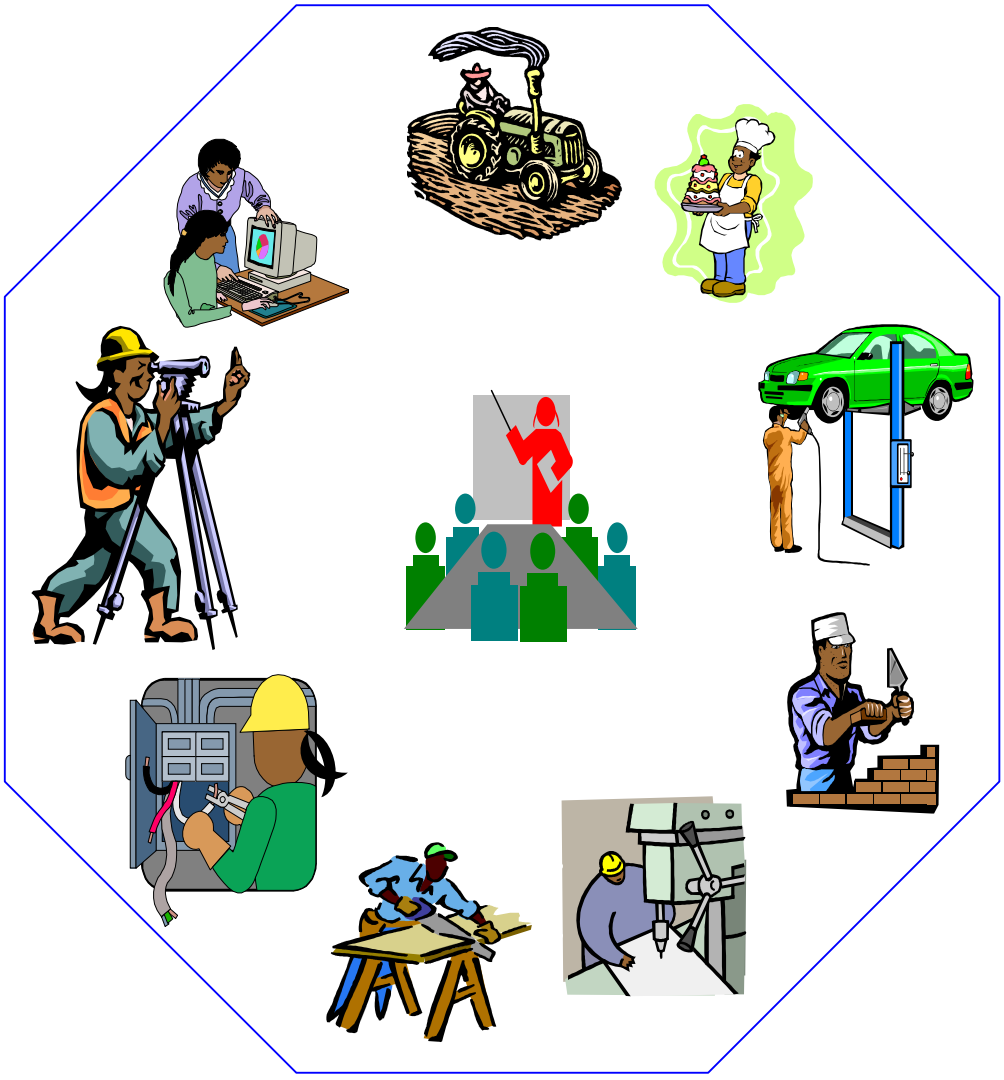
Federal Democratic Republic of Ethiopia

OCCUPATIONAL STANDARD
PHARMACEUTICALS

MANUFACTURING SUPERVISION

NTOF Level IV



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 labor 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: Pharmaceutical Manufacturing Supervision		
Occupational Code: IND PHR		
NTQF Level IV		
IND PHR4 01 0613 Facilitate and Monitor Good Manufacturing Practice	IND PHR4 02 0613 Implement and Monitor Environmentally Sustainable Work	IND PHR4 03 0613 Facilitate Contamination Control
IND PHR4 04 0613 Respond to non-conformance	IND PHR4 05 0613 Participate in Validation Processes	IND PHR4 06 0613 Lead a Manufacturing Team Using a Balanced Score card approach
IND PHR4 07 0613 Mistake Proof a Production Process	IND PHR4 08 0613 Participate in Product Recalls	IND PHR4 09 0613 Describe and Analyze Data Using Mathematical Principles
IND PHR4 10 0613 Apply Statistics to Processes in Manufacturing	IND PHR4 11 0613 Monitor and Control Work Permits	IND PHR4 12 0613 Diagnose Production Equipment Problems
IND PHR4 13 0613 Undertake Proactive Maintenance Analyses	IND PHR4 14 0613 Plan and Coordinate Maintenance	IND PHR4 15 0613 Participate in an Audit Process
IND PHR4 16 613 Report on workplace performance	IND PHR4 17 0613 Facilitate SCADA Systems in a Manufacturing Team or Work Area	IND PHR4 18 0613 Plan and Organize Work Activities
IND PHR4 19 0613 Migrate to New Technology	IND PHR4 20 0613 Establish Quality Standards	IND PHR4 21 0613 Develop Team and Individuals
IND PHR4 22 0613 Utilize Specialized Communication Skills	IND PHR4 23 0613 Manage and Maintain Small/Medium Business Operations	IND PHR4 24 613 Apply Problem Solving Techniques and Tools

Occupational Standard: Pharmaceuticals Manufacturing Supervision Level IV	
Unit Title	**Facilitate and Monitor Good Manufacturing Practice**
Unit Code	**IND PHR4 01 0613**
Unit Descriptor	It covers the skills and knowledge required to facilitate and monitor Good Manufacturing Practice (GMP) in a production/packaging work area. This unit applies to people working in supervisory or line management production/packaging roles. This person would typically work within defined GMP programs and procedures. They contribute to the development of these programs as a team member and are responsible to oversee implementation in their work area.

Elements	Performance Criteria
1. Prepare to meet GMP requirements in the work area	1.1 ***Regulations, codes and guides*** relevant to the work area are identified. 1.2 ***Workplace documentation*** relevant to work area activities is identified and reviewed to confirm that GMP requirements are met. 1.3 The required facilities, materials, storage, equipment and personnel are confirmed and available. 1.4 Operators who have the required competence to perform production/packaging activities to company and GMP standards are identified. 1.5 Line clearance procedures are carried out. 1.6 Critical processes are validated according to validation requirements. 1.7 Procedures to eliminate or control the risk of cross-contamination are followed.
2. Monitor the observance of GMP in the work area	2.1 ***Work practices*** conform to GMP parameters and standards. 2.2 In-process and environmental monitoring is carried out and recorded as required by GMP. 2.3 Personal hygiene and conduct of personnel in the work area meets GMP requirements. 2.4 Personnel movement between work areas complies with entry and exit procedures. 2.5 GMP-related data is recorded to meet workplace reporting requirements.
3. Respond to failures or non-conformances	3.1 The scope of failures or non-conformances is defined as the standard parameters.

	3.2 Procedures to follow in the event of a failure are documented. 3.3 Failures are investigated to determine root causes. 3.4 Risk assessment is conducted. 3.5 Findings are reported to meet GMP requirements. 3.6 Procedures are followed to implement and monitor corrective and preventative action.
4. Complete work to meet GMP requirements	4.1 Processes are reviewed to ensure all procedures are complete. 4.2 Line logs are reviewed to ensure documentation is complete. 4.3 End-of-batch procedures are followed and completed.

Variable	**Range**
Regulations, codes and guides	May include: • Therapeutic Goods Act • Therapeutic Goods Regulations • Code of Good Manufacturing Practice for Medicinal Products • Therapeutic Goods Act guides to interpretation of legal requirements • regulations, codes and guides related to other relevant international legislation (appropriate to product and market) • company policies and guidelines
Workplace documentation	May include: • company policies and guidelines • specifications • manufacturing formulae • processing and packaging instructions • batch production and packaging records • Standard Operating Procedures (SOPs) • Occupational Health and Safety (OHS) information, including Material Safety Data Sheets (MSDS)
Work practices carried out	May include: • company policies and procedures • legislative and licensing requirements, including therapeutic goods legislation, weights and measures and legislation relating to OHS, environmental management, equal opportunity and affirmative action, industrial awards and agreements
Sources of technical advice	May include but are not limited to: • Therapeutic Goods Administration • British Pharmacopeia

	• European Pharmacopeia • US Pharmacopeia
Systems, programs and procedures to support GMP	May includes but is not limited to: • line clearance • cleaning and sanitation • process control • control of cross-contamination • failure investigation • change control • validation • record keeping and documentation management • release for sale and internal audits

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • provide documented evidence through use of workplace documentation and records to show that the work preparation, processing and completion meet GMP requirements • lead response to a failure or non-conformance in the work area. This must include conducting risk assessment, analysing root cause analysis, identifying corrective and preventive action and monitoring implementation. This aspect of assessment may be undertaken as part of a team.
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • legislative framework and structure, including the role of regulations, codes and guides • corporate and personal responsibility and liability for maintaining GMP in the workplace • the Pharmaceutical Inspection Co-operation Scheme (PICS) and related cross-recognition agreements • the content covered by the Therapeutic Goods Act, relevant codes and guides • sources of technical advice on test methods and critical limits • regulatory mechanisms including audit processes • the principles of quality management, quality assurance and quality control and the role of these activities in supporting GMP • principles of risk management and related procedures • system for raising and managing corrective and preventative actions • specific requirements to be met by manufacturing and/or packaging activities in the work area to meet GMP requirements

	• calibration programs and responsibilities • procedures for reconciling materials and consumables and investigating discrepancies • training system, including assessment methods and documentation • purpose, procedure and responsibility for specific systems, programs and procedures to support GMP • root cause analysis techniques • workplace documentation and authorization procedures
Underpinning Skills	Must demonstrate skills to: • locate regulations, codes, guides and internal company documentation relevant to GMP and products/processes used in the work area • use communication and document management systems to access and review relevant documents • ensure that operators have the • use communication skills to interpret and complete work information to support operations of work team or area • demonstrate and support cooperative work practices 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 Supervision Level IV	
Unit Title	**Implement and Monitor Environmentally Sustainable Work Practices**
Unit Code	**IND PHR4 02 0613**
Unit Descriptor	This competency covers the outcomes required to effectively analyze the workplace in relation to environmentally sustainable work practices and to implement improvements and monitor their effectiveness.

Elements	Performance Criteria
1. Investigate current practices in relation to resource usage	1.1 Environmental regulations applying to the enterprise are identified. 1.2 Procedures for assessing ***compliance*** with environmental regulations are assessed. 1.3 Information on ***environmental and resource efficiency systems*** and ***procedures*** are collected, and provided to the work group where appropriate. 1.4 Current resource usages by members of the work group are measured and recorded. 1.5 Current ***purchasing strategies*** are analyzed and recorded. 1.6 Current work processes is analyzed to access information and data and assist in identifying areas for improvement.
2. Set targets for improvements	2.1 Input from stakeholders, key personnel and specialists are sought. 2.2 External sources of information and data as required are accessed. 2.3 Alternative solutions are evaluated to workplace environmental issues. 2.4 Efficiency targets are set.
3. Implement performance improvement strategies	3.1 ***Techniques***/***tools*** are sourced to assist in achieving targets. 3.2 Continuous improvement strategies are applied to own work area of responsibility and communicate ideas and possible solutions to the work group and management. 3.3 Environmental and resource efficiency improvement plans are integrated for own work group with other operational activities and implement them. 3.4 Seek ***suggestions*** and ideas about environmental and resource efficiency management from stakeholders and act upon them where appropriate.

