equipment performance is checked and adjusted as required in a ***workplace information***. 1.8 Equipment is ready and safe to operate.
2. Operate and monitor the production system	2.1 The ***system*** is started up and operated according to company procedures. 2.2 System equipment components are monitored to identify variation in operating conditions. 2.3 Variation in equipment operation is identified and maintenance requirements are reported according to workplace reporting requirements. 2.4 The production system is monitored to confirm that specifications are met. 2.5 Out-of-specification product/process outcomes are identified, rectified and/or reported to maintain the process within specification.

	2.6 The workplace meets housekeeping standards.
3. Hand over production system operation	3.1 Workplace records are maintained according to workplace recording requirements 3.2 ***Handover*** is carried out according to workplace procedures. 3.3 Process operators are aware of system and related equipment status at completion of handover.
4. Shut down the production system	4.1 The appropriate ***shutdown procedure*** is identified. 4.2 The system is shut down according to workplace procedures. 4.3 Maintenance requirements are identified and reported.
5. Contribute to continuous improvement of the production system	5.1 System performance is reviewed against output plan/targets. 5.2 Opportunities for system improvement are identified and investigated. 5.3 Proposals for improvement are developed and implemented within company planning arrangements, authority levels and according to company procedures

Variable	**Range**
Work	is carried out according to company procedures, regulatory and licensing requirements, legislative requirements, and industrial awards and agreements
Workplace information	May include standard Operating Procedures (SOPs), specifications, production schedules and instructions, performance records and reports
A system	typically involves a series of inter-related processes that must be co-ordinate and concurrently operated to produce the required outcome
System operation	May involve co-ordination of operators of system components
Handovers	May be done in person or via recording/communication systems according to workplace arrangements
Shutdown procedures	May include cleaning. In some cases cleaning may be carried out by a dedicated cleaning crew
Operation and monitoring of equipment and system processes	Typically requires: • the use of control panels and systems • usage , work , log & calibration sheet • equipment manual
Confirming cleaning requirements and status	May involve • accessing cleaning records as per cleaning SOPs • check cleaning log and usage sheet

Legislative requirements	Are typically reflected in procedures and specifications. Legislation relevant to this industry includes the Standards Code including labeling, weights and measures legislation; and legislation covering pharmaceuticals manufacturing safety, environmental management, occupational health and safety, anti-discrimination and equal opportunity. to the pharmaceutical industry, relevant GMP codes is applied

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • conduct pre-start checks on production system components • confirm machine setup is ready to achieve production requirements • correctly use required personal protective equipment • start, operate, monitor and adjust process equipment throughout the system to achieve required quality outcomes • identify system problems and take corrective action • conduct operational handovers • shut down system • identify and investigate opportunities for operational improvements within areas of responsibility • complete workplace records as required • apply safe work practices and identify OHS hazards and controls • safely shut down equipment
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • purpose and basic principles of the production system, including the system process flow, the interrelationships of each process to identify the impact of variation on related processes, and optimization options • basic operating principles of equipment and related accessories used by the system, including equipment adjustment points, status and purpose of guards, and range and location/alignment requirements of sensors and related feedback instruments • operating capacities of equipment used in the system, such as different types of equipment and/or components as required by processing/packaging operations • related systems and responsibilities for interaction, such as related production systems, services supply, packaging/warehousing, maintenance, laboratory/quality assurance and planning and scheduling • product characteristics and common types of variation in materials and/or ingredients used, including the effect of variation on each stage of the system and scope to adjust or correct • typical production related problems, including equipment faults, common causes and warning signs, incorrect or poor

	supply of materials, incorrect settings and poor operator control • relevant procedures, specifications and operating parameters for the system and the individual processes • isolation, lock out and tag out procedures and responsibilities • hazards, risks, controls and methods for monitoring processes within the system, including Occupational Health and Safety (OHS), food safety, quality and environmental hazards and risks • workplace system and approach to equipment maintenance • process improvement procedures and related consultative arrangements • troubleshooting procedures and problem solving techniques • communication responsibilities to inform related work areas/support functions and other shifts of operational status and production issues • procedures and responsibility for reporting production and performance information
Underpinning Skills	• access production schedule and related information to identify system output and operating requirements, such as planning daily production schedules and/or modifying plans to respond to operating conditions and customer requirements • liaise with relevant work areas to confirm and/or secure necessary materials, services, equipment and labour to meet production requirements • confirm supply of necessary equipment and related attachments, materials and services • select, fit and use personal protective clothing and/or equipment • set and/or adjust equipment to meet process output requirements, including inspecting equipment condition to identify any signs of wear, confirming selection of appropriate settings and/or related parameters, ensuring that isolation or lock outs are cancelled as required, confirming that equipment is clean and correctly configured for processing requirements, positioning sensors and controls correctly, ensuring any scheduled maintenance has been carried out, and confirming that all safety guards are in place and operational (checks may be done by the system operator or involve observing/supporting others setting and adjusting equipment and conducting pre-start checks) • load and/or position materials, ingredients and/or product as required • operate and monitor the production system, such as use of a process control system and/or observing/supporting others to follow correct operating procedures

	• monitor materials flow and work-in-progress through the system • confirm that the system operates within specified parameters and inspection/ control points are monitored • determine responses to out-of-specification results or non-conformance within level of responsibility • monitor operating efficiencies of the system, including recognition of signs and symptoms of faulty equipment and early warning signs of other potential problems • investigate, resolve and/or report problems and faults • plan scheduled events to minimise disruption to production • conduct/coordinate product or batch changeovers • conduct/coordinate shift handovers • review and maintain procedures to support system improvements • maintain work area to meet housekeeping standards • use oral communication skills/language competence to fulfill the job role as specified by the organization, including questioning, active listening, asking for clarification and seeking advice from supervisor • work cooperatively within a culturally diverse workforce
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competence may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competence may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level III	
Unit Title	**Operate Interrelated Processes in a Production System**
Unit Code	**IND PHR3 04 0613**
Unit Descriptor	This unit of competency covers the skills and knowledge required to set up, operate and adjust interrelated processes in a production system.

Elements	Performance Criteria
1. Prepare the production system for operation	1.1 Equipment, materials and services are confirmed and available to meet production requirements. 1.2 Cleaning requirements and equipment status are identified and confirmed according to ***workplace information***. 1.3 Machine settings are selected or adjusted as required to meet safety and production requirements. 1.4 Processing/operating parameters are entered as required to meet production requirements. 1.5 Materials, ingredients and/or product are loaded or positioned as required to meet production requirements. 1.6 Pre-start checks are carried out as required by workplace requirements. 1.7 Equipment performance is checked and adjusted as required. 1.8 Equipment is ready and safe to operate.
2. Operate and monitor the production system	2.1 The ***system*** is started up and operated according to company procedures. 2.2 System equipment components are monitored to identify variation in operating conditions. 2.3 Variation in equipment operation is identified and maintenance requirements are reported according to workplace reporting requirements. 2.4 The production system is monitored to confirm that specifications are met. 2.5 Out-of-specification product/process outcomes are identified, rectified and/or reported to maintain the process within specification. 2.6 The work area is maintained according to housekeeping standards. 2.7 Work is conducted in accordance with workplace environmental guidelines.

3. Hand over production system operation	3.1 Workplace records are maintained according to workplace recording requirements. 3.2 ***Handover*** is carried out according to workplace procedures. 3.3 Process operators are aware of system and related equipment status at completion of handover.
4. Shut down the production system	4.1 The appropriate ***shutdown procedure*** is identified. 4.2 The system is shut down according to workplace procedures. 4.3 Maintenance requirements are identified and reported.
5. Contribute to continuous improvement of the production system	5.1 System performance is reviewed against output plan/targets. 5.2 Opportunities for system improvement are identified and investigated. 5.3 Proposals for improvement are developed and implemented within company planning arrangements, authority levels and according to company procedures.

Variable	**Range**
Workplace information	May include: • Standard Operating Procedures (SOPs) • specifications • production schedules and instructions • performance records and reports
Systems	Typically involves: • a series of interrelated processes that must be coordinated and concurrently operated to produce the required outcome
System operation	May involve: • coordination of operators of system components
Handovers	May be done: • in person or via recording/communication systems according to workplace arrangements
Shutdown procedures	May include: • cleaning (in some cases cleaning may be carried out by a dedicated cleaning crew) • as per the SOPs' or equipment manual.
Operation and monitoring of equipment and system processes	Typically requires: • the use of control panels and systems • work , data sheet • usage and calibration log books
Legislative requirements	• are typically reflected in procedures and specifications. Legislation relevant to this industry includes: • the Standards Code, including labeling, weights and measures legislation

	• legislation covering safety pharmaceuticals manufacturing , environmental management, OHS, anti-discrimination and equal opportunity • to the pharmaceutical industry, relevant Good Manufacturing Practice (GMP) codes is applied
Policies and procedures	Work is carried out according to company procedures, regulatory and licensing requirements, legislative requirements, and industrial awards and agreements
Confirming cleaning requirements and status	May involve: • Accessing cleaning records, cleaning procedures and log book, residual analysis, perform cleaning validations.

Evidence Guide	
Critical Aspects of Competence	Must demonstrate skills and knowledge to: • conduct pre-start checks on production system components • confirm machine setup is ready to achieve production requirements • correctly use required personal protective equipment • start, operate, monitor and adjust process equipment throughout the system to achieve required quality outcomes • identify system problems and take corrective action • conduct operational handovers • shut down system • identify and investigate opportunities for operational improvements within areas of responsibility • complete workplace records as required • apply safe work practices and identify OHS hazards and controls • safely shut down equipment
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • purpose and basic principles of the production system, including the system process flow, the interrelationships of each process to identify the impact of variation on related processes, and optimization options • basic operating principles of equipment and related accessories used by the system, including equipment adjustment points, status and purpose of guards, and range and location/alignment requirements of sensors and related feedback instruments • operating capacities of equipment used in the system, such as different types of equipment and/or components as required by processing/packaging operations • related systems and responsibilities for interaction, such as related production systems, services supply, packaging/warehousing, maintenance, laboratory/quality assurance and planning and scheduling

	• product characteristics and common types of variation in materials and/or ingredients used, including the effect of variation on each stage of the system and scope to adjust or correct • typical production related problems, including equipment faults, common causes and warning signs, incorrect or poor supply of materials, incorrect settings and poor operator control • relevant procedures, specifications and operating parameters for the system and the individual processes • isolation, lock out and tag out procedures and responsibilities • hazards, risks, controls and methods for monitoring processes within the system, including Occupational Health and Safety (OHS), safety pharmaceuticals manufacturing , quality and environmental hazards and risks • workplace system and approach to equipment maintenance • process improvement procedures and related consultative arrangements • troubleshooting procedures and problem solving techniques • communication responsibilities to inform related work areas/support functions and other shifts of operational status and production issues • procedures and responsibility for reporting production and performance information
Underpinning Skills	Must demonstrate skills to: • access production schedule and related information to identify system output and operating requirements, such as planning daily production schedules and/or modifying plans to respond to operating conditions and customer requirements • liaise with relevant work areas to confirm and/or secure necessary materials, services, equipment and labour to meet production requirements • confirm supply of necessary equipment and related attachments, materials and services • select, fit and use personal protective clothing and/or equipment • set and/or adjust equipment to meet process output requirements, including inspecting equipment condition to identify any signs of wear, confirming selection of appropriate settings and/or related parameters, ensuring that isolation or lock outs are cancelled as required, confirming that equipment is clean and correctly configured for processing requirements, positioning sensors and controls correctly, ensuring any scheduled maintenance has been carried out, and confirming that all safety guards are in place and operational (checks may be done by the system

	operator or involve observing/supporting others setting and adjusting equipment and conducting pre-start checks) • load and/or position materials, ingredients and/or product as required • operate and monitor the production system, such as use of a process control system and/or observing/supporting others to follow correct operating procedures • monitor materials flow and work-in-progress through the system • confirm that the system operates within specified parameters and inspection/ control points are monitored • determine responses to out-of-specification results or non-conformance within level of responsibility • monitor operating efficiencies of the system, including recognition of signs and symptoms of faulty equipment and early warning signs of other potential problems • investigate, resolve and/or report problems and faults • plan scheduled events to minimise disruption to production • conduct/coordinate product or batch changeovers • conduct/coordinate shift handovers • review and maintain procedures to support system improvements • maintain work area to meet housekeeping standards • use oral communication skills/language competence to fulfil the job role as specified by the organisation, including questioning, active listening, asking for clarification and seeking advice from supervisor • work cooperatively within a culturally diverse workforce
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competence may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competence may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level III	
Unit Title	**Monitor and Maintain the Implementation of Good Manufacturing Practice Procedures**
Unit Code	**IND PHR3 05 0613**
Unit Descriptor	This is a Core unit for pharmaceutical processing. It covers the skills and knowledge required to provide a leadership role in supporting day-to-day implementation of Good Manufacturing Practices (GMP) in a work area. It also involves supporting others to implement the requirements of GMP. This unit applies to those with formal responsibility for others, and to those required to model workplace Policies and procedures but who have no formal management role.

Elements	Performance Criteria
1. Ensure others in the work area are able to meet GMP requirements	1.1 Relevant clothing and equipment appropriate to work requirements are available, functional and correctly fitted according to ***workplace information***. 1.2 Advice on GMP ***responsibilities*** and procedures is accessible and clearly explained. 1.3 GMP control measures used in the work area can be identified by those in the work area. 1.4 Mentoring and coaching support is available to support individuals/groups to implement GMP and related procedures. 1.5 Training needs are identified and addressed within level of responsibility.
2. Monitor personal hygiene and conduct of team members in the work area	2.1 Personal hygiene of work team meets GMP requirements. 2.2 Clothing is prepared, used, stored and disposed of according to GMP and workplace procedures. 2.3 Personal movement around the workplace complies with area entry and exit procedures.
3. Monitor implementation of GMP requirements in the work area	3.1 GMP procedures in the work area are clearly defined, documented and followed. 3.2 Non-compliance with identified procedures is reported and addressed within level of responsibility. 3.3 Personal behaviour is consistent with workplace policies and procedures that support GMP. 3.4 Workplace procedures to control resource allocation and process are followed to meet GMP requirements. 3.5 GMP non-conformance is identified and reported according to workplace procedure. 3.6 GMP information is recorded to meet workplace reporting requirements.

	3.7 The workplace is maintained in a clean and tidy order to meet GMP housekeeping standards.
4. Contribute to validation Processes	4.1 Validation practices and procedures are reviewed in consultation with relevant personnel. 4.2 Validation results and issues are identified and corrective action taken within level of responsibility. 4.3 Documentation and recording requirements meet GMP code and company requirements.
5. Take corrective action in response to GMP non-compliance	5.1 Processes, practices or conditions which could result in non-compliance with GMP are identified and reported according to workplace reporting requirements. 5.2 Corrective action is taken in accordance within level of ***responsibility.*** 5.3 GMP issues are raised with designated personnel.
6. Maintain and improve GMP in the work area	6.1 Processes or conditions which could result in non-conformance with GMP are identified, reported and corrected within level of responsibility. 6.2 Matters raised relating to GMP are promptly resolved and/or referred to appropriate personnel. 6.3 Effectiveness of control measures are monitored within level of responsibility others in the work area are advised of GMP matters relevant to work role. 6.4 Changes to documentation are proposed in accordance with workplace procedures to maintain GMP. 6.5 GMP audits are conducted to meet company and legislative requirements. 6.6 Action is taken to respond to audit recommendations within level of responsibility.

Variable	**Range**
Workplace information	May be provided in: • pharmaceuticals manufacturing safety and quality policies and programs, Standard Operating Procedures (SOPs), specifications, log sheets and written or verbal instruction incorporating safety and quality requirements
Work responsibilities	May include: • formal or informal responsibility for modelling appropriate quality/ safety policies and procedures and providing a support role to others in the work area
Quality systems	May be: • externally accredited, such as an • ISO system, or internally designed and managed

A pharmaceuticals manufacturing safety	May include: • incident is a situation where the safe limits or parameters identified by the standard safety program are not met
A quality incident	May include: • a situation where the quality limits or parameters identified in specifications or processing • instructions are not met
Monitoring	• describes the methods used to confirm that a standard safety or quality hazard is in control. Examples of monitoring procedures include taking temperatures, collecting samples, conducting visual inspections and testing as required
Responsibility for identifying breaches of pharmaceuticals manufacturing safety	• procedures and taking corrective action occurs in the context of the standard safety program and within scope of responsibility
Quality standards	• occurs within the context of defined standards: BP,USP European pharmacopeias or specifications and relates to work area (in house specifications).
Minimum personal hygiene requirements	• are specified by the standard safety program. At a minimum this must meet legal requirements as set out in the pharmaceuticals manufacturing Safety Standard and/or state legislation/regulation
Reporting of health conditions and illnesses requirements	• are specified by the standard safety program. At a minimum this must meet legal requirements as set out in the pharmaceuticals manufacturing Safety Standard and/or state legislation/regulation
The operator at this level	• may not have direct responsibility for overseeing the training/development of team members. At a minimum they must be able to identify development needs of others in the work area and refer this information to the relevant personnel • may not have responsibility for independently assessing risks and determining the effectiveness of control measures. However, they would be expected to observe day-to-day effectiveness and participate in assessment and review processes
Responsibilities at this level	May include facilitating consultation processes within level of responsibility
Record keeping	Complies with customer, legal and safety program requirements

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • identify the components of GMP and related roles and responsibilities as they relate to work role • provide a role model to others in the workplace to support implementation of GMP

	• Participate in GMP processes within level of responsibility. Examples of these processes include validation, line clearance, equipment calibration, change management, maintenance of documentation. This would typically be undertaken in a team context
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • the role of GMP in preventing contamination, its relationship to legal requirements of pharmaceutical manufacturers and potential implications of non-compliance • GMP arrangements in the workplace, including relevant GMP codes of practice and related workplace policies and procedures to implement these responsibilities • role of effective communication and consultation processes • workplace training and development system and responsibilities • role of quality assurance and related system components and activities in GMP • procedures followed to investigate contamination events and performance improvement processes • personal clothing and footwear requirements for working in and/or moving between work areas • personal clothing use, storage and disposal requirements • current technical and process knowledge required to monitor GMP and participate in investigating GMP non-compliance within level of responsibility, including common microbiological, physical and chemical contaminants, conditions under which types of contamination, e.g. cross-contamination, are likely to occur, related control methods and validation procedures and responsibilities • control methods and procedures used in the work area to maintain GMP, including the purpose of control, the consequences if not controlled and the method of control where relevant • methods used to monitor process control, purpose and requirements of validation procedures and purpose of equipment calibration • recall and traceability procedures relevant to work area • line clearance procedures and responsibilities • properties, handling and storage requirements of raw materials, packaging components and final product handled and used in the work area • standards for materials, equipment and utensils used in the work area • procedures for responding to out-of-specification or unacceptable performance/outcomes, including procedures for identifying and isolating or quarantining materials or product of unacceptable quality within level of responsibility

	• documentation system and procedures, including record keeping to meet both company and legal requirements, procedures for developing and/or reviewing workplace procedures and document control systems used in the workplace and responsibilities for reporting and recording information • housekeeping requirements and responsibilities relating to own work, and where relevant, use and storage of housekeeping/cleaning equipment • waste collection, recycling, handling and disposal, including handling/disposal requirements for different types of waste, such as hazardous waste where relevant
Underpinning Skills	Must demonstrate skills to: • communicate information on GMP requirements to others in the work area, including demonstration of two-way communication, such as active listening and constructive response to feedback • access and use document management systems • model personal conduct and work activities to meet requirements of GMP • monitor that data is recorded to meet GMP recording requirements within level of responsibility • provide guidance and support to others to in the work area to implement GMP responsibilities within level of responsibility • determine action required to respond to GMP non-compliance within level of responsibility • participate in improvement processes, such as investigating actual and potential GMP non-compliance • participate in and/or review practices and procedures to prevent or minimize the likelihood of unacceptable performance • work cooperatively within a culturally diverse workforce
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competence may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competence may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level III	
Unit Title	**Apply Raw Materials, Ingredient and Process Knowledge to Production Problems**
Unit Code	**IND PHR3 06 0613**
Unit Descriptor	This is a Specialist unit. It covers skills and knowledge required to apply knowledge of ingredients and processes to troubleshoot typical problems that occur in preparing, processing and/or packaging product. This unit applies where problem solving occurs over one or more processes and requires an understanding of the characteristics of raw materials/ingredients and processing methods used.

Elements	Performance Criteria
1. Respond to non-conforming ingredients/ raw materials	1.1 Non-conformance in ***raw materials/ingredients*** is identified and reported according to workplace reporting requirements. 1.2 Causes of non-conformance are investigated and reported according to workplace reporting requirements. 1.3 Corrective action is determined and implemented within level of responsibility and workplace procedures. 1.4 Action is taken to prevent recurrence of non-conformance of product/materials and process. 1.5 Action is reported according to workplace reporting Requirements.
2. Identify and respond to non-conforming product and processes	2.1 Processing parameters, stages and changes which occur during processing are monitored. 2.2 Non-conformance in processing, handling and/or storage is identified and corrective action taken according to workplace requirements. 2.3 Causes of non-conformance relating to processing, handling and/or storage are investigated and reported according to workplace reporting requirements. 2.4 Corrective action is determined and implemented within level of responsibility and workplace procedures. 2.5 Action is taken to prevent recurrence of non-conformance. 2.6 Action is reported according to workplace reporting requirements.

Variable	Range
Ingredients/raw materials	• are those used to manufacture product • active and inactive raw materials
Work	is carried out according to company procedures, regulatory and licensing requirements, legislative requirements, and industrial awards and agreements.

Legislative requirements	includes: • the Standards Code including labelling, weights and measures legislation; and legislation covering pharmaceuticals manufacturing safety, environmental management, occupational health and safety, anti-discrimination and equal opportunity. • to the pharmaceutical industry, current good manufacturing practice (GMP) codes is applied .
Typical processing and related techniques	Include but are not limited to raw materials/ingredient dispensing, preparation, mixing and blending, conditioning, primary and further processing, wrapping, packing and storage
Typical process parameters	include but are not limited to: • temperature, time, pressure, flow rate
Typical reactions depend on processing method.	Examples include but are not limited to : • gelatinization and hydration • solution preparation • powders mixing and paste preparations
Recurrence of a problem	Where cannot be prevented, procedures should be established to minimize the likelihood of recurrence and to identify any further incidents

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • Identify and respond to non-conforming ingredients/raw materials • Identify and respond to non-conforming product and processes
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • Basic composition and function of each main raw material/ingredient used. This may include awareness of ingredient grades or types • Common causes of contamination/unacceptable quality of raw materials/ ingredients • Methods used to confirm quality standard. This may include accessing information such as certificates of analysis and/or laboratory clearance information • The effect of variation in raw materials/ingredients on Processing stages and final product outcome. This includes an understanding of factors likely to cause variation, and scope to adjust or correct for variation at each processing stage • Appropriate handling and storage requirements for raw materials/ingredients and final product, and the effect of failing to meet required storage conditions • The changes and reactions that occur through processing stages and symptoms of poor/unacceptable processing or equipment operation

	• Factors that affect the shelf-life of product • The inter-relationships between processing stages and the effect of variation in processing parameters on process outcome and on final product. This includes understanding factors likely to cause variation, and scope to adjust or correct for variation at subsequent process stages • Procedures for identifying and isolating non-conforming product • Troubleshooting information and techniques • Procedures and related documentation required to amend or introduce a new method or procedure. This may include short term procedures for amending or updating specifications and processing parameters • Reporting requirements and responsibilities
Underpinning Skills	• Identify requirements of ingredient/raw material characteristics within level of responsibility • Follow procedures to identify, remove/isolate and report non-conforming ingredients/materials and/or product according to workplace reporting requirements • Determine likely causes of non-conformance of ingredients/raw materials • Recognize indicators of unacceptable or non-conforming processing, handling and/or storage outcomes • Act promptly to identify, remove/isolate and report non-conforming product and/or processes • Access and apply workplace information relating to process troubleshooting • Investigate non-conformance to determine likely causes and report findings to appropriate personnel • Identify action required to correct non-conformance and implement within level of responsibility • Identify action required to prevent or minimize and control recurrence of non-conformance and implement within level of responsibility • Complete workplace records including reporting non-conformance and documenting corrective actions according to workplace recording procedures
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competence may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competence may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level III	
Unit Title	**Contribute to Development of Plant Documentation**
Unit Code	**IND PHR3 07 0613**
Unit Descriptor	This unit of competency covers the development of relevant plant documentation and systems in response to identified information requirements including the development and/or amendment of workplace documents, procedures and record keeping systems.