	3.5 Implement costing strategies to fully value environmental assets.
4. Monitor performance	4.1 Document outcomes and communicate reports on targets to ***key personnel and stakeholders.***
	4.2 Evaluate strategies.
	4.3 Set new targets and investigate and apply new tools and strategies.
	4.4 Promote successful strategies and reward participants where possible.

Variable	**Range**
Compliance	Includes meeting relevant federal, state and local government laws, by-laws, regulations and codes of practice.
Environmental and resource efficiency issues	May include: • addressing environmental and resource sustainability initiatives such as Environmental Management Systems, action plans, surveys and audits • reference to standards, guidelines and approaches such as: ➢ ISO 14001 Environmental Management Systems ➢ Life Cycle Analyses ➢ Cradle to cradle ➢ Global Reporting Initiative ➢ Ecological foot printing ➢ Triple Bottom Line reporting and Product Stewardship • determining enterprise's most appropriate waste treatment including waste to landfill, recycling, re-use and wastewater treatment • applying the waste management hierarchy in the workplace • initiating and/or maintaining appropriate enterprise procedures for operational energy consumption, including stationary energy and non stationary (transport) • efficient use of water • minimizing greenhouse gas emissions • use of controls to minimize the risk of environmental damage from hazardous substances
Procedures	May include: • 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. • Where reference is made to industry codes of practice, and/or international standards, the latest version must be used.

Purchasing strategies	May include: • influencing suppliers to take up environmental sustainability • selecting materials/components with a lower environmental profile.
Measuring techniques	May include: • material fed to/consumed by plant/equipment • plant meters and gauges • job cards including kanbans • examination of invoices from suppliers • measurements made under different conditions • examination of relevant information and data • others as appropriate to the specific industry contexts.
Techniques and tools	May include: • visual workplace concepts • measurement, display and/or recording devices • changed work practices/procedures • competence development and awareness training • process and equipment items
Incidents	May include: • breaches or potential breaches of regulations • occurrences outside of standard procedure which may lead to lower environmental performance
Stakeholders**,** key personnel and specialists	Include individuals and groups both inside and outside the organization that have some direct interest in the enterprise's conduct, actions, products and services, including: • employees at all levels of the organization • customers • suppliers • other organizations • key personnel within the organization, and specialists outside it who may have particular technical expertise
Suggestions may include:	• prevent and minimize environmental risks and maximize opportunities • reduce emissions of greenhouse gases • reduce use of non-renewable resources • make more efficient use of energy, water and other resources • maximize opportunities to re use and recycle materials • identify strategies to offset or mitigate environmental impacts. e.g. purchasing of carbon credits • express purchasing power through the selection of suppliers with improved environmental performance. e.g. purchasing renewable energy and materials with lower embedded carbon • eliminate the use of hazardous and toxic materials increasing the reusability/recyclability of wastes/products.

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • monitor and investigate current resource usage • develop plans to improve sustainability • implement environmental improvements. • Consistent performance should be demonstrated. For example, look to see that: ➢ environmental performance is routinely monitored and investigated ➢ areas for improvements are followed through and the implemented changes are in turn monitored and investigated.
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • how to access and use relevant environmental and resource efficiency systems, tools and procedures • understanding of best practice approaches relevant to own area of responsibility • strategies to maximize opportunities and minimize impacts relevant to own work area • relevant environmental and resource efficiency issues specific to industry practices • methods for measuring and calculating resource usage
Underpinning Skills	Must demonstrate skills of: • using relevant environmental and resource efficiency systems, tools and procedures • applying quality assurance systems relevant to own work area • applying relevant supply chain procedures • measurement and calculation techniques • communication/consultation skills to ensure information is supplied to the work group • Reading and writing is required to comprehend documentation and interpret environmental and energy efficiency requirements and to document and maintain records • Numeracy is required to interpret numeric workplace information, readings and measurements, handle data as required and complete numeric components of workplace forms/reports.
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 Supervision Level IV	
Unit Title	**Facilitate Contamination Control**
Unit Code	**IND PHR4 03 0613**
Unit Descriptor	It covers the skills and knowledge required to facilitate contamination control in a work area. This unit provides an overview of the cleaning and sanitation systems, equipment and procedures used in a pharmaceutical workplace. This unit applies to people working in supervisory or line management production/packaging roles. This person would typically work within defined cleaning, sanitation, change control and validation programs and procedures. They need to be aware of the systems; equipment and procedures used and are responsible to oversee implementation in their work area.

Elements	Performance Criteria
1.Contamination risks and related control measures are identified and implemented to meet GMP requirements	1.1 Hazards that could present a contamination risk are identified by type, origin and product association. 1.2 Hazards and related control measures, critical limits, monitoring and recording requirements are reviewed and meet GMP requirements. 1.3 Control measures are verified or validated.
2.Review systems and procedures used to control risk of cross contamination	2.1 Effective ***barriers and control systems*** to minimize risk of cross contamination are identified and meet GMP requirements. 2.2 In-process and environmental monitoring occurs and is recorded as required by GMP. 2.3 Cleaning procedures are validated according to validation procedures, roles and responsibilities. 2.4 Line clearance checklists and procedures are followed in the work area. 2.5 Personal hygiene and conduct of personnel in the work area meets GMP requirements. 2.6 Operators have the required skills and knowledge required to support cleaning and sanitation and personal hygiene policies and procedures.

Variable	Range
Barriers and control systems	May include but are not limited to: • ventilation systems • appropriate clothing

	• area access restrictions and procedures • cleaning and sanitation procedures • environmental monitoring • line clearance checklists • personal hygiene and conduct • pest prevention • Code of Good Manufacturing Practice for Medicinal Products
Codes, guidelines and technical standards	May include but are not limited to: • Code of Good Manufacturing Practice for Medicinal Products,
Basic microbiology	Covers the ability to source information on: • likely microbiological contaminants given product/packaging used • origins • growth rates • transmission routes • likely carriers • control limits • control methods
Sources of technical advice	May include but are not limited to: • Therapeutic Goods Administration • British Pharmacopeia • European Pharmacopeia and US Pharmacopeia
Storage requirements	May include but are not limited to: • storage requirements of raw materials prior to use in manufacture • time limits and storage conditions for finished product prior to packaging • other requirements relevant to product range

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • identify legal, company and audit requirements of contamination control systems and conduct a system review to support audit readiness • Demonstrate methods used to monitor consistent observance of contamination control
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • principles of workflow design to minimize risk of contamination • facility and segregation requirements relevant to products produced • Basic microbiology microbiological limits, monitoring methods and reporting and recording formats and requirements

	• Sources of technical advice: ➢ ventilation system requirements ➢ personal hygiene and clothing requirements including decontamination and laundering ➢ cleaning records and logs ➢ line clearance procedures, roles and responsibilities ➢ equipment status labeling ➢ cleaning requirements and levels related to dedicated production, campaign processing and multiple product processing • Storage requirements: ➢ storage requirements of raw materials prior to use in manufacture, time limits and conditions of storage of finished product prior to packaging, and other requirements relevant to product range
Underpinning Skills	Must demonstrate skills to: • interpret and apply relevant legislation, codes, guidelines and technical standards • use management systems to ensure that procedures are understood and implemented • monitor that data is recorded to meet GMP recording requirements • read and interpret equipment drawings, piping and instrumentation diagrams (P&IDs) and process flow charting • read and interpret typical test results for in-process and environmental monitoring • use communication and document management systems to access and review relevant documents • use communication skills to interpret and complete work information to support operations of work team or area • demonstrate and support cooperative work practices 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 Supervision Level IV	
Unit Title	**Respond to Non-Conformance**
Unit Code	**IND PHR4 04 0613**
Unit Descriptor	This unit of competency covers the skills and knowledge required to respond to non-conformance within level of authority and consistent with legal requirements within the pharmaceutical sector. Typical applications of this unit would include responding to deviation and incident reporting results and may include participation in responding to customer complaints, product recalls and audit findings. Responding to non-conformance is typically within the parameters of established policies, plans and procedures.

Elements	Performance Criteria
1. Identify non-conformance	1.1 Workplace systems, reports and operating parameters are monitored to identify ***non-conformance***. 1.2 Nature of non-conformance is identified and described. 1.3 Corrective and preventative action and reporting procedures appropriate to nature of non-conformance are followed.
2. Identify causes of non-conformance	2.1 Workplace systems are used to investigate possible causes of non-conformance. 2.2 Risk assessment is conducted as standard procedures.
3. Review processes to minimise the risk of recurrence	3.1 Solutions are identified and assessed to eliminate or minimize the risk of recurrence. 3.2 An ***implementation plan*** is developed and reviewed/ evaluated according to procedures. 3.3 Workplace documentation is developed or reviewed to support implementation. 3.4 Consultative mechanisms are established and/or reviewed to support continuous improvement and communicate information.

Variable	Range
Non-conformance	May be assessed against policies, procedures, specifications and audit requirements
Implementation plan	May include but are not limited to: • allocation of responsibilities and roles • establishing and negotiating timelines and resources • documentation review • appropriate authorisation • identification of training/skill development requirements

Legal requirements	• are those prescribed in the Therapeutic Goods Act and other relevant legislation, regulations and codes (relating to product and markets)
Systems and responsibilities for identifying, investigating and responding to non-conformance	May include but are not limited to: • corrective and preventative action • customer complaints • product recall • audits (internal and external)

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • identify deviation • identify and determine the nature of non- conformance • implement required corrective action and reporting • investigate the causes of a non-conformance • identify changes to company systems and procedures required to minimize the risk of recurrence • follow procedures to participate in proposing changes • develop and implement required preventative action
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • legal requirements relating to management of non-conformance • systems and responsibilities for identifying, investigating and responding to non-conformance • consultation and communication methods required to investigate possible causes and communicate changed practices and procedures • change management procedures and responsibilities, including the role of corrective and preventative actions • procedures for reviewing, amending and validation • information systems, technologies and software to access and analyze information • problem solving methods
Underpinning Skills	Must demonstrate skills to: • identify systems under which non-conformance may be raised, including the provisions of the Therapeutic Goods Act as it relates to systems (e.g. customer complaints, product recalls and auditing) • identify relevant company policies and procedures relating to responding to non-conformance and confirm level of authority and responsibility for participating in these procedures • identify the components of the management system, including information recording systems (such as those to support traceability), identification of personnel responsible

	for assessing information and determining appropriate action, procedures to be followed in the event of a non-conformance, change management requirements and definitions of roles and levels of responsibility • participate in the investigation of causes and review of arrangements and procedures in response to a non-conformance, such as reviewing responses to previous incidents to assess effectiveness and/or developing recommendations on appropriate procedures • identify and/or develop the appropriate communication systems and channels for consulting with people affected by any proposed changes • use communication skills to interpret and complete work information to support operations of work team or area • demonstrate and support cooperative work practices 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 Supervision Level IV	
Unit Title	**Participate in Validation Processes**
Unit Code	**IND PHR4 05 0613**
Unit Descriptor	This unit provides an overview of validation processes used to support Good Manufacturing Practice (GMP) in the pharmaceutical sector. The unit covers the skills and knowledge required by production/packaging line managers or supervisors to participate in validation processes. This person would not typically have responsibility for validation but would require an understanding of the purpose, procedures and responsibilities for different types of validation. This unit applies to people working in a supervisory or line management role. Their involvement in validation would typically be as part of a multi-disciplinary team.