Elements	Performance Criteria
1. Identify information need/deficiency.	1.1 Determine the information requirements of the organization. 1.2 Evaluate current documentation. 1.3 Recognise information need/deficiency. 1.4 Discuss information requirements with appropriate personnel.
2. Develop/revise plant documentation.	2.1 Specify information need and set/prioritise objectives 2.2 Analyse existing ***documentation/records*** in accordance with specified requirements. 2.3 Develop/amend documentation as a draft in accordance with specifications to standard format. 2.4 Issue documentation to appropriate personnel for review. 2.5 Edit documentation and amend in accordance with review requirements. 2.6 Complete documentation to satisfy the initial identified need/deficiency.
3. Communicate changes to plant documentation.	3.1 Explain and communicate documentation to all relevant personnel. 3.2 Distribute documentation to all appropriate personnel. 3.3 Evaluate implementation of documentation. 3.4 Amend documents if required.

Variable	Range
Sources of documentation	May include: • maintenance logs • non-compliance reports • incidence and accident reports • permits • schematics/process flows/ engineering drawings. • job cards • standard operating procedures

	• work instructions • operating manuals • quality procedures • training program contents and materials safety data sheets.
Problems	• 'Anticipate and solve problems' means resolve a wide range of routine and non-routine problems, using product and process knowledge to develop solutions to problems which do not have a known solution/s recorded in the procedures. • Typical problems may include: ➢ inaccurate source documents ➢ out-of-date source documents ➢ source documents too technical/lacking detail/of wrong focus ➢ prioritizing of document drafting with other work. • Appropriate action for problems outside of area of responsibility may be reported to an appropriate person. • Appropriate action for solving problems within area of responsibility includes asking questions and seeking assistance from appropriate persons/sources
Procedures	All operations are performed in accordance with procedures. Procedures include all relevant workplace procedures, work instructions, temporary instructions and relevant industry and government codes and standards.
Context	• This competency applies to all work environments in the industry. • Work is governed by established workplace procedures, and extent of authority for drafting/document approval.

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills in: • information required is researched, and intended use is taken into account • documentation is completed accurately, concisely and in accordance with requirements • completed documentation is easily understood by the recipient • information is communicated in the appropriate manner • communication distinguishes between relevant and peripheral issues.
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • Organization information systems, procedures, equipment and relevant documentation sufficient to be able to develop or amend company documentation. • the relevant OHS and environmental requirements is required along with an ability to implement them in a manner which is relevant to the drafting of all relevant documentation.

	Competence also includes the ability to: • plan own work, including predicting consequences and identifying improvements • Identify and describe own role and role of other employees.
Underpinning Skills	Must demonstrate skills of: • Reading and interpreting typical product specifications, job sheets, work instructions and material labels as provided to operators. • Writing to the level of drafting documents for the required audience. • Numeracy is also required to the extent required by production data, work instructions and procedures.
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competence may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competence may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level III	
Unit Title	**Participate in Assessment Validation**
Unit Code	**IND PHR3 08 0613**
Unit Descriptor	This unit typically applies to those participating in assessment validation. It does not address leading the validation process.

Elements	Performance Criteria
1. Prepare for validation	1.1 Discuss and confirm the approach to validation according to defined purposes, context, and relevant ***assessment system policies and procedures***. 1.2 Analyze relevant ***benchmarks for assessment*** and agree on the evidence needed to demonstrate competence. 1.3 Arrange ***materials*** for ***validation activities***.
2. Contribute to validation process	2.1 Demonstrate active ***participation*** in validation sessions and activities using appropriate communication skills. 2.2 Participate in validation sessions and activities by applying the principles of assessment and rules of evidence. 2.3 Check all documents used in the validation process for accuracy and version control.
3. Contribute to validation outcomes	3.1 Collectively discuss validation findings to support improvements in the quality of assessment. 3.2 Discuss, agree and record recommendations to improve assessment practice. 3.3 Implement changes to own assessment practice, arising from validation.

Variable	Range
Assessment system policies and procedures	• candidate selection • rationale and purpose of competency-based assessment • assessment records, and data and information management • recognition of current competency, recognition of prior learning and credit arrangements • assessment reporting procedures • assessment appeals • candidate grievances and complaints • validation • evaluation and internal audit • costs and resourcing • access and equity, and reasonable adjustment • partnership arrangements • links with human resource or industrial relations system • links with overall quality management system.

Benchmarks for assessment	• refers to criterion against which the candidate is assessed • may be one or more units of competency or assessment criteria of course curricula.
Materials	May include: • assessment tools • samples of collected evidence • documentation outlining the basis of assessment decisions • reports and records of assessment decisions • samples of benchmarks of appropriate evidence • Assessment Guidelines of the relevant training packages • information from the evidence guide of the relevant units of competency.
Validation activities	May include: • analyzing and reviewing: ➢ assessment tools ➢ collected evidence ➢ assessment decisions and records of assessment outcomes ➢ other aspects of assessment policies, processes and outcomes • recording evidence of validation processes and outcomes.
Participation	May include comparison and evaluation of: • assessment practices • assessment plans • interpretation of units of competency • assessment methods and instruments • assessment decisions and collected evidence.

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • actively participate in a minimum of two validation sessions or meetings which, in combination, address the critical aspects of validation using different validation approaches and activities • clearly explain purposes of validation and the legal and ethical responsibilities of assessors • collate documentation relating to validation process in a logical manner • demonstrate communication and liaison with relevant people • provide feedback and interpret documentation in validation sessions • record contribution to validation findings.
Underpinning Knowledge and Attitudes	How to interpret competency standards and other related assessment information to determine the evidence needed to demonstrate competence, including: • criterion-referenced assessment as distinct from norm-referenced assessment

	• various reasons for carrying out validation and the different approaches to validation that may be appropriate before, during and after assessment • critical aspects of validation, including validation of assessment processes, methods and products • relevant OHS legislation, codes of practice, standards and guidelines, impacting on assessment • legal and ethical requirements of assessors, particularly in relation to validation activities • principles of assessment • rules of evidence.
Underpinning Skills	Must demonstrate skills of: • planning skills to participate in validation activities within agreed timeframes • problem-solving skills to identify information that is inconsistent, ambiguous or contradictory • evaluation skills to: ➢ determine evidence requirements from competency standards ➢ review assessment process, tools and methods ➢ review collected evidence • communication skills to share information in validation meetings.
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competence may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competence may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level III	
Unit Title	**Operate Interrelated Processes in a Packaging System**
Unit Code	**IND PHR3 09 0613**
Unit Descriptor	This unit of competency covers the skills and knowledge required to set up, operate and adjust interrelated processes in a packaging system.

Elements	Performance Criteria
1. Prepare the packaging system for operation	1.1 Equipment, materials and services are confirmed and available to meet packaging requirements. 1.2 Cleaning requirements and equipment status is identified and confirmed. 1.3 Machine settings are selected or adjusted as required to meet safety and production requirements. 1.4 Operating parameters are entered as required to meet production requirements. 1.5 Product and/or packaging components and consumables are loaded or positioned as required to meet packaging requirements. 1.6 Pre-start checks are carried out as required by workplace requirements. 1.7 Equipment performance is checked and adjusted as required. 1.8 Equipment is ready and safe to operate.
2. Operate and monitor the packaging system	2.1 The ***system*** is started up and operated according to company procedures. 2.2 System equipment components are monitored to identify variation in operating conditions. 2.3 Variation in ***equipment system operation*** is identified and maintenance requirements are reported according to workplace reporting requirements. 2.4 The system is monitored to confirm that packaging specifications are met. 2.5 Out-of-specification product/packaging outcomes are identified, rectified and/or reported to maintain the process within specification. 2.6 The work area is maintained according to housekeeping standards. 2.7 Work is conducted in accordance with workplace environmental guidelines.

3. Hand over packaging system operation	3.1 Workplace records are maintained according to workplace recording requirements. 3.2 ***Handover*** is carried out according to workplace procedures. 3.3 Process operators are aware of system and related equipment status at completion of handover.
4. Shut down the packaging system	4.1 The appropriate ***shutdown procedure*** is identified. 4.2 The system is shut down according to workplace procedures. 4.3 Maintenance requirements are identified and reported.
5. Contribute to continuous improvement of the system	5.1 System performance is reviewed against output plan/targets. 5.2 Opportunities for ***system improvement*** are identified and investigated. 5.3 Proposals for improvement are developed and implemented within company planning arrangements, authority levels and according to company procedures.

Variable	**Range**
System operation	May include a series of interrelated processes that must be coordinated and concurrently operated to produce the required outcome. System operation may involve: • coordination of operators of system components
Operation and monitoring of equipment and system processes	May include: • the use of control panels and systems
Handovers	May be done: • in person or via recording/communication systems according to workplace arrangements
Shutdown procedures	May include: • cleaning (in some cases cleaning may be carried out by a dedicated cleaning crew)
Policies and procedures	Work is carried out according to company procedures, regulatory and licensing requirements, legislative requirements, and industrial awards and agreements
Legislative requirements	May include: • typically reflected in procedures and specifications. Legislation relevant to this industry includes: • the Standards Code, including labeling, weights and measures legislation • legislation covering pharmaceuticals manufacturing safety, environmental management, OHS, anti-discrimination and equal opportunity

	• to the pharmaceutical industry, relevant Good Manufacturing Practice (GMP) codes is applied .
Workplace information	May include: • Standard Operating Procedures (SOPs) • specifications • production schedules and instructions • performance records and reports

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • conduct pre-start checks on packaging system components • confirm machine set up is ready to achieve packing requirements • correctly use required personal protective equipment • start, operate, monitor and adjust process equipment throughout the system to achieve required quality outcomes • identify system problems and take corrective action • conduct operational handovers • shut down system • identify and investigate opportunities for operational improvements within areas of responsibility • complete workplace records as required • apply safe work practices and identify OHS hazards and controls • safely shut down equipment
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • purpose and basic principles of the packaging system, including the process flow and the interrelationships of each previous processes that can affect packaging outcomes, packaging technology, and packaging equipment components • basic operating principles of equipment and related accessories used by the system, including equipment adjustment points, status and purpose of guards, and range and location/alignment requirements of sensors and related feedback instruments • operating capacities of equipment used in the system, such as different types of equipment and/or components as required by processing/packaging operations • related systems and responsibilities for interaction, such as related production and further packaging/storage stages, services supply, maintenance, laboratory/quality assurance and planning and scheduling • technical knowledge of product/packaging characteristics and the main factors that impact on shelf-life • typical packaging related problems, including equipment faults, common causes and warning signs, incorrect or poor

	supply of materials and finished product, incorrect settings and poor operator control • relevant procedures, specifications and operating parameters for the system and the individual processes • isolation, lock out and tag out procedures and responsibilities • hazards, risks, controls and methods for monitoring processes within the system, including Occupational Health and Safety (OHS), pharmaceuticals manufacturing safety, quality and environmental hazards and risks • workplace system and approach to equipment maintenance • process improvement procedures and related consultative arrangements • troubleshooting procedures and problem solving techniques • communication responsibilities to inform related work areas/support functions and other shifts of operational status and production issues • procedures and responsibility for reporting production and performance information
Underpinning Skills	Must demonstrate skills to: • access production/packaging schedule and related information to identify packaging output and operating requirements, such as establishing daily packaging priorities and/or modifying plans to respond to customer requirements • liaise with relevant work areas to confirm and/or secure necessary materials, services, equipment and labour to meet production requirements • confirm supply of necessary equipment and related attachments, materials and services • select, fit and use personal protective clothing and/or equipment • set and/or adjust equipment to meet packaging requirements, such as inspecting equipment condition to identify any signs of wear, confirming selection of appropriate settings and/or related parameters, ensuring that isolation or lock outs are cancelled as required, confirming that equipment is clean and correctly configured for packaging requirements, positioning sensors and controls correctly, ensuring any scheduled maintenance has been carried out, and confirming that all safety guards are in place and operational (checks may be done by the system operator or involve observing/supporting others setting and adjusting equipment and conducting pre-start checks) • load and/or position product, packaging components and consumables as required • operate and monitor the packaging system, such as use of a process control system and/or observing/supporting others to follow correct operating procedures

	• monitor materials flow and work-in-progress to and from the packaging system • confirm that the packaging system operates within specified parameters and inspection/control points are monitored • determine responses to out-of-specification packaging or non-conformance within level of responsibility • monitor operating efficiencies of the system, including recognition of signs and symptoms of faulty equipment and early warning signs of other potential problems • investigate, resolve and/or report problems and faults • plan scheduled events to minimize disruption to production • conduct/coordinate product/packaging changeovers • conduct/coordinate shift handovers • review and maintain procedures to support system improvements • maintain work area to meet housekeeping standards • use oral communication skills/language competence to fulfill the job role as specified by the organization, including questioning, active listening, asking for clarification and seeking advice from supervisor • work cooperatively within a culturally diverse workforce
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competence may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competence may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level III	
Unit Title	**Identify Equipment Faults**
Unit Code	**IND PHR3 10 0613**
Unit Descriptor	This unit requires the application of planning, technical knowledge and skills to check and isolate routine and non-routine equipment faults used in production and report on the status of equipment. It applies to all sectors of the industry. This competency is typically performed by operators demonstrating some relevant theoretical knowledge and using a range of well-developed skills requiring some discretion and judgment.

Elements	Performance Criteria
1. Identify scope of operational check.	1.1 Identify and classify equipment components and operating systems. 1.2 Match appropriate tests and procedures to the ***equipment*** operating systems. 1.3 Identify special test ***procedures*** and parameters in manufacturer's specifications and procedures. 1.4 Explain the operating principles of hydraulic, pneumatic, mechanical and electrical/electronic systems as related to workplace equipment. 1.5 Implement measures to control identified ***hazards*** in line with procedures and duty of care. 1.6 Observe and undertake checks on the physical condition of equipment as per procedures. 1.7 Record preliminary observations. 1.8 Discuss test procedures with appropriate personnel and obtain necessary permission where required.
2. Plan operational checks.	2.1 Check specifications and notes from preliminary observations and identify areas to be clarified. 2.2 Plan testing sequence/s noting areas where results and observations should be recorded. 2.3 Identify safe area for testing. 2.4 Make arrangements for any additional resources (including other employees).
3. Check unit through full operational range.	3.1 Undertake testing, observing relevant safety and operational requirements. 3.2 Confirm results and findings.

4. Identify fault and/or formulate recommendations .	4.1 Identify impact of fault on work schedule. 4.2 Record proposals for equipment repair based on faults found, cost/time implications and workplace approval systems. 4.3 Explain report to relevant workplace personnel including any options and recommendations. 4.4 Undertake repairs where appropriate in accordance with procedures.

Variable	**Range**
Use of equipment and tools	May include: • hand tools specific for the task • product testing equipment (e.g. flowmeter, scales, tape measure, micrometer, caliper, ultrasonic thickness) • machinery measuring equipment (e.g. vibration meter, tachometer, current tester, thermal imaging, temperature gauge) • measuring and aligning equipment
Procedures	• All operations are performed in accordance with procedures. • Procedures mean all relevant workplace procedures, work instructions, temporary instructions, standard operating procedures, plant description manuals, manufacturer's instructions, specifications, service manuals, machine circuit diagrams for hydraulic/pneumatic and electrical/electronic circuits and relevant industry and government codes and standards
Typical hazards	May include: • rotating and moving machinery • process materials, solids, fluids and gases under pressure or flowing • temporary connections or by-passes • electrical, hydraulic or pneumatic energy sources • out-of-specification operation
Problems	May include: • Respond to/rectify 'non-routine problems' means 'apply known solutions to a variety of predictable problems'. Typical process and product problems may include: ➢ out-of-specification product or variations ➢ response of equipment to materials variations ➢ new or changed materials ➢ changed equipment settings (eg higher speed or throughput) ➢ equipment in need of maintenance ➢ procedures requiring update or modification
Key variables to be monitored	May include: • equipment performance (e.g. speed, output, variations)

	• equipment component performance • sequences and timing of operations • materials changes (desired and not desired)
Typical information sources, observed data and plant records	may include: • plant data • log sheets • operational and performance reports • physical aspects such as noise, smell, feel and pressure condition monitoring information • planned maintenance schedules • procedures
Context	This competency applies to all work environments and sectors within the industry. It does not include maintenance that would require trade level skills. It is not intended that this competency would cover maintenance that is carried on in a workshop

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • understand the procedures and know the importance of critical operational systems • recognize potential situations requiring action and then implement appropriate action. • Consistent performance should be demonstrated. For example, look to see that: • early warning signs of equipment in need of attention/with potential problems are recognized • appropriate tests are undertaken and tests are analyzed appropriately • proposals for equipment repair are based upon the most appropriate and cost effective method to return equipment to full performance in a timely manner • items initiated are followed through until final resolution has occurred.
Underpinning Knowledge and Attitudes	• equipment operation and maintenance practices sufficient to recognize fault and no-fault conditions in standard and non-standard situations and then determine appropriate action which is consistent with operational guidelines is required. • organization procedures and relevant regulatory requirements along with the ability to implement them within appropriate time constraints and work standards. • managing risks using the hierarchy of controls applied to the process. Application of approved hazard control, safety procedures, use of PPE in relation to handling materials, equipment operation and clean up. • as a basis for solving processing and material problems, including principles of the operation of the equipment to be maintained

	• functions and troubleshooting of internal components and their problems • routine and non-routine causes of equipment failures and the service conditions which may increase maintenance • maintenance techniques, (e.g. reactive maintenance, predictive and preventative operational maintenance) • appropriate testing procedures and use of equipment for a range of equipment faults • operating principles for mechanical, hydraulic, pneumatic, electrical/electronic systems • urgency and timeliness factors in planning maintenance activities in relation to production requirements • collection, analysis and reporting of data.
Underpinning Skills	Must demonstrate skills to: • identify and select testing methods based on cost and time effectiveness • conduct inspections, checks and tests on equipment as appropriate • read and interpret circuit diagrams for mechanical, hydraulic, pneumatic and electrical/electronic operating systems • use technical information and manufacturer information to locate relevant data • interpret technical specifications and manufacturer instructions • ensure workplace is safe for testing and maintenance of equipment • identify hazards of the materials and process • implement appropriate procedures for hazard control • use PPE, safely handle products and materials, read relevant safety information • apply safety precautions appropriate to the task. • Language**,** literacy and numeracy requirements: ➢ the ability to read and interpret typical equipment specifications schematics and diagrams. ➢ Writing is required to the level of completing workplace forms and production reports. ➢ Basic numeracy is required, to the level of calculating equipment throughputs and performance.
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competence may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competence may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level III	
Unit Title	**Use Structured Problem Solving Tools**
Unit Code	**IND PHR3 11 0613**
Unit Descriptor	This competency covers the solving of process and other problems, beyond those associated directly with the process unit/equipment, using structured process improvement tools to identify improvements and/or solve problems.

Elements	Performance Criteria
1. Identify the problem	1.1 Identify variances from normal operating parameters and product quality. 1.2 Define the extent, cause and nature of the problem by observation and investigation. 1.3 State and specify the problem clearly.
2. Determine fundamental cause of problem	2.1 Identify possible causes based on experience and the use of problem solving tools/analytical techniques. 2.2 Develop possible cause statements. 2.3 Identify fundamental cause.
3. Determine corrective action	3.1 Consider all possible options for resolution of the problem. 3.2 Consider strengths and weaknesses of possible options. 3.3 Determine corrective action to remove the problem and possible future causes. 3.4 Develop implementation plans identifying measurable objectives, resource needs and timelines in accordance with safety and operating ***procedures***. 3.5 Develop recommendations for ongoing monitoring and testing.
4. Communicate recommendations	4.1 Prepare report on recommendations. 4.2 Present recommendations to appropriate personnel. 4.3 Follow up recommendations if required.

Variable	Range
Procedures	• All operations are performed in accordance with procedures. • Procedures include all relevant workplace procedures, work instructions, temporary instructions and relevant industry and government codes and standards.
Context	• The competency unit applies to a wide range of processes and equipment. The process manufacturing technical units of competency include a problem solving element where problems specific to that competency unit are to be

	resolved. This competency unit is where structured problem solving techniques are to be applied more broadly, or with greater depth/rigour than is implied by the problem solving element of the technical units. • In large plants or manufacturing organizations with multiple processes, it may apply to more than one process if those processes interact with each other. It applies to all operators across all functions.
Typical hazards	• include leaks, spillages and equipment hazards that can occur during the walk-through of a plant.
Problems	• 'Anticipate and solve problems' means resolve a wide range of routine and non-routine problems, using product and process knowledge to develop solutions to problems which do not have a known solution/a solution recorded in the procedures.
Typical process and product problems	may include: • non- routine process and quality problems • equipment selection, availability and failure • teamwork and work allocation problems • safety and emergency situations and incidents.

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills in: • relevant equipment and operational processes • enterprise policies and procedures • enterprise goals, targets and measures • enterprise quality, OHS and environmental requirements • principles of decision-making strategies and techniques • enterprise information systems and data collation • company codes and standards. • Consistent performance should be demonstrated. For example, look to see that: ➢ problems are recognised and clarified ➢ possible causes are identified, based on experience and use of analytical techniques in solving the problem, including: ➢ identifying variations ➢ identifying cause and effect ➢ separating single problems from multiple problems ➢ recognising recurring problems. ➢ fundamental cause of process or equipment faults is determined ➢ corrective/preventative implementation plans are developed to avoid recurrence of the problem ➢ Implementation plan is presented to relevant personnel.
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • analytical techniques in problem solving such as: ➢ brainstorming

	➢ fishbone diagrams/cause and effect diagrams ➢ process logic/process requirements ➢ logic tree ➢ similarity/difference analysis ➢ Pareto analysis ➢ force field/SWOT analysis ➢ flow charts ➢ control charts, run charts and graphs ➢ Scatter grams. • Action plans to solve problems are prepared including: ➢ priority requirements ➢ measurable objectives ➢ resource requirements ➢ methods for reaching objectives ➢ timelines ➢ coordination and feedback requirements ➢ safety requirements ➢ risk assessment ➢ Environmental requirements.
Underpinning Skills	Must demonstrate skills of: • Reading and interpreting typical product specifications, job sheets and material labels as provided to operators. • Writing is required to the level of report writing and completing workplace forms. • Basic numeracy is also required, e.g. to interpret quality data and graphs.
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competence may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competence may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level III	
Unit Title	**Monitor Storage Facilities**
Unit Code	**IND PHR3 12 0613**
Unit Descriptor	This unit involves the skills and knowledge required to monitor storage facilities in accordance with workplace requirements including determining site functions and operations; monitoring storage operations in accordance with workplace procedures; and taking appropriate action in response to identified discrepancies, changes to storage requirements, or breaches in operational procedures.

Elements	Performance Criteria
1. Determine site functions and operations	1.1 Layout of storage facilities, work flow and activities undertaken in each zone are identified. 1.2 Type of storage facilities, their purpose and (any) associated risk factors are identified. 1.3 Inventory lists are accessed through record management system. 1.4 Storage separations and co-storage applications are identified.
2. Monitor storage operations	2.1 Inventory data is confirmed to match goods/freight and applicable ***storage requirements***. 2.2 ***Storage areas*** are supervised to ensure movement of personnel and goods/freight are in accordance with workplace procedures. 2.3 Storage facilities are checked to ensure appropriate operational capacity. 2.4 Integrity of ***goods/materials*** are monitored to ensure appropriate quality is maintained. 2.5 Discrepancies/changes to storage requirements and/or inventory lists are noted and action undertaken in accordance with workplace procedures. 2.6 Appropriate action(s) are initiated in response to breaches of operational procedures or to an emergency/incident. 2.7 Operational actions and investigative outcomes are documented in accordance with workplace procedures.