Elements	Performance Criteria
1. Participate in qualification processes for new or modified facilities, systems or equipment	1.1 Responsibilities and procedures for developing and implementing ***design qualification***, ***installation qualification***, ***operational qualification*** and ***performance qualification*** are identified. 1.2 Qualification processes and documentation are developed or reviewed within level of responsibility. 1.3 Workplace procedures are documented to support operational requirements.
2. Participate in validation processes for new or modified facilities, systems or equipment	2.1 ***Validation requirements*** in the work area are identified. 2.2 The ***validation protocol*** is followed to support validation activities in the work area. 2.3 Data is collected, analyzed and reported to meet GMP requirements.

Variable	Range
Design qualification	Design requirements of facilities and equipment must meet those outlined in Ethiopian Code of Good Manufacturing Practice for Medicinal Products
Installation qualification may include but are not limited to:	• checking of equipment, piping, instrumentation and services installation checked against current engineering drawings and specifications • piping and instrumentation diagrams (P&IDs), operating manuals and other supplier information relating to operation and maintenance

	• calibration requirements • cleaning and sanitation inspection requirements • safety issues • environmental issues
Operational qualification	May include but are not limited to: • tests of processes, systems and equipment to confirm that functioning meets agreed criteria within operating conditions • calibration plans • preventative maintenance plans • operating, cleaning and sanitation operating procedures • training programs and schedules • recording requirements
Performance qualification	May include but are not limited to: • tests, using production materials, qualified substitutes or simulated product, that have been developed from knowledge of the process, facilities, systems or equipment • tests to include a condition or set of conditions encompassing upper and lower operating limits
Validation requirements	May include but are not limited to: • process validation • packaging validation • cleaning validation • calibration validation • test method validation • validation of computerised systems • re-validation of in-use processes
Validation protocol	May include but are not limited to: • a short description of the process • summary of the critical step/s being investigated • list of equipment/facilities to be used (including measuring/monitoring equipment) together with its calibration status • finished product specifications for release • list of analytical methods, as appropriate • proposed in-process controls with acceptance criteria • additional testing to be carried out, with acceptance criteria and analytical validation, as appropriate • sampling plan • methods for recording and evaluating results • roles and responsibilities • proposed timetable
Validation documentation	May include but are not limited to: • validation master plan • protocols

	• reports • operating procedures and work instructions • Occupational Health and Safety (OHS) and environmental requirements • manufacturers' specifications

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • review the qualification and validation protocols to assess implications for a work area and related departments/functions • participate in qualification procedures - design qualification, installation qualification, operational qualification, and/or performance qualification
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • principles and purpose of qualification and related procedures and responsibilities • principles and purpose of validation and related procedures and responsibilities • purpose and application of prospective, concurrent and retrospective validation • data collection, analysis and reporting requirements • scope, application and timing of validation including any relevant circumstances that could trigger the need to validate or re-validate or justify not carrying out a validation process prior to production starting • relationship between validation and change control • equipment design drawings and process flow charting • relevant investigation methods including process capability and root cause analysis • recording and reporting requirements • training and assessment arrangements and responsibilities • workplace documentation and authorization procedures
Underpinning Skills	Must demonstrate skills to: • apply principles of risk management to identify critical facilities, systems and equipment • identify and interpret validation documentation relating to qualification and validation requirements for a work area • participate in qualification and validation procedures within level of responsibility • identify and manage the impact of qualification and validation procedures on related processes or work areas/personnel within level of responsibility • liaise with other relevant departments/functions to coordinate and schedule validation processes

	• develop documentation to support qualification and validation according to required formats and within level of responsibility • ensure that operators in the work area have the • prepare workplace documentation in plain English and suited to purpose and audience • use communication skills to interpret and complete work information to support operations of work team or area • demonstrate and support cooperative work practices 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 Supervision Level IV	
Unit Title	**Lead a Manufacturing Team Using a Balanced Score Card Approach**
Unit Code	**IND PHR4 06 0613**
Unit Descriptor	This unit covers the knowledge and skills required to lead a team in a manufacturing organization where a balanced score card approach is used. This unit applies to an environment where a team is operating in a manufacturing enterprise and the competitive manufacturing strategy of the enterprise is the balanced scorecard. The team leader is required to use balanced score card information to lead, assist and motivate team members and suggest improvements to both team effectiveness and the balanced score card strategy. This unit requires the application of skills associated with communication, teamwork, problem solving, initiative, enterprise, planning and organizing in order to provide leadership in the interpretation, review and strategic response to balanced score card results. This unit has a strong emphasis on identifying and planning required performance measures and requires an ability to use new information to improve performance.

Elements	Performance Criteria
1. Interpret balanced score card results.	1.1 Pattern(s) of performance shown on strategy map is identified. 1.2 Actions indicated by ***score card*** results are identified. 1.3 Results with team members and other relevant stakeholders are discussed. 1.4 Required actions with team members are developed. 1.5 Implementation plans with team members are developed. 1.6 The implementation of required actions from developed plans is facilitated. 1.7 Up on implementation is followed up to ensure it occurs as planned.
2. Review key performance indicators (KPIs) in the balanced scorecard for the enterprise and the team	2.1 Team key performance indicators are related to strategy map/strategic objective. 2.2 The ***actions*** required by team members are reviewed to meet each key performance indicator. 2.3 Current team actions are compared to the optimal actions to achieve strategy. 2.4 Team modifications are discussed with to key performance indicators which will better meet strategy.

	2.5 Amendments are recommended to key performance indicators to relevant personnel.
3. Review reporting systems for balanced scorecard information	3.1 Reports are reviewed to ensure information needed by team and enterprise is available 3.2 The mix of operational and strategic information are reviewed to ensure it is appropriate to the needs of the team 3.3 Information provided for relevance and currency, and that it is meaningful and not excessive are reviewed. 3.4 Improvements are recommended to reports and reporting system as appropriate
4. Lead improvement to team total performance	4.1 Actual total team performances with desired total performance using key performance indicators and other balanced scorecard information are compared. 4.2 Team ways of improving total team performance are discussed with. 4.3 Processes for improvement in team total performance are led.

Variable	**Range**
Balanced scorecard	May include: • an approach to competitive manufacturing that sets out an enterprise's vision and strategy by establishing and measuring enterprise activity in a number of different perspectives in addition to the normal financial perspective. Other perspective areas are customer, environmental, internal business process and learning and growth. For each perspective area the balanced scorecard emphasises establishing and measuring performance (metrics).
Actions indicated	May include: • corrective action for poor results • confirming action for acceptable results • taking steps to ensure actions for good results are consistently maintained • changes to performance indicators or performance measurement

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • interpret Balanced Scorecard results • review KPIs in the Balanced Scorecard • review related reporting systems • lead improvement to team performance.

Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • components of the Balanced Scorecard, including perspectives, feedback loops, targets and metrics, and reporting systems • responsibilities of self and others in a Balanced Scorecard strategy • health, safety and environment (HSE) principles and requirements for area of responsibility • change implementation contacts and procedures relevant to work area • employee assistance mechanisms in the organisation
Underpinning Skills	Must demonstrate skills of: • identifying KPIs and their application to own work and the work of other employees • analyzing Balanced Scorecard results and determining implications for a work area • solving problems associated with use or interpretation of Balanced Scorecard • planning strategies for use of Balanced Scorecard, including: ➢ required communication with others ➢ negotiations if any required with internal and external suppliers, customers and delegates ➢ analysis of any skill gaps in self and others ➢ required training ➢ data collection ➢ work organization and procedure changes ➢ risk identification and contingency measures • communicating effectively in informal and formal meetings, and with personnel at all levels • providing effective feedback
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 Supervision Level IV	
Unit Title	**Mistake Proof a Production Process**
Unit Code	**IND PHR4 07 0613**
Unit Descriptor	This unit of competency covers the skills and knowledge required to make changes to own and others work in a work area which prevents errors and/or backsliding to a pre-improvement level of practice.

Elements	Performance Criteria
1. Analyze process	1.1 Sources of variability/non-conformance in the process are identified. 1.2 Critical control points in process are identified. 1.3 Causes of variability/non-conformance are analyzed.
2. Develop preventative techniques/ systems	2.1 Team members and other people are liaised with to develop mistake proof options for performing operation 2.2 ***Mistake proofing*** options is tested and validated.
3. Implement permanent fix	3.1 Relevant people are liaised with to have ***systems/***procedures changed to implement solution. 3.2 Relevant people are liaised with to implement the solution. 3.3 Relevant people are liaised with to ensure self and others in the team or work area have an appropriate skills set. 3.4 Ensure implementation occurs are followed through.
4. Monitor implementation	4.1 The implementation is critically observed. 4.2 The results of the implementation against the expected outcomes are compared. 4.3 Solution is modified to improve outcomes. 4.4 ***Procedures*** reflect change is ensured. 4.5 Training/assessment reflects change is ensured. 4.6 Change at agreed period/cycle is audited. 4.7 Any observed deviation is taken action.
5. Seek improvements	5.1 Changes are observed. 5.2 Process again, if required is analyzed, to ensure improvements are sustained.

Variable	Range
Mistake proofing	Is based on the concept of zero defects. The first priority is to eliminate the possibility of an error occurring. However, where this is not feasible mistake proofing can be used to reduce the occurrence of errors and/or to minimize their impact. • Mistake proofing should target an error in the following priority order: • eliminate the possibility of the error via changes to the process • prevent the error from occurring via physical or virtual barriers, • reduce likelihood of the error by encouraging correct action (e.g. through warning systems) • mitigate the impact of the error if it does occur • mistake proofing is also called error proofing or baka-yoke or poka-yoke
Options for mistake proofing	Factors to consider when prioritizing options for mistake proofing will vary according to the process and may include: • success rate in eliminating errors • feasibility • skills required by employees • cost • capacity to reduce waste
Competitive systems and practices	May include, but are not limited to: • lean operations • agile operations • preventative and predictive maintenance approaches • monitoring and data gathering systems, such as Systems Control and Data Acquisition (SCADA) software, Enterprise Resource Planning (ERP) systems, Materials Resource Planning (MRP) and proprietary systems • statistical process control systems, including six sigma and three sigma • Just in Time (JIT), kanban and other pull-related operations control systems • supply, value, and demand chain monitoring and analysis • 5S • continuous improvement (kaizen) • breakthrough improvement (kaizen blitz) • cause/effect diagrams • Overall Equipment Effectiveness (OEE) • takt time • process mapping • problem solving • run charts

	• standard procedures • current reality tree Competitive systems and practices should be interpreted so as to take into account: • the stage of implementation of competitive systems and practices • the size of the enterprise • the work organization, culture, regulatory environment and the industry sector
Procedures	May include: • all work instructions • standard operating procedures • formulas/recipes • batch sheet • temporary instructions and similar instructions provided for the operation of the plant • good operating practice as may be defined by industry codes of practice (e.g. good manufacturing practice (GMP) and responsible care) • government regulations may be: • written, verbal, computer-based or in some other format

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • analyze variability and non-conformances • identify, analyze and evaluate information from a variety of sources to identify errors and options for mistake proofing • facilitate implementation of mistake proofing activities that reduce waste • facilitate sustaining the mistake proofing activities.
Underpinning Knowledge and Attitudes	Must demonstrate knowledge in: • mistake proofing concepts, including, in priority order • eliminate the possibility of the error via changes to the process • prevent the error from occurring via physical or virtual barriers • reduce likelihood of the error by encouraging correct action • mitigate the impact of the error if it does occur • understanding of processes undertaken by team • factors in the processes which may cause variability • methods of controlling the variability in the process • mistake proofing methods relevant to the process/product

Underpinning Skills	Must demonstrate skills of: • communicating with team or work group members, technical support personnel and other relevant staff • explaining mistake proofing and related concepts • facilitating input of others and encouraging acceptance of changes • analyzing and visualizing operations in terms of flow and contribution to customer outcomes • solving problems to determine root cause of errors and possible solutions • analyzing and interpreting information about errors and mistake proofing options in terms of cost, feasibility, regulations and value to the customer • suggesting design changes to operations and products that eliminate the potential for errors • suggesting mechanisms or procedures that warn of errors where operations cannot be designed to eliminate errors,
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 Supervision Level IV	
Unit Title	**Participate in Product Recalls**
Unit Code	**IND PHR4 08 0613**
Unit Descriptor	This unit of competency covers the skills and knowledge required to identify circumstances that could warrant a product recall and to initiate and/or participate in recall processes within level of authority. This unit can apply where a person has primary responsibility for initiating a product recall or where they are required to participate in the recall decision and related process as part of a team. Product recalls occur in the context of an established recall procedure.

Elements	Performance Criteria
1. Identify product recall situations	1.1 Circumstances that could result in a product recall are identified according to an established recall procedure. 1.2 Appropriate controls are in place to manage risks. 1.3 Criteria used to initiate a product recall are identified. 1.4 Legal responsibilities and requirements of a recall program are identified.
2. Participate in a product recall	2.1 The components of the product recall system in the workplace are identified. 2.2 Workplace systems are used to trace ingredients, materials and batch information. 2.3 Product recall procedures are implemented within level of responsibility. 2.4 ***Procedures*** to define roles and levels of authority in the event of a product recall are established/reviewed.
3. Review processes to minimise the risk of recurrence	3.1 The cause of the product recalls are investigated. 3.2 Purchasing arrangements and in-house procedures are established or reviewed to minimize the risk of recurrence. 3.3 Consultative mechanisms are established and/or reviewed to support continuous improvement and communicate information on product recalls.

Variable	Range
Policies and procedures	Product recalls and related work processes are consistent with company policies and procedures, regulatory and licensing requirements, legislative requirements, and industrial awards and agreements and takes account of Occupational Health and Safety (OHS) and environmental impact

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • identify criteria and circumstances for a product recall • identify controls designed to prevent product recall • identify legal implications of a product recall • identify features of the workplace product recall system and procedures • participate in the implementation of the product recall procedures • determine and examine the cause of product fault • establish mechanisms to improve operations and minimise the risk of occurrence.
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • circumstances that could result in a product recall • legal responsibilities and requirements of a recall program • components of the recall system to meet company and legal requirements • company's safety plan and vendor assurance arrangements • risks that could result in the need to initiate a product recall and the control measures in place to prevent incidents occurring • social, financial and legal consequences of failing to initiate a recall or for delaying the decision • procedures for investigating causes • communication requirements and procedures
Underpinning Skills	Must demonstrate skills to: • identify relevant workplace information, including the company's safety plan and vendor assurance arrangements • identify the risks that could result in the need to initiate a product recall and the control measures in place to prevent incidents occurring • identify legal and company requirements of the product recall system, including the provisions of safety legislation and related company system and criteria for determining when a recall is required • for a given range of circumstances that could result in the need for a product recall, outline appropriate responsive action within company policy and procedures • identify and/or develop the components of the recall system to meet company and legal requirements, including information recording systems to support traceability; identification of personnel responsible for assessing information and determining appropriate action, and procedures that define roles and levels of responsibility • identify the social, financial, environmental and legal

	consequences of failing to initiate a recall or for delaying the decision • identify and/or develop procedures for the investigation of causes and review of arrangements and procedures in the event of an incident, such as reviewing responses to previous incidents to assess effectiveness and/or developing recommendations on appropriate procedures • identify and/or develop the appropriate communication systems and channels for consulting with people affected by the recall procedure and communicating information on improvements to be implemented • use communication skills to interpret and complete work information to support operations of work team or area • demonstrate and support cooperative work practices 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 Supervision Level IV	
Unit Title	**Describe and Analyze Data Using Mathematical Principles**
Unit Code	**IND PHR4 09 0613**
Unit Descriptor	This unit of competency covers the skills and knowledge required to apply mathematical principles to interpret data relating to properties and production of products.

Elements	Performance Criteria
1. Identify common units of measurement and dimensions used to describe physical properties of materials and products	1.1 SI units of ***measurement*** and related unit symbols are identified according to standard test procedures. 1.2 Common formulae used to measure characteristics of materials are identified and applied. 1.3 Calculations involving fractions and ratios are performed.
2. Apply linear algebra to analyze workplace information	2.1 Given two known values, an unknown value is calculated. 2.2 The principles of transposing values are applied to solve workplace problems.
3. Use graphs to analyze workplace information	3.1 Data analysis and presentation requirements are identified. 3.2 ***Graphs*** are generated to analyze and display workplace information. 3.3 A process control chart is constructed.

Variable	Range
Common measurements	May include but are not limited to: • density • specific gravity • volume • weight • mass • speed • length • width • thickness • diameter • hardness • disintegration test

Graphs	May include but are not limited to: • Statistical Process Control (SPC) charts • x-y charts

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • identify SI units of measurement • identify common derived units/measurements, related formulae and their application in a processing context • apply relevant formulae to measure physical characteristics of manufacturing products and/or processes • calculate standard deviation • construct charts • identify mean value • identify upper and lower control limits.
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • SI units of measurement and related unit symbols • common formulae used to measure characteristics of • principles of transposing values to solve workplace problems • relevant formulae to measure physical characteristics of manufacturing products and/or processes • processes for developing charts and graphs • calculations to determine unknown values, percentages and ratios, standard deviation, conversion of units into compatible formats, target (mean value) for the process, upper and lower control limits
Underpinning Skills	Must demonstrate skills to: • identify the fundamental units (SI) of measurement (metres, kilograms and seconds) • identify common derived units/measurements, related formulae and their application in a pharmaceuticals processing context, such as: ➢ density, specific gravity ➢ viscosity ➢ temperature ➢ volume, weight and mass ➢ velocity ➢ other measures as appropriate to a production process • apply relevant formulae to measure physical characteristics of products and/or processes • select production calculation requirements, such as the adjustment of a recipe formulation, to: ➢ select required formulae ➢ express the problem as an equation ➢ identify the known and unknown values

	➢ manipulate equations by transposing values as required ➢ convert units into compatible formats (i.e. SI units, multiples and sub-multiples) ➢ calculate of percentages and ratios ➢ conduct the calculation to obtain a solution ➢ record the result in the appropriate units and level of detail • identify graphs commonly used in the workplace and relevance to displaying workplace information • construct charts to analyze and illustrate workplace information, such as use of relevant software • calculate standard deviation for a given data set • apply an understanding of standard deviation to determine capability of a process • identify the target (mean value) for the process • identify upper and lower control limits to provide for 98% of units to fall within the limits • use communication skills to interpret and complete work information to support operations of work team or area • demonstrate and support cooperative work practices 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 Supervision Level IV	
Unit Title	**Apply Statistics to Processes in Manufacturing**
Unit Code	**IND PHR4 10 0613**
Unit Descriptor	This unit covers the knowledge and skills required to apply statistical theory and principles to the analysis and control of processes in manufacturing. To do this the person will apply their knowledge of frequency distribution and variation to the data/chart to distinguish between random and non-random variation and their understanding of the process and/or equipment to help interpret those results. This unit primarily requires the application of skills associated with gathering and analysing data and communicating statistical information to others. This unit also has a strong emphasis on problem solving, initiative and enterprise, planning and organising, and self management to solve problems and manage processes.

Elements	Performance Criteria
1. Collect process data.	1.1 Interpret ***sampling scheme***. 1.2 Obtain measurements in accordance with ***procedures***. 1.3 ***Handle data*** according to procedures.
2. Interpret data	2.1 Plot data on appropriate ***control chart***. 2.2 Distinguish between ***random and non-random*** patterns of results. 2.3 Identify results outside the ***control limits.*** 2.4 Recognize situations requiring action. 2.5 Take appropriate action in accordance with standard procedures. 2.6 Determine ***cost of non-conformance.***
3. Calculate control limits.	3.1 Consult relevant stakeholders to determine ***appropriate limits.*** 3.2 Use relevant methods to calculate/revise control limits. 3.3 Plot limits on control chart. 3.4 Explain impact of limit to relevant stakeholders.

Variable	Range
Sampling scheme	May include: • sampling for attributes or sampling for variables • batch, continuous or custom made products • number of items/samples • size of sample • timing of sampling • location of sampling points • type of sample • number/type of measurements to be done on each sample • sampling equipment • measurement/testing equipment/methods
Procedures	• includes all work instructions, standard operating procedures, formulas/ recipes, batch sheets, temporary instructions and similar instructions provided for the smooth running of the plant. They may be written, verbal, computer based or in some other form. • For the purposes of this Training Package, ' procedures' also includes good operating practice as may be defined by industry codes of practice (eg Good Manufacturing Practice (GMP), Responsible Care and government regulations.
Handle data	May include: • calculating means, ranges, mean of means, standard deviation (using appropriate calculation aids) • entering data into a software package • recording data either in writing or electronically • other required manipulations of the data.
Control chart	May include: • run • tally • mean/range • attributes • other relevant charts
Random variation	• is the term used in statistical control to refer to those variations for which no cause can be found.
Non-random	Non-random, also called identifiable cause, or assignable cause or special cause is those variations for which a cause can be found and so the cause of the variation eliminated. Non-random variation may also be used to predict possible breaches of the control limits.
Control limits	Control limits, also referred to as process capability are those limits within which the process will operate if it is 'under control'.
Cost of non-conformance	May include: • reprocessing/rework

	• expediting • unplanned service • excess inventory • complaint hand line • downtime • returns • scrap • labour costs • material costs • infrastructure costs/overhead • utility costs
Appropriate limits	May include: • 1 sigma warning limits • 2 sigma warning limits • 3 sigma control limits • 6 sigma limits

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • collect or obtain data relevant process capability data from a variety of sources data • work with people and analyze data to determine assignable causes • plan and prepare improvement proposals • monitor implementation of improvement proposals.
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • data collection methods • data processing techniques required to establish variability and normal distribution • calculate three sigma or six sigma processes, as relevant • random and non-random results and processes for recognition of assignable causes • causes of different types of non-random results • causes of random variation • process understanding sufficient to translate the data into variations in the process and determine methods of controlling them
Underpinning Skills	Must demonstrate skills of: • using a variety of statistical methods and calculations • communicating and negotiating at all levels in the organisation and value stream and with individuals of different levels of literacy and numeracy

	• negotiating with employees, suppliers and customers, where necessary, to achieve access to, or collection of, data • planning process and data collection changes required for process improvement, including: ➢ objectives ➢ performance indicators to be monitored to indicate success of change ➢ resources required ➢ training required ➢ communication and liaison required with employees, suppliers and customers ➢ implementation period required • analyzing variations and categorizing into assignable and random cause • undertaking self-directed problem solving and decision-making on issues of abroad and/or highly specialized nature and in a wide variety of contexts • working in and leading teams for data collection and process improvement • using software computers and terminals, as required, to collect and analyze data
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 Supervision Level IV	
Unit Title	**Monitor and Control Work Permits**
Unit Code	**IND PHR4 11 0613**
Unit Descriptor	This competency covers the monitoring of the operational conditions in which a permit to work has been issued, and the required activities and functions associated with the production/process of chemical, hydrocarbons, oil, and other process manufactured products. This role may be carried out by the standby person or other appropriately qualified persons. While this competency carries with it high levels of responsibility the role is usually prescribed by the permit process and may be exercised by any competent operator.