Variable	Range
Storage types	May include but are not limited to: • bin/binning systems • rack refrigeration/freezers/cold rooms • marked floor space • containers

	• racks and racking systems • block/stacks • pallets
Work	May be conducted in: • restricted spaces • exposed conditions • controlled or open environments • environments involving the movement of equipment, goods, materials and/or vehicular traffic
Inventory systems	May be: • Automated • manual • paper-based • computerised • microfiche
Goods	May involve: • special handling, location, storage and/or packaging requirements, including temperature controlled goods and dangerous goods
Customers	May be: • internal or external
Workplaces	May comprise: • large, medium or small worksites
Requirements for work	May include: • restricted spaces • site restrictions and procedures • use of safety and personal protective equipment • communications equipment • specialized lifting and/or handling equipment • incident/accident breakdown procedures • additional gear and equipment • noise restrictions • hours of operations • authorities and permits
Modes of transfer	May be: • manual or motorized
Categories or groups of products/stock	May include: • small parts • perishable goods • overseas export • dangerous goods • refrigerated products • temperature controlled stock • fragile goods
The characteristics of products/stock	May include: • small parts

	• toxicity • flammability • form • weight • size • state • perishability • fragility • security risk
Labeling systems	May include but are not limited to: • batch code • bar code • identification numbering systems • serial numbers • symbols for safe handling
Hazards in the work area	May include: • hazardous or dangerous materials • contamination of, or from, materials being handled • noise, light, energy sources • stationary and moving machinery, parts or components • service lines • skills, leakages, ruptures • dust/vapours • oil or water on floor • a fire or explosion • damaged packaging or pallets • debris on floor • faulty racking • poorly stacked pallets • faulty equipment
Communication in the work area	May include: • Phone • Electronic Data Interchange (EDI) • fax • email • internet • RF systems • oral, aural or signed communications
Depending on the type of organization concerned and the local terminology used, workplace procedures	May include: • company procedures • enterprise procedures • organizational procedures • established procedures
Personal protective equipment	May include: • Gloves

	• safety headwear and footwear • safety glasses • two-way radios • high visibility clothing
Consultative processes	May involve: • other employees and supervisors • suppliers, customers and clients • relevant authorities and institutions • management and union representatives • industrial relations and OHS specialists • other maintenance, professional or technical staff
Information/documents	May include: • goods identification numbers and codes • manifests, picking slips, merchandise transfers, stock requisitions and bar codes • codes of practice and regulations relevant to workplace operations • international regulations and codes of practice for the handling, stacking and transport of dangerous goods and hazardous substances • operations manuals, job specifications and induction documentation • manufacturers specifications for equipment • workplace procedures and policies • supplier and/or client instructions • dangerous goods declarations and material safety data sheets (where applicable) • award, enterprise bargaining agreement, other industrial arrangements • relevant standards and certification requirements • quality assurance procedures • emergency procedures
Applicable regulations and legislation	May include: • codes and regulations relevant to the monitoring of storage facilities • and international regulations and codes of practice for the storage of dangerous goods and hazardous substances. • license, patent or copyright arrangements • water and road use and license arrangements • export/import/quarantine/bond requirements • marine orders • relevant state/territory OHS and environmental protection legislation • workplace relations regulations • workers compensation regulations

Evidence Guide	
Critical Aspects of Competence	The requirements of the elements and performance criteria of this unit and include demonstration of applying: • the underpinning knowledge and skills • relevant legislation and workplace procedures • other relevant aspects of the range statement
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • regulations, permit and license requirements relevant to the workplace activities • Relevant OHS and environmental protection procedures and guidelines • Workplace procedures and policies relevant to the monitoring of storage facilities • Focus of operation of work systems, equipment, management and site operating systems • Information on various categories or groups of products including their key characteristics and hazards and the special handling, stacking and storage requirements for each • Types of storage areas and related equipment appropriate for different types of goods including perishable, fragile, dangerous, composition/state goods • Equipment applications, capacities, configurations, safety hazards and control mechanisms • Requirements for workplace documentation reports and records • Problems that may occur when monitoring storage facilities and appropriate action that can be taken • Site layout • Housekeeping standards and procedures required in the workplace
Underpinning Skills	Must demonstrate skills to: • Communicate effectively with others when monitoring storage facilities • Read and interpret instructions, procedures, information and signs relevant to the monitoring of storage facilities • Complete documentation related to the monitoring of storage facilities • Work collaboratively with others when monitoring storage facilities • Adapt appropriately to cultural differences in the workplace, including modes of behavior and interactions with others • Promptly report and/or rectify any identified problems, faults or malfunctions when monitoring storage facilities in accordance with regulatory requirements and workplace procedures

	• Implement contingency plans for unplanned events related to the monitoring of storage facilities • Apply precautions and required action to minimize, control or eliminate hazards that may exist during work activities • Modify activities depending on differing operational contingencies, risk situations and environments • Work systematically with required attention to detail without injury to self or others, or damage to goods or equipment • Operate and adapt to differences in equipment in accordance with standard operating procedures • Use information on products and stock to determine, plan and organize processes used for the monitoring of storage facilities • Select and use relevant communications, computing and office equipment when monitoring storage facilities • Monitor performance of equipment • Select and use required personal protective equipment conforming to industry and OHS standards
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competence may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competence may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceutical Manufacturing Level III	
Unit Title	**Monitor and Operate Trade Waste**
Unit Code	**IND PHR3 13 0613**
Unit Descriptor	This unit covers the skills and knowledge required to monitor, operate, measure and report on trade waste system performance and process quality control.

Elements	Performance Criteria
1. Monitor treatment plant performance	1.1 Routine plant inspections are assessed in accordance with organisational and plant requirements. 1.2 ***Process*** samples are collected and ***tests*** conducted. 1.3 Process ***data*** is collected and reported according to organisational and plant requirements.
2. Control chemical use	2.1 Chemicals are used, handled, stored in accordance with organisational and statutory requirements. 2.2 Chemical dosing is prepared in accordance with plant processes and organisational and statutory requirements. 2.3 Information related to chemical supply and usage is maintained in accordance with statutory requirements.
3. Operate and control processes	3.1 Processes are monitored to maintain parameters of operation. 3.2 Process faults and operational conditions of plant are identified and reported in accordance with organisational and statutory requirements. 3.3 Basic ***system adjustments*** are assessed to enhance system performance in accordance with organisational and statutory requirements.
4. Compile process records	4.1 Reports are compiled from plant and system data to meet organisational and statutory requirements.

Variable	Range
Process	May include: • chemical precipitation, • activated sludge, • BOD reduction and solids handling
Tests	May include: • settling tests, • pH • dissolved oxygen
Data	May include plant performance data and chemical usage
System adjustments	May include: • pH correction and dissolved oxygen levels

Equipment	may include: • electronic monitoring and metering systems • manual chart recording systems • laboratory testing and sampling equipment • computerized equipment
Legislative/regulatory requirements	All work must comply with relevant Federal and State or Territory legislative or regulatory requirements.
OHS practices	Must include hazard identification and control, risk assessment and implementation of risk reduction measures specific to the tasks described by this unit, and may include: • manual handling techniques • standard operating procedures • personal protective equipment • safe materials handling • taking of rest breaks • ergonomic arrangement of workplaces • following marked walkways • safe storage of equipment • housekeeping • reporting accidents and incidents • other OHS practices relevant to the job and enterprise

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • select and apply sampling and testing procedures • collect data from recording systems • operate and control chemical dosing • use equipment such as listed in the range of variables • apply relevant enterprise and legislative requirements
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • industry process and equipment • system hydraulics and layout, control systems • chemical dosing processes • hazardous material handling procedures • safety and environmental aspects of relevant testing processes • workplace procedures and reporting processes • OHS practices, including hazard identification and control measures • quality practices • recording and reporting practices
Underpinning Skills	Must demonstrate skills to: • solve operational problems • prepare and apply chemical and biological dosing • sample and test products • maintain accurate records of test results/work records

	• communicate effectively within the workplace • interpret and apply established procedures • document, assess and transfer information • read, interpret and follow information on work specifications, standard operating procedures and work instructions and other reference material • maintain accurate records • sequence operations • meet specifications • clarify and check task-related information • carry out work according to OHS practices
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competence may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competence may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level III	
Unit Title	**Apply First Aid**
Unit Code	**IND PHR3 14 0613**
Unit Descriptor	This unit of competency describes the skills and knowledge required to provide first aid response, life support, management of casualty(s), the incident and other first aiders, until the arrival of medical or other assistance

Elements	Performance Criteria
1. Assess the situation	1.1 Identify assess and minimize ***hazards*** in the situation that may pose a risk of injury or illness to self and others. 1.2 Minimize immediate ***risk*** to self and casualty's health and safety by controlling any hazard in accordance with occupational health and safety requirements. 1.3 Assess casualty and identify injuries, illnesses and conditions.
2. Apply first aid procedures	2.1 Calmly provide information to reassure casualty, adopting a communication style to match the casualty's level of consciousness. 2.2 Use available ***resources and equipment*** to make the casualty as comfortable as possible. 2.3 Respond to the casualty in a culturally aware, sensitive and respectful manner. 2.4 Determine and explain the nature of casualty's injury/condition and relevant first aid procedures to provide comfort. 2.5 Seek consent from casualty prior to applying first aid management. 2.6 Provide ***first aid management*** in accordance with ***established first aid principles*** and Guidelines and/or State/Territory regulations, legislation and policies and industry requirements. 2.7 Seek first aid assistance from others in a timely manner and as appropriate. 2.8 Correctly operate first aid equipment as required for first aid management according to manufacturer/supplier's instructions and local policies and/or procedures. 2.9 Use safe manual handling techniques as required. 2.10 Monitor ***casualty's condition*** and respond in accordance with effective first aid principles and procedures.

	2.11 Finalize casualty management according to casualty's needs and first aid principles.
3. Communicate details of the incident	3.1 Request ambulance support and/or appropriate medical assistance according to relevant circumstances using relevant ***communication media and equipment***. 3.2 Accurately convey assessment of casualty's condition and management activities to ambulance services /other emergency services/relieving personnel. 3.3 Prepare reports as appropriate in a timely manner, presenting all relevant facts according to established procedures. 3.4 Accurately record details of casualty's physical condition, changes in conditions, management and response to management in line with established procedures. 3.5 Maintain confidentiality of records and information in line with privacy principles and statutory and/or organization policies.
4. Evaluate own performance	4.1 Seek feedback from ***appropriate clinical expert***. 4.2 Recognize the possible psychological impacts on rescuers of involvement in critical incidents. 4.3 Participate in debriefing/evaluation as appropriate to improve future response and address individual needs.

Variable	**Range**
A hazard	Is a source or situation with the potential for harm in terms of human injury or ill-health, damage to property, the environment, or a combination of these
Hazards	May include: • Physical, biological and chemical hazards & • Hazards associated with manual handling
Risks	May include: • Risks from equipment, machinery and substances • Risks from first aid equipment • Environmental risks • Exposure to blood and other body substances • Risk of further injury to the casualty • Risks associated with the proximity of other workers and bystanders • Risks from vehicles
Resources and equipment are used appropriate to the risk to be met and	May include*:* • AED • First aid kit • Auto-injector • Puffer/inhaler

	• Resuscitation mask or barrier • Spacer device
First aid management	Must take into account applicable aspects of*:* • The setting in which first aid is provided, including: • workplace policies and procedures • industry/site specific regulations, codes etc. • OHS requirements • state and territory workplace health and safety legislative requirements • location and nature of the incident • situational risks associated with, for example, electrical and biological hazards, weather, motor vehicle accidents • location of emergency services personnel. • The use and availability of first aid equipment and resources • Infection control • Legal and social responsibilities of first aider
Casualty's condition	Is managed for*:* • Abdominal injuries • Airway obstruction • Allergic reactions • Altered and loss of consciousness • Bleeding • Burns - thermal, chemical, friction, electrical • Chest pain/cardiac arrest • Injuries: cold and crush injuries; eye and ear injuries; head, neck and spinal injuries; minor skin injuries; needle stick injuries; soft tissue injuries including sprains, strains, dislocations • Near drowning • Envenomation - snake, spider, insect and marine bites • Environmental conditions such as hypothermia, hyperthermia, dehydration, heat stroke • Fractures • Medical conditions, including cardiac conditions, epilepsy, diabetes, asthma and other respiratory conditions • No signs of life • Poisoning and toxic substances (including chemical contamination) • Respiratory distress/arrest • Seizures • Shock • Stroke • Substance misuse - common drugs and alcohol, including illicit drugs.
Communication media and equipment	May include but are not limited to: • Telephones, including landline, mobile and satellite phones

	• HF/VHF radio • Flags • Flares • Two way radio • Email • Electronic equipment • Hand signals
Established first aid principles	May include: • Preserve life • Prevent illness, injury and condition(s) becoming worse • Promote recovery • Protect the unconscious casualty
Vital signs	May include: • Consciousness • Breathing • Circulation
Appropriate clinical expert	May include: • Supervisor/manager • Ambulance officer/paramedic • Other medical/health worker
Documentation	May include: • Injury report forms • Workplace documents as per organisation requirements
Documentation	May include recording: • Time • Location • Description of injury • First aid management • Fluid intake/output, including fluid loss via: ➢ blood ➢ vomit ➢ feces ➢ urine
Contextualization to address specific requirements	May include: • Focus on first aid management of specific types of injury • First aid provision under specific constraints or circumstances (e.g. in confined spaces, in maritime work environment or in work environment involving identified risks/hazards)
Administration of medication	May include: • time • date • person administering • dose • Vital signs

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills of: • must provide evidence of specified essential knowledge as well as skills • Competence should be demonstrated working individually and, where appropriate, as part of a first aid team • Consistency of performance should be demonstrated over the required range of situations relevant to the workplace or community setting • Currency of first aid knowledge and skills is to be demonstrated in line with State/Territory regulations, legislation and policies, ARC and industry guidelines
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • envenomation - snake, spider, insect and marine bites • environmental impact such as hypothermia, hyperthermia, dehydration, heat stroke • fractures • medical conditions, including cardiac conditions, epilepsy, diabetes, asthma and other respiratory conditions • near drowning • poisoning and toxic substances (including chemical contamination) • respiratory distress • seizures • shock • stroke • substance misuse - common drugs and alcohol, including illicit drugs • Social/legal issues: • duty of care • need to be culturally aware, sensitive and respectful • importance of debriefing • confidentiality • own skills and limitations • Understanding of the use of an Automated External Defibrillator (AED), including when to use and when not to • basic occupational health and safety requirements in the provision of first aid • basic principles and concepts underlying the practice of first aid • chain of survival • first aiders' skills and limitations • infection control principles and procedures, including use of standard precautions • priorities of management in first aid when dealing with life threatening conditions

	• procedures for dealing with major and minor injury and illness
Underpinning Skills	Must demonstrate skills to: • Administer medication in line with state/territory regulations, legislation and policies • Apply first aid principles • Call an ambulance and/or medical assistance according to relevant circumstances and report casualty's condition • Communicate effectively and assertively in an incident • Conduct an initial casualty assessment • Demonstrate correct procedures for performing CPR using a manikin, including standard precautions (i.e. as per unit HLTCPR201A Perform CPR) Demonstrate: • ability to call an ambulance • consideration of the welfare of the casualty • safe manual handling • site management to prevent further injury • Evaluate own response and identify appropriate improvements where required • Follow OHS guidelines • Infection control, including use of standard precautions • Make prompt and appropriate decisions relating to managing an incident in the workplace • Plan an appropriate first aid response in line with established first aid principles, policies and procedures, ARC Guidelines and/or State/Territory regulations, legislation and policies and industry requirements and respond appropriately to contingencies in line with own skills • Prepare a written incident report or provide information to enable preparation of an incident report • Provide assistance with self-medication as per subject's own medication regime and in line with State/Territory legislation, regulations and policies and any available medical/pharmaceutical instructions • Use literacy and numeracy skills as required to read, interpret and apply guidelines and protocols
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competence may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competence may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level III	
Unit Title	**Monitor the Implementation of Occupational Health and Safety Policies and Procedures**
Unit Code	**IND PHR3 15 0613**
Unit Descriptor	This is a Core unit. It covers the skills and knowledge required to provide a leadership role in supporting day-to-day implementation of Occupational Health and Safety (OHS) policies and procedures in a work area. This unit applies to those with formal responsibility for others, and to those required to model workplace policies and procedures but who have no formal management role.

Elements	Performance Criteria
1. Ensure others in the work area are able to implement safe work practices	1.1 Hazard control and personal protective clothing and equipment appropriate to work requirements are available and functional. 1.2 Information on OHS policies, procedures and programs is current, accessible and communicated to others in the ***work*** area. 1.3 Information about identified hazards and the outcomes of risk assessment and risk control procedures is accessible and communicated to others in the work area. 1.4 Health and safety hazards and control measures relating to ***work responsibilities*** can be identified by those in the work area. 1.5 Mentoring and coaching support is available to support individuals/groups to implement work procedures to support safety. 1.6 Training needs are identified and addressed within level of responsibility.
2. Monitor observance of safe work practices in the work area	2.1 Work procedures in the work area are clearly defined, documented and followed. 2.2 Deviation from identified procedures is identified, reported and addressed within level of responsibility. 2.3 Personal behaviour is consistent with workplace policies and procedures. 2.4 Safety hazards in the work area are identified and reported according to workplace procedure. 2.5 OHS information is recorded to meet workplace reporting requirements. 2.6 Housekeeping standards in the work area are maintained.

3. Implement emergency procedures to respond to a hazardous event	3.1 Workplace procedures for dealing with hazardous events are promptly implemented as required. 3.2 Hazardous events are investigated to identify cause. 3.3 Control measures to prevent recurrence and minimize risks of hazardous events are implemented.
4. Maintain and improve health and safety in the work area	4.1 Potential hazards are identified, assessed, removed or and/reported within level of responsibility and according to workplace procedure. 4.2 Risk assessments are conducted and appropriate control measures are identified and implemented in the work area. 4.3 Recommendations arising from risk assessments are implemented within level of responsibility. 4.4 Inadequacies in control measures are identified and reported according to company reporting requirements. 4.5 The work group is consulted and advised of OHS matters relevant to work role. 4.6 Matters raised relating to OHS are promptly resolved or referred to the appropriate personnel. 4.7 Opportunities for improving OHS performance are identified and raised with relevant personnel. 4.8 Procedures are developed or revised to support effective control of health and safety hazards. 4.9 Safety information is recorded according to company reporting requirements.

Variable	Range
Work	is carried out in accordance with company procedures, regulatory and licensing requirements, legislative requirements and industrial awards and agreements.
Work responsibilities	May include: • responsibility for modeling appropriate OHS policies and procedures and may include formal or informal responsibility for providing a support role to others in the work area
Legislative requirements	May include state/Territory/Commonwealth occupational health and safety Acts and regulations, including regulations and codes of practice relating to hazards present in the workplace. They also include general duty of care under occupational health and safety legislation and common law
Company procedures	May include job-related SOPs and OHS-specific procedures. Examples of OHS procedures include consultation and participation, emergency response, response to specific hazards, incident investigation, risk assessment, reporting arrangements and issue resolution procedures

Workplace information	May include: • OHS system and related documentation including policies and procedures, Standard Operating Procedures (SOPs), information on hazards and the work process, hazard alerts, safety signs and symbols, labels, Material Safety Data Sheets (MSDSs) and manufacturers' advice. Technical advice may include codes of practice and industry standards
Safe work procedures	May include: • relate to the work area which may include: • special requirements covered by the issuing of permits
Employee and employer rights and responsibilities are	May include: • those established by legislation and reflected in company • policies and procedures
OHS incidents	May include: • near misses, injuries, illnesses and • property damage
Hazards found in the work area	May include: • noise • confined spaces • working with steam and hot services/product • airborne particulates • handling hazardous substances • working with and near moving equipment/load shifting • equipment • stress • broken or damaged equipment or materials • slip, trip and fall hazards • manual handling • working with 240V power supply • poor ventilation • working in exposed weather conditions • working with combustible materials
Safety hazards	May include work conditions covered by National Occupational Health and Safety Commission and/or state health and safety authorities, the assessment criteria and methods prescribed by these authorities must also be met
Consultation	Would typically involve discussing issues, considering and responding to feedback on issues including but not limited to identification of hazards, assessment of risk level, hazard control options, injury and accident investigation, development and/or review of safe work procedures and proposed changes to the work environment that may impact on risk
The operator at this level	May not have: • direct responsibility for overseeing the training/development of team members. At a minimum they must be able to identify development needs of others in the work area and refer this information to the relevant personnel

The operator at this level	May not have: • Responsibility for independently assessing risks and determining the effectiveness of control measures. However, they would be expected to observe day-to-day effectiveness and participate in assessment and review processes • Responsibilities at this level may include facilitating consultation processes within level of responsibility • Record keeping complies with legal and OHS program requirements

Evidence Guide	
Critical Aspects of Competence	Include demonstration of applying: • the underpinning knowledge and skills • relevant legislation and workplace procedures • other relevant aspects of the range statement
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • Legislation relating to OHS responsibilities. This requires an understanding of the main provisions of national and state health and safety legislation, regulations and codes of practice. This includes OHS rights and responsibilities and codes of practice related to consultation, safe workplace, workers compensation and return to work • The system for managing OHS in the workplace. This • includes an understanding of: • site layout including emergency exits signage, symbols and signals relating to OHS • location, use and meaning of safety alarms and responses required • specific programs to manage OHS • the role of operating and safety procedures, incident • reporting and investigation processes • requirements and procedures for reporting OHS • hazards and incidents including injuries, illness and near misses • training arrangements • structure and role of consultative processes • sources of information on workplace health and safety • OHS personnel including managers, representatives, emergency wardens, first aid officers and internal and external auditors where appropriate • Principles of risk management including hazard identification, risk assessment and risk control according to hierarchy of control • The personal protective and emergency clothing and/or equipment requirements of work roles in the work area and procedures for fitting, using, storing and ordering clothing and/or equipment as required

	• Purpose, application and limitations of protective clothing and equipment • Common types of injuries relevant to work tasks, likely causes and control options • Hazards and control measures in place in the work area. This requires an understanding of safe work requirements relevant to the work area, including lock out/tag out and isolation procedures • Health and safety resources and advice relating to typical hazards and control methods relevant to the work area. This includes an awareness of relevant technical advice and support • Work functions carried out in the work area that are covered by special training requirements such as for entry to confined spaces, hot work, working at heights • The role of consultation in supporting OHS program implementation • Appropriate communication skills and techniques to convey health and safety information to others in the workplace • Emergency response system, procedures and personnel • Return to work responsibilities and procedures • Auditing arrangements, roles and responsibilities as they relate to own work responsibilities. This may include an understanding of internal and external audit processes • Documentation system and procedures. This includes record keeping to meet both company and legal requirements, procedures for developing and/or reviewing workplace procedures, and document control systems used in the workplace • Purpose of OHS records and an understanding of how this information is used to support the management of OHS in the workplace
Underpinning Skills	Must demonstrate skills to: • Access, interpret and communicate information about OHS and related procedures to others in the work area. This requires demonstration of two-way communication including active listening and constructive response to feedback • Provide access to and maintain current OHS information in the work area. This typically includes Standard Operating Procedures and/or safe work procedures. It may also include relevant signage and permits to work where relevant • Model safe work policies and procedures in own work • Identify OHS hazards and controls relevant to work processes and practices in the work area • Support others to follow OHS procedures. This involves ensuring that all personnel in the work area receive the information required, that they have met the necessary competency/regulatory and licensing requirements to carry

	out their work responsibilities and they are equipped with the relevant personal protective clothing and equipment. This may apply to both company employees and subcontractors • Identify, report and/or address OHS training and development needs of others in the work area • Regularly inspect the work area to identify OHS hazards • Report and take action to remove or control hazards according to workplace procedure and level of responsibility • Ensure that appropriate and timely action is taken in response to emergencies • Participate in investigations of non-compliance and risk assessment processes • Participate in consultation processes to improve OHS in the workplace • Respond to OHS hazard identification and incidents in an appropriate and timely way • Review practice and procedures to implement recommendations arising from risk assessments and/or improvement proposals within level of responsibility. This may include collection and analysis of OHS records, reviewing operating procedures and communicating changes to others in the work area • Support return to work arrangements in the work area within level of responsibility • Ensure that housekeeping standards are maintained and that equipment is safe to operate • Ensure that OHS records and documentation is accurate, complete and timely
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competence may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competence may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level III	
Unit Title	**Apply Quality Control**
Unit Code	**IND PHR3 16 0613**
Unit Descriptor	This unit covers the knowledge, attitudes and skills required in applying quality control in the workplace.