Elements	Performance Criteria
1. Identify and monitor permit conditions	1.1 Permit requirements are identified. 1.2 Permit holder and conditions are monitored to ensure that the work being conducted conforms to the issued permit requirements. 1.3 Changes in the operating conditions or requirements of the permit are identified and communicated to permit holders to ensure they are kept aware of any ***hazards***.
2. Monitor work permit systems	2.1 Work activities are controlled to comply with the organization or site ***work permit*** system and safety ***procedures***. 2.2 The permit holder's knowledge of the issued permit and its requirements before allowing any repair or maintenance work to be undertaken on the production/process equipment are checked and verified. 2.3 Site inspections are undertaken to ensure that the work to be undertaken is in sequence and completed in a safe and coordinated manner. 2.4 Hazards are identified, and confirmed with those undertaking the permitted work that control measures, as defined in the permit are established.
3. Identify and action non-compliance	3.1 Conditions of active permits are identified. 3.2 Incidents of non-compliance according to procedures are reported and recorded. 3.3 ***Corrective action*** upon incidences of non-compliance is taken with permit conditions through the withdrawal or suspension of the issued permit.

4. Confirm compliance with permit	4.1 Checklists in accordance with standard procedures are completed. 4.2 Findings are documented and communicated to appropriate personnel.

Variable	Range
Typical hazards	May include: • heat, smoke, dust or other atmospheric hazards • sharp edges, protrusions or obstructions • limited head spaces or overhangs • equipment or product mass • slippery surfaces, spills or leaks • noise, rotational equipment or vibration.
Health, Safety and Environment (HSE)	All operations to which this unit applies 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 HSE requirements take precedence.
The types of work permits	May include: • evacuation • clearance • hot work • vehicle entry • confined space • minor repairs • working at heights and other special permits.
Procedures	All operations are performed in accordance with procedures. Procedures cover all relevant workplace procedures, work instructions, temporary instructions and relevant industry and government codes and standards. These may include: • legislation/codes • OHS legislation, codes of practice and guidance material • EPA • National standards • licence and certification requirements • internal permit control system. • process isolations complete • mechanical and electrical isolations in place • atmospheric testing complete and atmosphere safe. If it is not safe and cannot be made safe, then appropriate measures are implemented as per SOPs • relevant personnel informed of work and agree that it is safe and appropriate to proceed.

Corrective action	May include: • ceasing job • leaving the job site safe if it is safe and practical to do so • report reason for ceasing job and request new permit when safe.
Key variables to be monitored	May include: • sites under which permit activities must be applied • type of permit to be executed • types of tools and equipment to be employed • size of work team • scope and urgency of work
Problems	'Respond to routine problems' means 'apply known solutions to a limited range of predictable problems'. Typical process and product problems may include: • provision of the wrong permit • incorrect information being supplied with the permit • errors being made in the understanding of permit data • failure to correctly correspond to the requirements of the permit • failure to seek clarification when anomalies occur.
Safety equipment	May include: • eye protection (e.g. goggles) • ear protection • gloves • clothing • respirators and masks • helmets.
Tools and equipment may include:	• danger tags and lockouts • out of service tags • blinds/blanks • blind/blank list • gas testers and monitors • lights • ladders • cathodic protection bonds • barricades • signage • communications equipment • process and equipment drawings.
Indicative functions	May include: • supervision/monitoring of contractors • verification of permits, licences, tests • document control • compliance with legislation/codes.

Monitor	Means continual personnel presence to observe conditions of the workplace and work practices to ensure compliance with permit conditions. This may include: • supervision/monitoring of contractors • verification of permits, licences, tests • document control • compliance with legislation/codes.
Context	• Legislative and site specific safety procedures and/or requirements, including in hazard identification, assessment and application of control measures, must be met. • Compliance is required with: ➢ legislation/codes: ✓ OHS ✓ EPA ✓ OHS authorities and NOHSC ✓ license and certification requirements ✓ other relevant standards ✓ workplace specific permit control system.

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • provide reasons for a permit system • recognize the importance of different work permits • comply with permit conditions including the wearing of appropriate Personal Protective Equipment (PPE) • take appropriate action to resolve faults or report faults to appropriate personnel • explain and implement incident response procedures. • Consistent performance should be demonstrated. For example, look to see that: ➢ communications are timely and effective ➢ deviations from permit conditions are recognized, reported, corrected and re-authorization arranged ➢ action specified in the permit/standard procedures is carried out ➢ all safety procedures are followed.
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • blank/blind lists and P&IDs • tagging procedures • isolation procedures • incident response procedures, including evacuation • gas types, toxicity and explosivity and limits of each • oxygen levels • area knowledge including plant and processes • permit types and limitations

	• product tolerances and specifications • static electricity and cathodic protection • environmental hazards • hot work protective measures • columns • vessels • fire fighting equipment • blinds/blanks • pumps • compressors • prime movers • valves. An understanding of alarm and communication systems is required. The regulatory framework to include: • OHS • EPA • OHS authorities and NOHSC • licence and certification requirements • company policy and permit control systems. Language**,** literacy and numeracy requirements This unit requires the ability to: • read and correctly interpret complex P&IDs • speak clearly and unambiguously in English • explain, describe and verify sometimes complex needs and issues. Writing is required to the level of completing workplace forms and producing reports. Numeracy is required to the level of being able to correctly differentiate between high and low pressures and temperatures, voltages or masses.
Underpinning Skills	Must demonstrate skills in: • an awareness of hazards associated with the permit • Safe working in a confined space and relevant legislation • identification of container and goods coding and HAZCHEM markings • production workflow sequences and requirements for working in confined spaces • focus of operation of work systems and equipment • application of relevant agreements, codes of practice and other legislative requirements • hazards of the materials and process and appropriate hazard control procedures • identification and correct use of equipment, processes and procedures

	• planning own work including predicting consequences and identifying improvements; as is relevant to the practical completion of the job.
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 Supervision Level IV	
Unit Title	**Diagnose Production Equipment Problems**
Unit Code	**IND PHR4 12 0613**
Unit Descriptor	This competency covers diagnosing the causes of products faults and problems arising from the equipment/plant. These problems may be caused by inappropriate process conditions and/or equipment faults. The competency does not include the rectification of such faults or equipment diagnostic skills more appropriate to maintenance tradespersons, but does include diagnosis to a sufficient level so that identification of faults as equipment or process based can be made and appropriate directions can be given to rectify the problem.

Elements	Performance Criteria
1. Identify faults in products/production.	1.1 Products/production process is ***examined***. 1.2 ***Faults*** according to test ***procedures*** are identified. 1.3 Faults according to type/likely caused are categorized. 1.4 Faults are prioritized for action.
2. Determine most probable possible cause(s) of fault	2.1 Faults are analyzed to determine possible causes. 2.2 ***Possible causes are investigated*** to eliminate less probable cause. 2.3 Probable causes are shortlisted. 2.4 Hypotheses of cause(s) are checked if supported by the data available. 2.5 Most probable cause is identified.
3. Implement solution to fault	3.1 Recommended solutions to fault are developed. 3.2 ***HSE*** implications of solution are checked and solution as appropriate is modified. 3.3 This recommendation as appropriate is communicated. 3.4 Recommendation is checked if it has been understood and can be implemented. 3.5 All hazard controls are checked in place. 3.6 Progress of implementation is monitored. 3.7 Recommended solution as required is modified.

4. Check fault solution has worked.	4.1 Product/process for fault is monitored. 4.2 HSE impacts of changes is monitored. 4.3 Analysis and solution process if required are repeated. 4.4 Records and procedures are updated to reflect successful solution.

Variable	Range
Examination of products/process	May include: • visual examination • examination of product quality or other records • examination of inspection records (if used) • examination of test results (routine or otherwise) • specific examination testing undertaken as part of a product improvement activity.
Fault	Is any defect in a product, whether it causes the product to be defective or not. Typical faults may include: • colour variation (non-uniform, not to standard hue/intensity/opacity) • surface blemishes (specs, marks) • surface finish (gloss level, uneven) • size/shape (distorted, wrong, variable) • within specification, but highly variable, forms patterns etc (ie has 'assignable cause') • strength/stiffness/physical properties (too high/low, variable, uneven) • chemical properties • physical/mechanical properties • biological/biochemical/microbiological properties
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.
Possible causes	Include all feasible causes of the problem, before checking to eliminate some.
Investigating possible causes	May include: • talking with operators and others • checking machine histories for prevailing process conditions • checking current process/equipment conditions • carrying out small tests to determine the likelihood of a causal link between a condition and a fault.
Health Safety and Environment (HSE)	All operations to which this unit applies 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 HSE requirements take precedence.
Tools and equipment	Includes use of equipment and tools such as: • laboratory test facilities for the product (although the conduct of tests is not part of this unit) • equipment test instruments for checking the condition of plant (although the conduct of these tests may not be part of this unit)
Process/equipment conditions	May include: • settings such as temperature, pressure • rates such as feed rate, flow rate • setting and adjustment of equipment parts • worn and broken equipment parts.
Context	• This competency applies to technicians who have a role of problem solving product faults as it relates specifically to equipment/process problems. While the technician will take the lead role in this activity, they will need to liaise with a range of people at all levels in the organization to obtain information and to implement the solution. • This diagnosis and improvement may take place as a result of a problem where the fault level is causing reject product, or it may occur as part of continuous improvement, or a kaizen blitz or other situation where the products are not faulty, but are being improved.

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • recognize defective product • isolate one or two most likely causes, and justify the selection of those causes • devise a permanent solution to the problem and justify that solution • check that the solution works • work with all the required people to make it happen. • Consistent performance should be demonstrated. For example, look to see that: ➢ defects with different root causes are analyzed ➢ defects with both process condition and equipment problem causes are solved ➢ defects across the applicable range of products and processes are solved
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • how the process/equipment works • how raw material changes into product through the

	process/equipment • impacts of different process conditions on the product • impacts of different equipment settings/components on the product • impacts of equipment failure/change/variation on the product • product faults and their categories according to causes • causes of all possible product faults due to process/equipment problems.
Underpinning Skills	Must demonstrate skills of: • the ability to communicate to operators, trades people and other technical experts about technical issues. • Reading is required to the level of being able to interpret and apply procedures, technical manuals and manufacturer manuals. Writing is also required to be able to write maintenance and similar requests/orders, update procedures and write equipment/process condition specifications. • Numeracy is required to interpret test data, technical specifications, instrument readings and measurements. Some calculation may be involved in developing and implementing solutions.
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 Supervision Level IV	
Unit Title	**Undertake Proactive Maintenance Analyses**
Unit Code	**IND PHR4 13 0613**
Unit Descriptor	This unit covers the skills needed for the most common forms of analyses associated with predictive maintenance strategies. This unit primarily requires the application of skills associated with communication, teamwork, problem solving, initiative and enterprise, and planning and organising in order to undertake maintenance analyses. This is normally done in the context of using computer technology, and requires aspects of learning and self management to ensure team involvement and facilitation of learning.