Elements	Performance Criteria
1. Implement quality standards	1.1 Agreed quality standard and procedures are acquired and confirmed. 1.2 Standard procedures are introduced to organizational staff/personnel. 1.3 Quality standard and procedures documents are provided to employees in accordance with the organization policy. 1.4 Standard procedures are revised / updated when necessary.
2. Assess quality of service delivered	2.1 Services delivered are ***quality checked*** against organization ***quality standards*** and specifications. 2.2 Service delivered are evaluated using the appropriate evaluation ***quality parameters*** and in accordance with organization standards. 2.3 Causes of any identified faults are identified and corrective actions are taken in accordance with organization policies and procedures.
3. Record information	3.1 Basic information on the quality performance is recorded in accordance with organization procedures. 3.2 Records of work quality are maintained according to the requirements of the organization.
4. Study causes of quality deviations	4.1 Causes of deviations from final outputs or services are investigated and reported in accordance with organization procedures. 4.2 Suitable preventive action is recommended based on organization quality standards and identified causes of deviation from specified quality standards of final service or output.
5. Complete documentation	5.1 Information on quality and other indicators of service performance is recorded. 5.2 All service processes and outcomes are recorded.

Variable	Range
Quality check	May include but not limited to: • Check against design / specifications • Visual inspection and Physical inspection

Quality standards	May include but not limited to: • Materials • Components • Process • Procedures
Quality parameters	May include but not limited to: • Standard Design / Specifications • Material Specification

Evidence Guide	
Critical Aspects of Competence	Demonstrates skills and knowledge to: • Check completed work continuously against organization standard • Identify and isolate faulty or poor service • Check service delivered against organization standards • Identify and apply corrective actions on the causes of identified faults or error • Record basic information regarding quality performance • Investigate causes of deviations of services against standard • Recommend suitable preventive actions
Underpinning Knowledge	Demonstrates knowledge of: • Relevant quality standards, policies and procedures • Characteristics of services • Safety environment aspects of service processes • Evaluation techniques and quality checking procedures • Workplace procedures and reporting procedures
Underpinning Skills	Demonstrates skills to: • interpret work instructions, specifications and standards appropriate to the required work or service • carry out relevant performance evaluation • maintain accurate work records • meet work specifications and requirements • communicate effectively within defined workplace procedures
Resource Implications	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competence may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competence may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level III	
Unit Title	**Lead Workplace Communication**
Unit Code	**IND PHR3 17 0613**
Unit Descriptor	This unit covers the knowledge, attitudes and skills needed to lead in the dissemination and discussion of information and issues in the workplace.

Elements	Performance Criteria
1. Communicate information about workplace processes	1.1 Appropriate ***communication method*** is selected. 1.2 Multiple operations involving several topics areas are communicated accordingly. 1.3 Questions are used to gain extra information. 1.4 Correct sources of information are identified. 1.5 Information is selected and organized correctly. 1.6 Verbal and written reporting is undertaken when require. 1.7 Communication skills are maintained in all situations.
2. Lead workplace discussion	2.1 Response to workplace issues is sought. 2.2 Response to workplace issues are provided immediately. 2.3 Constructive contributions are made to workplace discussions on such issues as production, quality and safety. 2.4 Goals/objectives and action plan undertaken in the workplace are communicated.
3. Identify and communicate issues arising in the workplace	3.1 Issues and problems are identified as they arise. 3.2 Information regarding problems and issues are organized coherently to ensure clear and effective communication. 3.3 Dialogue is initiated with appropriate staff/personnel. 3.4 Communication problems and issues are raised as they arise.

Variable	Range
Methods of communication	May include but not limited to: • Non-verbal gestures • Verbal • Face to face • Two-way radio • Speaking to groups • Using telephone • Written • Using Internet • Cell phone

Evidence Guide	
Critical Aspects of Competence	Demonstrates skills and knowledge to: • Deal with a range of communication/information at one time • Make constructive contributions in workplace issues • Seek workplace issues effectively • Respond to workplace issues promptly • Present information clearly and effectively written form • Use appropriate sources of information • Ask appropriate questions • Provide accurate information
Underpinning Knowledge and Attitudes	Demonstrates knowledge of: • Organization requirements for written and electronic communication methods • Effective verbal communication methods
Underpinning Skills	Demonstrates skills to: • Organize information • Understand and convey intended meaning • Participate in variety of workplace discussions • Comply with organization requirements for the use of written and electronic communication methods
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competence may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competence may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level III	
Unit Title	**Lead Small Teams**
Unit Code	**IND PHR3 18 0613**
Unit Descriptor	This unit covers the skills, knowledge and attitudes required to determine individual and team development needs and facilitate the development of the work group.

Elements	Performance Criteria
1. Provide team leadership	1.1 ***Learning and development needs*** are systematically identified and implemented in line with ***organizational requirements***. 1.2 Learning plan to meet individual and group training and developmental needs is collaboratively developed and implemented. 1.3 Individuals are encouraged to self-evaluate performance and identify areas for improvement. 1.4 ***Feedback on performance*** of team members is collected from relevant sources and compared with established team learning process.
2. Foster individual and organizational growth	2.1 Learning and development program goals and objectives are identified to match the specific knowledge and skills requirements of competence standards. 2.2 ***Learning delivery methods*** are appropriate to the learning goals, the learning style of participants and availability of equipment and resources. 2.3 Workplace learning opportunities and coaching/ mentoring assistance are provided to facilitate individual and team achievement of competencies. 2.4 Resources and timelines required for learning activities are identified and approved in accordance with organizational requirements.
3. Monitor and evaluate workplace learning	3.1 Feedback from individuals or teams is used to identify and implement improvements in future learning arrangements. 3.2 Outcomes and performance of individuals/teams are assessed and recorded to determine the effectiveness of development programs and the extent of additional support. 3.3 Modifications to learning plans are negotiated to improve the efficiency and effectiveness of learning. 3.4 Records and reports of competence are maintained within organizational requirement.

4. Develop team commitment and cooperation	4.1 Open communication processes to obtain and share information is used by team. 4.2 Decisions are reached by the team in accordance with its agreed roles and responsibilities. 4.3 Mutual concern and camaraderie are developed in the team.
5. Facilitate accomplishment of organizational goals	5.1 Team members actively participated in team activities and communication processes. 5.2 Teams' members developed individual and joint responsibility for their actions. 5.3 Collaborative efforts are sustained to attain organizational goals.

Variable	**Range**
Learning and development needs	May include but not limited to: • Coaching, mentoring and/or supervision • Formal/informal learning program • Internal/external training provision • Work experience/exchange/opportunities • Personal study • Career planning/development • Performance appraisals • Workplace skills assessment • Recognition of prior learning
Organizational requirements	May include but not limited to: • Quality assurance and/or procedures manuals • Goals, objectives, plans, systems and processes • Legal and organizational policy/guidelines and requirements • Safety policies, procedures and programs • Confidentiality and security requirements • Business and performance plans • Ethical standards • Quality and continuous improvement processes and standards
Feedback on performance	May include but not limited to: • Formal/informal performance appraisals • Obtaining feedback from supervisors and colleagues • Obtaining feedback from clients • Personal and reflective behavior strategies • Routine and organizational methods for monitoring service delivery
Learning delivery methods	May include but not limited to: • On the job coaching or mentoring • Problem solving • Presentation/demonstration • Formal course participation

	• Work experience and Involvement in professional networks • Conference/seminar attendance and induction

Evidence Guide	
Critical Aspects of Competence	Demonstrates skills and knowledge to: • identify and implement learning opportunities for others • give and receive feedback constructively • facilitate participation of individuals in the work of the team • negotiate learning plans to improve the effectiveness of learning • prepare learning plans to match skill needs • access and designate learning opportunities
Underpinning Knowledge and Attitude	Demonstrates knowledge of: • coaching and mentoring principles • how to work effectively with team members who have diverse work styles, aspirations, cultures and perspective • how to facilitate team development and improvement • methods and techniques for eliciting and interpreting feedback • methods for identifying and prioritizing personal development opportunities and options • career paths and competence standards in the industry
Underpinning Skills	Demonstrates skills to: • read and understand a variety of texts, prepare general information and documents according to target audience; spell with accuracy; use grammar and punctuation effective relationships and conflict management • receive feedback and report, maintain effective relationships and conflict management • organize required resources and equipment to meet learning needs • provide support to colleagues • organize information; assess information for relevance and accuracy; identify and elaborate on learning outcomes • facilitation skills to conduct small group training sessions • relate to people from a range of social, cultural, physical and mental backgrounds
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competence may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competence may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level III	
Unit Title	**Improve Business Practice**
Unit Code	**IND PHR3 19 0613**
Unit Descriptor	This unit covers the skills, knowledge and attitudes required in promoting, improving and growing business operations.

Elements	Performance Criteria
1. Diagnose the business	1.1 ***Data required*** for diagnosis is determined and acquired. 1.2 ***Competitive advantage*** of the business is determined from the data. 1.3 ***SWOT analysis*** of the data is undertaken.
2. Benchmark the business	2.1 Sources of relevant benchmarking data are identified. 2.2 ***Key indicators*** for benchmarking are selected in consultation with key stakeholders. 2.3 Like indicators of own practice are compared with benchmark indicators. 2.4 Areas for improvement are identified.
3. Develop plans to improve business performance	3.1 A consolidated list of required improvements is developed. 3.2 Cost-benefit ratios for required improvements are determined. 3.3 Work flow changes resulting from proposed improvements are determined. 3.4 Proposed improvements are ranked according to agreed criteria. 3.5 An action plan is developed and agreed to implement the top ranked improvements. 3.6 ***Organizational structures*** are checked to ensure they are suitable.
4. Develop marketing and promotional plans	4.1 The practice vision statement is reviewed. 4.2 Practice ***objectives*** are developed/reviewed. 4.3 Target markets are identified/refined. 4.4 ***Market research data*** is obtained. 4.5 ***Competitor analysis*** is obtained. 4.6 ***Market position*** is developed/reviewed. 4.7 ***Practice brand*** is developed. 4.8 ***Benefits*** of practice/practice products/services are identified. 4.9 ***Promotion tools*** are selected/developed.

5. Develop business growth plans	5.1 Plans are developed to increase ***yield per existing client***. 5.2 Plans are developed to add new clients. 5.3 Proposed plans are ranked according to agreed criteria. 5.4 An action plan is developed and agreed to implement the top ranked plans. 5.5 Practice work practices are reviewed to ensure they support growth plans.
6. Implement and monitor plans	6.1 Implementation plan is developed in consultation with all relevant stakeholders. 6.2 Indicators of success of the plan are agreed. 6.3 Implementation is monitored against agreed indicators. 6.4 Implementation is adjusted as required.

Variable	**Range**
Data required	May include but not limited to: • organization capability • appropriate business structure • level of client service which can be provided • internal policies, procedures and practices • staff levels, capabilities and structure • market, market definition • market changes/market segmentation • market consolidation/fragmentation • revenue • level of commercial activity • expected revenue levels, short and long term • revenue growth rate • break even data • pricing policy • revenue assumptions • business environment • economic conditions • social factors • demographic factors • technological impacts • political/legislative/regulative impacts • competitors, competitor pricing and response to pricing • competitor marketing/branding • competitor products
Competitive advantage	May include but not limited to: • services/products • fees • location and timeframe

SWOT analysis	May include but not limited to: • internal strengths such as staff capability, recognized • quality • internal weaknesses such as poor morale, • under-capitalization, poor technology • external opportunities such as changing market and • economic conditions • external threats such as industry fee structures, strategic • alliances, competitor marketing
Key indicators	May include but not limited to: • salary cost and staffing • personnel productivity (particularly of principals) • profitability • fee structure • client base • size staff/principal • overhead/overhead control
Organizational structures	May include but not limited to: • Legal structure (partnership, Limited Liability Company, etc.) • organizational structure/hierarchy • reward schemes
Objectives should be 'SMART'	May include but not limited to: • S: Specific • M: Measurable • A: Achievable • R: Realistic • T: Time defined
Market research data	May include but not limited to: • data about existing clients • data about possible new clients • data from internal sources • data from external sources such as: ➢ trade associations/journals ➢ Yellow Pages small business surveys ➢ libraries ➢ Internet ➢ Chamber of Commerce ➢ client surveys ➢ industry reports ➢ secondary market research • primary market research such as: ➢ telephone surveys ➢ personal interviews and mail surveys
Competitor analysis	May include but not limited to: • competitor offerings • competitor promotion strategies and activities • competitor profile in the market place

Market position	May include but not limited to: • product • the good or service provided • product mix • the core product - what is bought • the tangible product - what is perceived • the augmented product - total package of consumer • features/benefits • product differentiation from competitive products • new/changed products • Price and pricing strategies (cost plus, supply/demand, ability to pay, etc.) • Pricing objectives (profit, market penetration, etc.) • cost components • market position • distribution strategies • marketing channels • promotion • promotional strategies • target audience • communication • promotion budget
Practice brand	May include but not limited to: • practice image • practice logo/letter head/signage • phone answering protocol • facility decor • slogans • templates for communication/invoicing • style guide • writing style • AIDA (Attention, Interest, Desire and Action)
Benefits	May include but not limited to: • features as perceived by the client • benefits as perceived by the client
Promotion tools	May include but not limited to: • networking and referrals • seminars • advertising • press releases • publicity and sponsorship • brochures • newsletters (print and/or electronic) • websites • direct mail • telemarketing/cold calling

Yield per existing client	May include but not limited to: • raising charge out rates/fees • packaging fees • reduce discounts • sell more services to existing clients

Evidence Guide	
Critical Aspects of Competence	Demonstrates skills and knowledge in: • ability to identify the key indicators of business performance • ability to identify the key market data for the business • knowledge of a wide range of available information sources • ability to acquire information not readily available within a business • ability to analyze data and determine areas of improvement • ability to negotiate required improvements to ensure implementation • ability to evaluate systems against practice requirements and form recommendations and/or make recommendations • ability to assess the accuracy and relevance of information
Underpinning Knowledge and Attitudes	Demonstrates knowledge of: • data analysis • communication skills • computer skills to manipulate data and present information • negotiation skills • problem solving • planning skills • marketing principles • ability to acquire and interpret relevant data • current product and marketing mix • use of market intelligence • development and implementation strategies of promotion and growth plans
Underpinning Skills	Demonstrates skill in: • data analysis and manipulation • ability to acquire and interpret required data, current practice systems and structures and sources of relevant benchmarking data • applying methods of selecting relevant key benchmarking indicators • communication skills • working and consulting with others when developing plans for the business • planning skills, negotiation skills and problem solving • using computers to manipulate, present and distribute information

Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competence may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competence may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Level III	
Unit Title	**Prevent and Eliminate MUDA**
Unit Code	**IND PHR3 20 0613**
Unit Descriptor	This unit of competence covers the knowledge, skills and attitude required by a worker to prevent and eliminate MUDA/wastes in his/her their workplace. It covers responsibility for the day-to-day operation of the work and ensures Kaizen elements are continuously improved and institutionalized.

Elements	Performance Criteria
1. Prepare for work.	1.1 Work instructions are used to determine job requirements, including method, material and equipment. 1.2 Job specifications are read and interpreted following working manual. 1.3 ***OHS requirements***, including dust and fume collection, breathing apparatus and eye and ear personal protection needs are observed throughout the work. 1.4 Appropriate material is selected for work. 1.5 ***Safety equipment and tools*** are identified and checked for safe and effective operation.
2. Identify MUDA.	2.1 Plan of MUDA identification is prepared and implemented. 2.2 Causes and effects of MUDA are discussed. 2.3 ***Tools and techniques*** are used to draw and analyze current situation of the work place. 2.4 Wastes/MUDA are identified and measured based on ***relevant procedures***. 2.5 Identified and measured wastes are reported to relevant personnel.
3. Eliminate wastes/MUDA.	3. 1. Plan of MUDA elimination is prepared and implemented. 3. 2. Necessary attitude and ***the ten basic principles for improvement*** are adopted to eliminate waste/MUDA. 3. 3. Tools and techniques are used to eliminate wastes/MUDA based on the procedures and OHS. 3. 4. Wastes/MUDA are reduced and eliminated in accordance with OHS and organizational requirements. 3. 5. Improvements gained by elimination of waste/MUDA are reported to relevant bodies.
4. Prevent occurrence of wastes/MUDA.	4.1 Plan of MUDA prevention is prepared and implemented. 4.2 Standards required for machines, operations, defining normal and abnormal conditions, clerical procedures and procurement are discussed and prepared.

	4.3 Occurrences of wastes/MUDA are prevented by using ***visual and auditory control methods***. 4.4 Waste-free workplace is created using ***5W and 1H***sheet. 4.5 The completion of required operation is done in accordance with standard procedures and practices. 4.6 The updating of standard procedures and practices is facilitated. 4.7 The capability of the work team that aligns with the requirements of the procedure is ensured.

Variable	**Range**
OHS requirements	May include but not limited to: • Are to be in accordance with legislation/ regulations/codes of practice and enterprise safety policies and procedures. This may include protective clothing and equipment, use of tooling and equipment, workplace environment and safety, handling of material, use of fire fighting equipment, enterprise first aid, hazard control and hazardous materials and substances. • Personal protective equipment is to include that prescribed under legislation/regulations/codes of practice and workplace policies and practices. • Safe operating procedures are to include, but are not limited to the conduct of operational risk assessment and treatments associated with workplace organization. • Emergency procedures related to this unit are to include but may not be limited to emergency shutdown and stopping of equipment, extinguishing fires, enterprise first aid requirements and site evacuation.
Safety equipment and tools	May include but not limited to: • dust masks / goggles • glove • working cloth • first aid • safety shoes
Tools and techniques	May include but not limited to: • Plant Layout • Process flow • Other Analysis tools • Do time study by work element • Measure Travel distance • Take a photo of workplace • Measure Total steps • Make list of items/products, who produces them and who uses them & those in warehouses, storages etc.

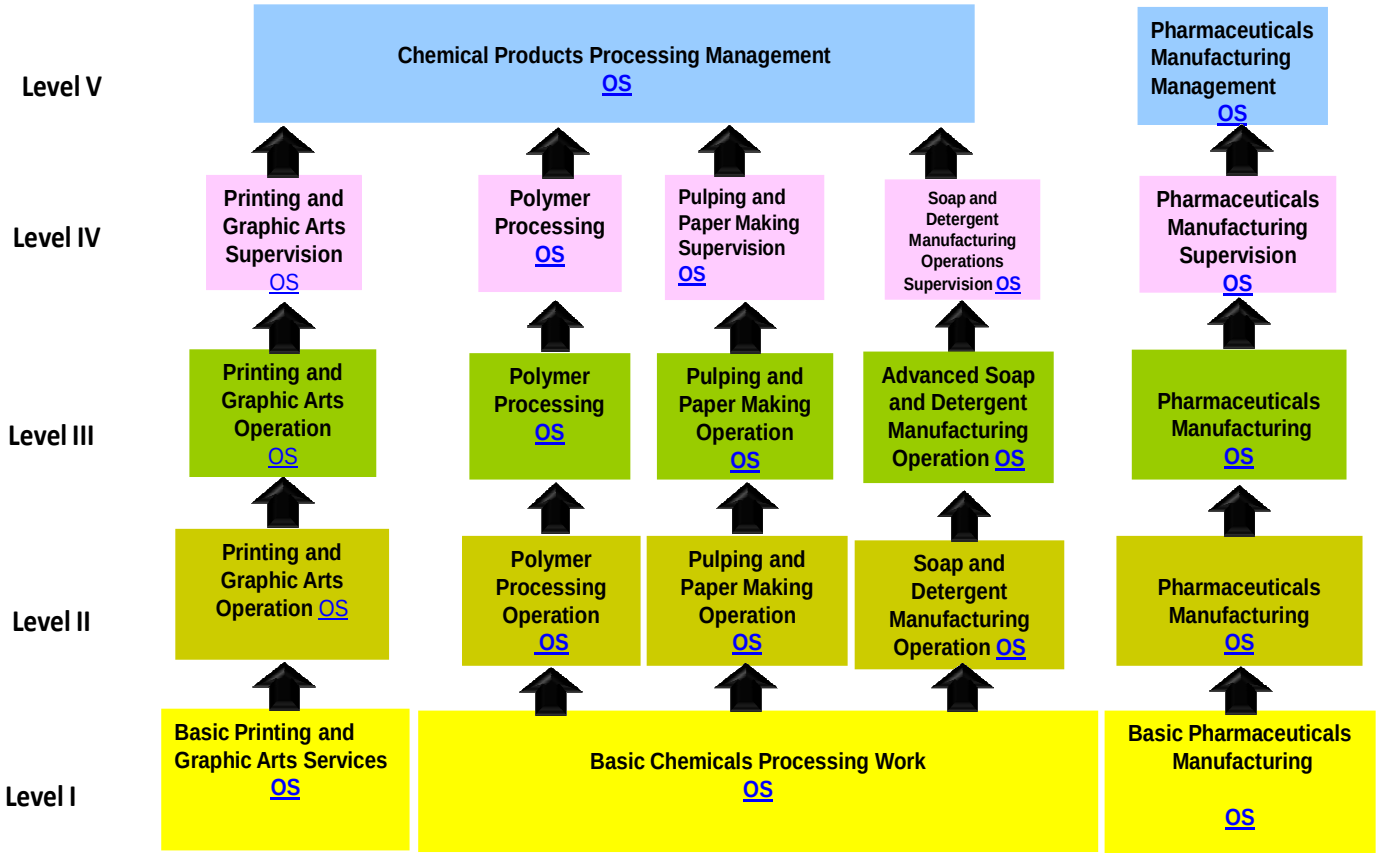
	• Focal points to Check and find out existing problems • 5S • Layout improvement • Brainstorming • Andon • U-line • In-lining • Unification • Multi-process handling & Multi-skilled operators • A.B. control (Two point control) • Cell production line • TPM (Total Productive Maintenance)
Relevant procedures	May include but not limited to: • Make waste visible • Be conscious of the waste • Be accountable for the waste. • Measure the waste.
The ten basic principles for improvement	May include but not limited to: • Throw out all of your fixed ideas about how to do things. • Think of how the new method will work- not how it won. • Don't accept excuses. Totally deny the status quo. • Don't seek perfection. A 5o percent implementation rate is fine as long as it's done on the spot. • Correct mistakes the moment they are found. • Don't spend a lot of money on improvements. • Problems give you a chance to use your brain. • Ask "why?" at least five times until you find the ultimate cause. • Ten people's ideas are better than one person's. • Improvement knows no limits.
Visual and auditory control methods	May include but not limited to: • Red Tagging • Sign boards • Outlining • Andons • Kanban, etc.
5W and 1H	May include but not limited to: • Who • What • Where • When • Why and How

Evidence Guide	
Critical Aspects of Competence	Demonstrates skills and knowledge to: • discuss why wastes occur in the workplace

	• discuss causes and effects of wastes/MUDA in the workplace • analyze the current situation of the workplace by using appropriate tools and techniques • identify, measure, eliminate and prevent occurrence of wastes by using appropriate tools and techniques • use 5W and 1H sheet to prevent
Underpinning Knowledge and Attitudes	Demonstrates knowledge of: • Targets of customers and manufacturer/service provider • Traditional and kaizen thinking of price setting • Kaizen thinking in relation to targets of manufacturer/service provider and customer • value • The three categories of operations • the 3“MU” • waste/MUDA • wastes occur in the workplace • The 7 types of MUDA • The Benefits of identifying and eliminating waste • Causes and effects of 7 MUDA • Procedures to identify MUDA • Necessary attitude and the ten basic principles for improvement • Procedures to eliminate MUDA • Prevention of wastes • Methods of waste prevention • Definition and purpose of standardization • Standards required for machines, operations, defining normal and abnormal conditions, clerical procedures and procurement • Methods of visual and auditory control • TPM concept and its pillars. • Relevant Occupational Health and Safety (OHS) and environment requirements • Plan and report • Method of communication
Underpinning Skills	Demonstrates skills to: • draw & analyze current situation of the work place • use measurement apparatus (stop watch, tape, etc.) • calculate volume and area • use and follow checklists to identify, measure and eliminate wastes/MUDA • identify and measure wastes/MUDA in accordance with OHS and procedures • use tools and techniques to eliminate wastes/MUDA in accordance with OHS procedure • apply 5W and 1H sheet

	• update and use standard procedures for completion of required operation • work with others • read and interpret documents • observe situations • solve problems • communicate • gather evidence by using different means • report activities and results using report formats
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competence may be assessed through: • Interview / Written Test • Observation / Demonstration with Oral Questioning
Context of Assessment	Competence may be assessed in the work place or in a simulated work place setting.

Sector: Industry
Chemical Products Processing



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This occupational standard was developed on May 2013 at Ethiopian Management Institute (EMI), Debre Zeyit.

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