Elements	Performance Criteria
1. Liaise with operator	1.1 A relationship with the operator/s of equipment/plant is established. 1.2 The operator has the required skills and resources to keep the equipment/plant clean are ensured. 1.3 The operator is able to effectively monitor the operation of the equipment/plant is ensured. 1.4 Operator is regularly communicated with about the ***Overall Equipment Efficiency*** (***OEE***) of their equipment/plant. 1.5 Operators, team leader and other key personnel in identification of skill needs and means of skill acquisition are involved to fill any identified gaps.
2. Analyse history	2.1 ***Mean Time Between Failures (MTBF)*** (or similar statistical history analysis) from maintenance records are analyzed. 2.2 Performance data of the equipment/plant are analyzed. 2.3 Causes of changes to historic trends/status are identified. 2.4 Methods of ensuring causes of improvements are determined if locked in and deterioration is resolved.
3. Undertake Failure Mode Effects Analysis (FMEA) (or similar)	3.1 Analyses are undertaken. 3.2 Results of analysis are recorded. 3.3 Methods of eliminating possibility of failure and/or minimizing the impact of the failure are investigated. 3.4 Operators, team leader and other key personnel regarding possible solutions are liaised with. 3.5 Most appropriate solutions are selected. 3.6 Selected solutions are implemented.

4. Undertake condition monitoring analysis	4.1 Data for ***condition monitoring*** analysis is obtained. 4.2 Condition monitoring data is interpreted. 4.3 Required maintenance type and timing from condition monitoring data is predicted. 4.4 Operators, team leader and other key personnel regarding implications of condition monitoring report is liaised with. 4.5 Team members in development of changes are involved to maintenance strategy to ensure awareness, learning and commitment.

Variable	**Range**
Overall Equipment Efficiency (OEE)	is the combination of the main factors causing loss of productive capacity from equipment/plant and is: OEE = availability x performance x quality rate where: • availability takes into account losses due to breakdown, set up and adjustments • performance takes into account losses due to minor stoppages, reduced speed and idling • quality rate takes into account t losses due to rejects, reworks and start up waste.
Mean Time Between Failure (MTBF)	• is one key measure of the effectiveness of a maintenance procedure, and is an indicator as to whether root causes are being found and resolved. If MTBF is reducing, then it is an indicator that the maintenance regime is failing. • There are many possible causes of any problem. Eliminating some will have no impact, others will ameliorate the problem. However, elimination of the root cause will eliminate the problem. There should only be one root cause for any problem and so the analysis should continue until this one cause is found. Elimination of the root cause permanently eliminates the problem.
Failure Mode and Effects Analysis (FMEA)	• is a systematic approach that identifies potential failure modes in a system, product, or manufacturing/assembly operation caused by either design or manufacturing/assembly process deficiencies. It also identifies critical or significant design or process characteristics that require special controls to prevent or detect failure modes. FMEA is a tool used to prevent problems from occurring. • Some industry sectors have highly adapted forms of FMEA and may practice traditional FMEA in say their routine maintenance while using another technique (such as HAZOP) for design and modification. • Hazard and Operability Studies (HAZOP) is a form of FMEA

	which has been practiced by the process industries for over 30 years and examines the implications of changes in process conditions to process stability.
Condition monitoring	In this unit condition monitoring is used to describe the process of analyzing the implications of condition monitoring data for proactive maintenance whether it be obtained from non destructive testing reports, visual assessment by experts, diagnostic reports obtained from SCADA or other enterprise or equipment software and product or process quality analyses. It does not require the actual undertaking of the NDT or condition monitoring assessment or test. If this is required appropriate units from other Training Packages will be required.
Competitive manufacturing	Is used to describe the range of systemic manufacturing practice concepts and approaches. It covers but is not limited to: • lean manufacturing • agile manufacturing • preventative and predictive maintenance approaches • monitoring and data gathering systems such as Systems Control and Data Acquisition (SCADA) software, Enterprise Resource Planning (ERP) systems, Manufacturing Resource Planning (MRP), and proprietary systems such as SAP etc. • statistical process control systems including six sigma and three sigma • Just in Time (JIT), kanban and other pull related manufacturing control systems • supply, value, and demand chain monitoring and analysis • other continuous improvement systems. Competitive manufacturing should be interpreted so as to take into account the stage of implementation of competitive manufacturing approaches, the enterprise's size and work organisation, culture, regulatory environment and manufacturing sector.

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • identify and analyze data and other information on the historical performance of equipment • involve operators, maintenance and other stakeholders in decisions on proactive maintenance strategies • identify root cause of failure and deterioration in equipment performance • select and implement failure elimination or minimization solutions
Underpinning Knowledge and Attitudes	Demonstrates knowledge of: • cleaning needs, techniques and principles • methods of assessing skill gaps and filling them

	• techniques for determining MTBF or similar • techniques for undertaking FMEA or similar • underpinning principles of competitive manufacturing strategies being implemented and how to adapt them to maintenance • root cause analysis • techniques to analyze condition monitoring data
Underpinning Skills	Demonstrates skills of: • communication • teamwork • analysis • problem solving • mathematics • planning • reading and interpreting engineering specifications/drawings • computer use • prioritizing • recording data
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 Supervision Level IV	
Unit Title	**Plan and Coordinate Maintenance**
Unit Code	**IND PHR4 14 0613**
Unit Descriptor	This unit of competency covers the skills and knowledge required to plan and coordinate maintenance of production equipment. This unit is appropriate for production management personnel. It does not require that the person who coordinates maintenance is also responsible for conducting maintenance.

Elements	Performance Criteria
1. Identify maintenance requirements	1.1 The approach to maintaining production equipment is identified. 1.2 Advice on equipment maintenance requirements is identified and assessed. 1.3 Special maintenance requirements are assessed and prioritized.
2. Plan maintenance	2.1 Resources required to carry out maintenance are identified and secured. 2.2 A ***maintenance schedule*** is developed to provide reliable equipment performance with minimal disruption to production. 2.3 The maintenance ***schedule*** takes account of production schedules, equipment capability, special maintenance requirements and efficient resource utilization and workplace environmental guidelines. 2.4 The maintenance schedule is recorded in the appropriate workplace format. 2.5 Responsibilities for implementing the maintenance schedule are defined and communicated. 2.6 Work areas and personnel affected by the maintenance program are consulted and advised of maintenance progress.
3. Monitor implementation of the maintenance schedule	3.1 Progress of maintenance is monitored to identify variance to schedule. 3.2 Unplanned events that could affect the schedule are identified, assessed and addressed. 3.3 Potential failure to meet maintenance deadlines are identified and communicated to relevant personnel in a timely manner.

4. Contribute to the improvement of equipment reliability	4.1 Equipment performance information is reviewed to identify patterns or trends. 4.2 Factors that affect equipment reliability are identified. 4.3 Production and maintenance personnel are consulted to identify opportunities to improve equipment reliability. 4.4 Action is taken to improve equipment reliability. 4.5 The maintenance schedule and related programs and procedures are reviewed to reflect improvements.

Variable	**Range**
Maintenance scheduling and work practices	are consistent with company policies and procedures, regulatory and licensing requirements, legislative requirements, and industrial awards and agreements and takes account of OHS and environmental impact of scheduling arrangements
Scheduling	May involve: • the use of planning and systems control software, such as SAP and MRPII
Maintenance schedules	May relate to: • lubrication schedules • service schedules and major cleaning where cleaning requires equipment dismantling or strip down
Sources of information	May include: • manufacturers' specifications • equipment capability data • condition monitoring data • equipment operation/performance reports and log sheets • workplace environmental guidelines
Coordination	May Involve: • the management of contracts with external maintenance service providers and/or internal maintenance personnel

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • determine maintenance requirements for work area • establish and document maintenance schedule • coordinate implementation of maintenance • ensure maintenance schedule is communicated and reported to all appropriate personnel • manage unplanned maintenance issues • assess equipment reliability and contribute to improving outcomes

Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • basic maintenance approaches and differences between reactive, preventative and proactive maintenance models, such as Reliability Centered Maintenance (RCM) and Total Productive Maintenance (TCM) • company systems, processes and responsibilities for collecting equipment condition information, analyzing information and carrying out required servicing and maintenance tasks • sources of data on equipment performance and maintenance requirements, related recording systems and data analysis tools • the requirements of the maintenance scheduling process, including the production process to identify the impact of scheduling on production in order to oversee maintenance activities and establish maintenance priorities • links to related activities, such as purchasing and contract management • factors that influence the reliability of equipment, including equipment capability, equipment/process design, and operating conditions and practices • methods used to measure effectiveness of maintenance including measures of plant availability, cost of maintenance, downtime and alternate resource utilization • OHS, environmental and safety requirements and responsibilities associated with maintenance activities • relevant personnel and departments to be consulted/notified of maintenance schedule and related amendments, including the information relevant to each group/person • awareness of conditions that can affect achievement of the maintenance schedule, including conditions that are unusual or unplanned, and related options for response to equipment breakdowns/emergencies • communication skills to consult and communicate with relevant personnel • recording systems and requirements, including relevant software packages • process improvement procedures • maintenance service supplier capacity
Underpinning Skills	Must demonstrate skills to: • describe the company's approach to equipment maintenance • collect information on equipment maintenance requirements to identify routine lubrication and servicing requirements as appropriate • analyze equipment maintenance data, such as the use of data analysis techniques to plot and interpret trends and patterns in

	equipment performance • identify components of the maintenance program and related responsibilities for implementation, such as equipment monitoring, lubrication schedules, routine servicing and cleaning schedules and breakdown or emergency response (implementation is typically shared between production and maintenance personnel and/or external service providers) • identify and confirm resource requirements to meet maintenance requirements, including the nature of maintenance tasks involved to identify the required maintenance equipment, materials/consumables and competencies and where required, • identify and liaise with external maintenance service providers • confirm that personnel with the required competencies are available to conduct maintenance activities, such as reporting and/or developing competencies required to implement the maintenance schedule, and where required, manage contracts with maintenance providers • develop a schedule for equipment maintenance to support reliable equipment performance with minimal disruption to production, including consulting relevant personnel to confirm schedule feasibility, and notifying relevant personnel of any possibility that maintenance cannot be completed within scheduled timeframe • record and communicate the schedule in appropriate formats, such as use of software, and communicating information to meet workplace and audience requirements • ensure that operating procedures are available and include information on occupational health and safety (OHS), environmental management and safety requirements and responsibilities • monitor maintenance activities against the schedule to identify variances and take appropriate corrective action, such as assessing the consequences of any adjustments to the schedule, and where required, monitor completion of maintenance within maintenance budget constraints • respond to unplanned events, such as major equipment breakdowns to minimize disruption and optimize efficiency • communicate maintenance requirements and report outcomes, including ensuring effective communication between production and maintenance personnel to enhance equipment reliability and identify improvement opportunities • use planning and systems control software • use communication skills to interpret and complete work information to support operations of work team or area

	• demonstrate and support cooperative work practices 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 Supervision Level IV	
Unit Title	**Participate in an Audit Process**
Unit Code	**IND PHR4 15 0613**
Unit Descriptor	This unit of competency covers the skills and knowledge required to participate in an internal audit process and is appropriate where internal audit processes are conducted to support externally audited programs.

Elements	Performance Criteria
1. Participate in planning an audit	1.1 Roles and responsibilities for participating in the ***audit*** are identified. 1.2 The purpose and scope of the audit is identified. 1.3 Information and resources required to conduct the audit are identified and located.
2. Participate in conducting an audit	2.1 ***Information is collected*** that is adequate, representative and meets audit requirements. 2.2 Information is analyzed to assess adequacy of performance against program. 2.3 Records are reviewed to confirm compliance with the program. 2.4 Compliance with the program is observed in the workplace. 2.5 Areas requiring ***corrective action*** are identified.
3. Report and follow up audit outcomes	3.1 Situations presenting an imminent and serious risk to the program objectives are identified and reported immediately in accordance with reporting requirements. 3.2 Audit reports are prepared to address audit scope requirements. 3.3 The results of the audit are communicated according to audit purpose and requirements. 3.4 A corrective action plan is developed.

Variable	Range
Audits	May be conducted against workplace programs and/or legislative requirements. Audits may be undertaken for advisory or regulatory purposes and may be led by internal or external auditors
Information collection methods	May include: • interviews

	• observation • review of workplace records • accessing relevant technical information
Corrective action plans	A corrective action plan identifies non-conformance, corrective actions, date by which action must be taken and any other follow up requirements

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • identify the requirements and procedures for participating in the audit • identify the purpose and scope of the audit • collect, assess and provide information as required by the audit process • identify and act on inconsistencies or issues which may affect audit processes or outcomes • comply with audit requirements • follow up on audit outcomes.
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • the purpose and intent of the program being audited • personal roles and responsibilities in the audit process and related responsibilities of other members of the audit team • the purpose and stages involved in the audit process • workplace information and related information management systems • techniques for collecting information, including options, relevance and strengths and weaknesses of each method to ensure data is adequate and representative • data analysis methods relevant to the audit process • communication skills and techniques appropriate to the workplace • technical knowledge relevant to the program being audited in order to verify compliance and assess adequacy of existing control measures, including relevant industry standards • purpose and responsibilities for maintaining records
Underpinning Skills	Must demonstrate skills to: • identify personal roles and responsibilities for participating in the audit process • identify audit purpose, scope, steps and timelines • identify and locate information required to conduct the audit • review workplace documentation to confirm that required information is available • prepare tools as required to collect information, such as checklists and interview schedules

	• identify any changes that have occurred in the workplace since initiating the program or since the last program audit that could affect program outcomes • apply appropriate questioning, observation and related communication skills to support information collection • review records, conduct interviews, observe workplace practice and collect other relevant information as required to assess compliance with program requirements • take immediate action to report non-conformities that present an imminent and serious risk to the program objectives within level of responsibility • identify, investigate and record evidence of non-conformance and judge significance • assess the adequacy of the program by analyzing the information collected against the program objectives • form conclusions on audit outcomes based on an objective assessment of evidence collected • report the findings of the audit in appropriate format • communicate audit outcomes within level of responsibility using techniques and presentation styles appropriate to the audience • where findings indicate either a failure to comply with the program or inadequacy of the program, participate in investigation of causes of failure and identification of corrective action options • 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
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 Supervision Level IV	
Unit Title	**Report on Workplace Performance**
Unit Code	**IND PHR4 16 0613**
Unit Descriptor	This unit of competency covers the skills and knowledge required to collate and maintain workplace records to enable the monitoring and reporting of workplace performance.

Elements	Performance Criteria
1. Identify recording and reporting requirements	1.1 The purpose of recording performance-related information is identified. 1.2 ***Recording and reporting*** responsibilities are identified. 1.3 ***Recording and reporting systems*** and formats are identified.
2. Maintain workplace information	2.1 Records are complete, timely and accurate. 2.2 Performance information is recorded in required format to meet workplace reporting requirements. 2.3 Errors or discrepancies in recording are identified and corrected or notified to appropriate personnel. 2.4 Variances are identified, investigated and reported according to workplace procedure. 2.5 Requests for information are assessed, prioritized and addressed to meet required timelines.
3. Maintain security of workplace information	3.1 Access levels and authorities are identified. 3.2 Security of workplace records and reports is maintained. 3.3 Security breaches are identified and reported to appropriate personnel.

Variable	Range
Information recorded and reported	May include but is not limited to: • collation of information recorded by others, such as timesheets, log sheets, recipes/specifications, operating procedures, production statistics, downtime, labour and materials usage levels
Recording systems	May be carried out manually or involve the use of use of planning and systems control software, such as SAP and MRPII
Policies and procedures	Work is carried out in accordance with company policies, procedures, regulatory and licensing requirements, legislative requirements and industrial awards and agreements

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • describe the reporting and recording systems and procedures for work area • record information on work performance in accordance with reporting procedures • report variances and inconsistencies • maintain security of work documentation.
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • the purpose and responsibilities for the information records and reports to be maintained or produced, including accuracy levels and timeliness of recording and reporting • techniques used to collate and assess information, including typical recording outcomes to identify unusual or incorrectly recorded information • likely causes of variation and related reporting responsibilities • information system access levels and codes, such as levels within software • communication skills relevant to reporting role
Underpinning Skills	Must demonstrate skills to: • identify and use recording/reporting formats and systems • identify information security requirements and procedures for responding to/reporting a security breach • collect and collate information to be recorded as required • assess information to confirm that it is complete and accurate and follow up inaccurate recording with relevant personnel • identify significant performance variation, investigate and report cause/s • prepare reports in required format to meet reporting timelines • respond to information requests on a timely basis • 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
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 Supervision Level IV	
Unit Title	**Facilitate SCADA Systems in a Manufacturing Team or Work Area**
Unit Code	**IND PHR4 17 0613**
Unit Descriptor	This unit covers the knowledge and skills required by a person who is required to use System Control and Data Acquisition (SCADA), or other similar systems, and support the team in their use of SCADA. This unit primarily requires the application of skills associated with using communication technology and supporting team use of SCADA systems. Problem solving, initiative and enterprise, and planning and organizational skills are required to ensure that system is used efficiently. This requires aspects of learning and self management to ensure own performance and that of the team.

Elements	Performance Criteria
1. Communicate using the SCADA system	1.1 Information using ***SCADA*** is sent and received. 1.2 Messages using SCADA are sent and received.
2. Make decisions using SCADA	2.1 The SCADA system is interrogated to find required current, historical or predicted information. 2.2 Appropriate action is taken to the information.
3. Monitor the use of SCADA	3.1 SCADA information is routinely monitored and used along the value chain. 3.2 Poor uses of SCADA system within team and system inadequacies are identified. 3.3 Team members who require additional support are identified. 3.4 Appropriate actions are taken to provide required support. 3.5 Appropriate actions are taken to improve SCADA system and its use.
4. Support team use SCADA	4.1 Team is regularly communicated with, both using SCADA based communication and face to face. 4.2 System improvements required is identified. 4.3 Skill improvement needs are identified. 4.4 Appropriate actions are taken to have the identified improvements implemented.

Variable	Range
System Control and Data Acquisition (SCADA)	• is a general term applied to a number of systems which automatically collect critical process data, perform required mathematical manipulations on it and then make control

	decisions and/or give required information personnel for action. • In the continuous manufacturing sector, the SCADA system is sometimes integrated into other sophisticated computer control systems such as Distributed Control System (DCS) and indeed these systems do merge in advanced systems. These organizations may simply refer to their SCADA as the DCS or other similar term (such as the proprietary name of the computer system).
Value chain	Competitive manufacturing organizations encompass the entire production system, beginning with the customer, and include the product sales outlet, the final assembler, product design, raw material mining and processing and all tiers of the value chain (sometimes called the supply chain). Any truly 'competitive' system is highly dependent on the demands of its customers and the reliability of its suppliers. No implementation of competitive manufacturing can reach its full potential without including the entire 'enterprise' in its planning.

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • identify team or area information and operations requirements and relate to SCADA system • lead and motivate others in using SCADA system • obtain regular and one-off information from SCADA system • make decisions using SCADA generated information.
Underpinning Knowledge and Attitudes	Demonstrates knowledge of: • hierarchy of SCADA system and operation • information available from and controls exercised by/through the SCADA system • facilities and information offered by SCADA • support/training/skill development mechanisms available for access by team member.
Underpinning Skills	• keyboarding/mousing • communication • teamwork • problem solving, planning and organizing
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 Supervision Level IV	
Unit Title	**Plan and Organize Work**
Unit Code	**IND PHR4 18 0613**
Unit Descriptor	This unit covers the knowledge, skills and attitude required in planning and organizing work. It may be applied to a small independent operation or to a section of a large organization.

Element	Performance Criteria
1. Set objectives	1.1 ***Objectives*** are consistent with and linked to work activities in accordance with organizational aims. 1.2 Objectives are stated as measurable targets with clear time frames. 1.3 Support and commitment of team members are reflected in the objectives. 1.4 Realistic and attainable objectives are identified.
2. Plan and schedule work activities	2.1 Tasks/work activities to be completed are identified and prioritized as directed. 2.2 Tasks/work activities are broken down into steps in accordance with set time frames achievable components in accordance with set time frames. 2.3 ***Resources*** are allocated as per requirements of the activity. 2.4 ***Schedule of work activities*** is coordinated with personnel concerned.
3. Implement work plans	3.1 ***Work methods and practices*** are identified in consultation with personnel concerned. 3.2 ***Work plans*** are implemented in accordance with set time frames, resources and ***standards***.
4. Monitor work activities	4.1 Work activities and work performance are monitored and compared with set objectives. 4.2 Deviations from work activities are reported and recommendations are coordinated with appropriate personnel and in accordance with set standards. 4.3 Reporting requirements are complied with in accordance with recommended format. 4.4 Observe timeliness of report. 4.5 Files are established and maintained in accordance with standard operating procedures.

5. Review and evaluate work plans and activities	5.1 Work plans, strategies and implementation are reviewed based on accurate, relevant and current information. 5.2 Review is based on comprehensive consultation with appropriate personnel on outcomes of work plans and reliable feedback. 5.3 Results of review are provided to concerned parties and formed as the basis for adjustments/simplifications to be made to policies, processes and activities. 5.4 Performance appraisal is conducted in accordance with organization rules and regulations. 5.5 Performance appraisal report is prepared and documented regularly as per organization requirements. 5.6 Recommendations are prepared and presented to ***appropriate personnel/authorities.*** 5.7 ***Feedback mechanisms*** are implemented in line with organization policies.

Variable	**Range**
Objectives	May include but not limited to: • Specific • General
Resources	May include but not limited to: • Personnel • Equipment and technology • Services • Supplies and materials • Sources for accessing specialist advice • Budget
Schedule of work activities	May include but not limited to: • Daily • Work-based • Contractual • Regular • Confidential • Disclosure / Non-disclosure
Work methods and practices	Work methods and practices may include but not limited to: • Legislated regulations and codes of practice • Industry regulations and codes of practice • Occupational health and safety practices
Work plans	May include but not limited to: • Daily work plans • Project plans

	• Program plans • Organization strategic and restructuring plans • Resource plans • Skills development plans • Management strategies and objectives
Standards	May include but not limited to: • Performance targets • Performance management and appraisal systems • Occupational standards and safety standards • Employment contracts • Client contracts • Discipline procedures and Internal quality assurance • Internal and external accountability and auditing requirements
Appropriate personnel/ authorities	May include but not limited to: • Appropriate personnel include: • Management • Line Staff
Feedback mechanisms	May include but not limited to: • Feedback mechanisms include: • Verbal feedback • Informal feedback • Formal feedback • Questionnaire • Survey • Group discussion

Evidence Guide	
Critical Aspects of Competence	Must demonstrate skills and knowledge of: • setting objectives • planning and scheduling work activities • implementing work plans • monitoring work activities • reviewing and evaluating work plans and activities
Underpinning Knowledge	Must demonstrate knowledge of: • Organization's strategic plan, policies rules and regulations, laws and objectives for work unit activities and priorities • Organizations policies, strategic plans, guidelines related to the role of the work unit • Team work and consultation strategies
Underpinning Skills	Must demonstrate skills in: • Leading • Planning, Organizing and Coordinating • Communication Skills

	• Inter-and intra-person/motivation skills • Presentation skills
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: Pharmaceutical Manufacturing Supervision Level IV	
Unit Title	**Migrate to New Technology**
Unit Code	IND **PHR4 19 0613**
Unit Descriptor	This unit defines the competence required to apply skills and knowledge in using new or upgraded technology. The rationale behind this unit emphasizes the importance of constantly reviewing work processes, skills and techniques in order to ensure that the quality of the entire business process is maintained at the highest level possible through the appropriate application of new technology. To this end, the person is typically engaged in on-going review and research in order to discover and apply new technology or techniques to improve aspects of the organization's activities.

Elements	Performance Criteria
1. Apply existing knowledge and techniques to technology and transfer	1.1 Situations are identified where existing knowledge can be used as the basis for developing new skills. 1.2 New or upgraded technology skills are acquired and used to enhance learning. 1.3 New or upgraded equipment are identified, classified and used where appropriate, for the benefit of the organization.
2. Apply functions of technology to assist in solving organizational problems	2.1 Testing of new or upgraded equipment is conducted according to the specification manual. 2.2 Features of new or upgraded equipment are applied within the organization 2.3 Features and functions of new or upgraded equipment is used for solving organizational problems 2.4 Sources of information is accessed and used relating to new or upgraded equipment
3. Evaluate new or upgraded technology performance	3.1 New or upgraded equipment is evaluated for performance, usability and against OHS standards**.** 3.2 ***Environmental considerations*** are determined from new or upgraded equipment. 3.3 ***Feedback*** is sought from users where appropriate.

Variable	Range
Environmental Considerations	May include but is not limited to recycling, safe disposal of packaging (e.g. cardboard, polystyrene, paper, plastic) and correct disposal of waste materials by an authorized body
Feedback	May include surveys, questionnaires, interviews and meetings.

Evidence Guide	
Critical Aspects of Competence	Must demonstrate skills and knowledge in: • transferring the application of existing skills and knowledge to new technology • knowledge of vendor product directions • assess and analyze value chain • evaluate and apply new technology to assist in solving organizational problems • general analytical skills in relation to known problems
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • Broad awareness of current technology trends and directions in construction industry (e.g. systems/procedures, services, new developments, new protocols) • Knowledge of vendor product directions • Assess and analyze value chain • Ability to locate appropriate sources of information regarding building construction and new technologies • Current industry products/services, procedures and techniques with knowledge of general features • Information gathering techniques
Underpinning Skills	Must demonstrate skills in: • Research skills for identifying broad features of new technologies • Ability to assist in the decision making process • Literacy skills in regard to interpretation of technical manuals • Ability to solve known problems in a variety of situations and locations • Evaluate and apply new technology to assist in solving organizational problems • General analytical skills in relation to known problems
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: Pharmaceutical Manufacturing Supervision Level IV	
Unit Title	**Establish Quality Standards**
Unit Code	**IND PHR4 20 0613**
Unit Descriptor	This unit covers the knowledge, attitudes and skills required to monitor quality of work, establish quality specifications for work outcomes, participate in maintaining and improving quality at work, identify hazards and critical control points in the production of quality output, assist in planning of quality assurance procedures, report problems that affect quality and implement quality assurance procedures.

Elements	Performance Criteria
1. Establish quality specifications for service	1.1 Market specifications are **sourced** and ***legislated requirements*** identified. 1.2 Quality specifications developed and agreed upon 1.3 Quality specifications are documented and introduced to organization staff / personnel in accordance with the organization policy 1.4 Quality specifications are updated when necessary
2. Identify hazards and critical control points	2.1. Critical control points impacting on quality are identified. 2.2. Degree of risk for each hazard is determined. 2.3. Necessary documentation is accomplished in accordance with organization quality procedures
3. Assist in planning of quality assurance procedures	3.1 Procedures for each identified control point are developed to ensure optimum quality. 3.2 Hazards and risks are minimized through application of appropriate controls. 3.3 Processes to monitor the effectiveness of quality assurance procedures are developed.
4. Implement quality assurance procedures	4.1 Responsibilities for carrying out procedures are allocated to staff and contractors. 4.2 Instructions are prepared in accordance with the enterprise's quality assurance program. 4.3 Staff and contractors are given induction Train/vehicle on the quality assurance policy. 4.4 Staff and contractors are given in-service Train/vehicle relevant to their allocated procedures.

5. Monitor quality of work outcome	5.1 Quality requirements are identified 5.2 Inputs are inspected to confirm capability to meet quality requirements 5.3 Work is conducted to produce required outcomes 5.4 Work processes are monitored to confirm quality of output and/or service 5.5 Processes are adjusted to maintain outputs within specification.
6. Participate in maintaining and improving quality at work	6.1 Work area, materials, processes and services are routinely monitored to ensure compliance with quality requirements 6.2 Non-conformance in inputs, process, product and/or service is identified and reported according to workplace reporting requirements 6.3 Corrective action is taken within level of responsibility, to maintain quality standards 6.4 Quality issues are raised with designated personnel
7. Report problems that affect quality	7.1 Recognize potential or existing quality problems. 7.2 Identify instances of variation in quality from specifications or work instructions. 7.3 Report variation and potential problems to supervisor/manager according to enterprise guidelines.

Variable	**Range**
Sourced	May include end-users and customers or stakeholders
Legislated requirements	May include Verification of service quality as part of consumer legislation or specific legislation related to service content or composition.
Safety procedures	May include but is not limited to: • use of tools and equipment for construction works • workplace environment and handling of material safety, • following occupational health and safety procedures designated for the task • respect the policies, regulations, legislations, rule and procedures for construction works
Materials	May include but is not limited to: • gloves, bucket, scrubbing brush, gauze, cotton and plasters • aluminum foils, gowns, apron, rubber boots, disinfectants, antiseptics, scalpel blade, stationeries, tap water, alcohol, and soap, detergents, protective eyewear, overall, cleaning reagents cleaning materials

Tools and Equipment	May include but is not limited to: • projector, white board, computers, printers, calculators, copying machines, bucket, wheelbarrow/trolley for disposal of carcass, different quality evaluating equipment

Evidence Guide	
Critical Aspect of Competence	Demonstrates skills and knowledge in: • Monitoring quality of work • Establishing quality specifications for service • Participating in maintaining and improving quality at work • Identifying hazards and critical control points in the production of quality service • Assisting planning of quality assurance procedures • Reported problems that affect quality • Implementing quality assurance procedures
Underpinning Knowledge	Demonstrates knowledge of: • Monitoring quality of work • Establishing quality specifications for product • Participating in maintaining and improving quality at work • Identifying hazards and critical control points in the production of quality product • Assisting in planning of quality assurance procedures • Reporting problems that affect quality • Implementing quality assurance procedures
Underpinning Skills	Demonstrate skills to: • Monitor quality of work • Establish quality specifications for service • Participate in maintaining and improving quality at work • Identifying hazards and critical control points in the production of quality service • Assist in planning of quality assurance procedures • Report problems that affect quality • Implement quality assurance 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: Pharmaceutical Manufacturing Supervision Level IV	
Unit Title	**Develop Team and Individuals**
Unit Code	**IND PHR4 21 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 workgroup.

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 Train/vehicle 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: • Coaching, monitoring and/or supervision • Formal/informal learning program • Internal/external vehicle provision • Work experience/exchange/opportunities • Personal study and Career planning/development • Performance evaluation • Workplace skills assessment and Recognition of prior learning
Organizational requirements	May Include: • 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: • Formal/informal performance evaluation • 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 is not limited to: • On the job coaching or monitoring • Problem solving

	• Presentation/demonstration • Formal course participation • Work experience and involvement in professional networks • Conference and seminar attendance

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 plans to improve the effectiveness of learning • learning plans to match skill needs • access and designate learning opportunities
Underpinning Knowledge and Attitude	Demonstrates knowledge of: • coaching and monitoring 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 to obtain 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, preparing general information and documents according to target audience; spell with accuracy; use grammar and punctuation effective relationships and conflict management • communicate including receiving feedback and reporting, maintaining effective relationships and conflict management • plan and organize required resources and equipment to meet learning needs • coach and mentor skills to provide support to colleagues • report to organize information; assess information for relevance and accuracy; identify and elaborate on learning outcomes • facilitate and conduct small group training sessions • relate to people from a range of social, cultural, physical and mental backgrounds
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: Pharmaceutical Manufacturing Supervision Level IV	
Unit Title	**Utilize Specialized Communication Skills**
Unit Code	**IND PHR4 22 0613**
Unit Descriptor	This unit covers the knowledge, skills and attitudes required to use specialized communication skills to meet specific needs of internal and external clients, conduct interviews, facilitate group discussions, and contribute to the development of communication strategies.

Elements	Performance Criteria
1. Meet common and specific communication needs of clients and colleagues	1.1 Specific communication needs of clients and colleagues are identified and met. 1.2 Different approaches are used to meet communication needs of clients and colleagues. 1.3 Conflict is addressed promptly and in a timely way and in a manner which does not compromise the standing of the organization.
2. Contribute to the development of communication strategies	2.1 ***Strategies*** for internal and external dissemination of information are developed, promoted, implemented and reviewed as required. 2.2 Channels of communication are established and reviewed regularly. 2.3 Coaching in effective communication is provided. 2.4 Work related network and relationship are maintained as necessary. 2.5 Negotiation and conflict resolution strategies are used where required. 2.6 Communication with clients and colleagues is appropriate to individual needs and organizational objectives.
3. Represent the organization	3.1 When participating in internal or external forums, presentation is relevant, appropriately researched and presented in a manner to promote the organization. 3.2 Presentation is clear and sequential and delivered within a predetermined time. 3.3 Utilize appropriate media to enhance presentation. 3.4 Differences in views are respected. 3.5 Written communication is consistent with organizational standards.

	3.6 Inquiries are responded in a manner consistent with organizational standard.
4. Facilitate group discussion	4.1 Mechanisms which enhance ***effective group interaction*** is defined and implemented. 4.2 Strategies which encourage all group members to participate are used routinely. 4.3 Objectives and agenda for meetings and discussions are routinely set and followed. 4.4 Relevant information is provided to group to facilitate outcomes. 4.5 Evaluation of group communication strategies is undertaken to promote participation of all parties. 4.6 Specific communication needs of individuals are identified and addressed.
5. Conduct interview	5.1 A range of appropriate communication strategies are employed in ***interview situations***. 5.2 Records of interviews are made and maintained in accordance with organizational procedures. 5.3 Effective questioning, listening and nonverbal communication techniques are used to ensure that required message is communicated.

Variable	**Range**
Strategies	May include but is not limited to: • Recognizing own limitations • Utilizing techniques and aids • Providing written drafts • Verbal and non verbal communication
Effective group interaction	May include but is not limited to: • Identifying and evaluating what is occurring within an interaction in a non-judgmental way • Using active listening • Making decision about appropriate words, behavior • Putting together response which is culturally appropriate • Expressing an individual perspective • Expressing own philosophy, ideology and background and exploring impact with relevance to communication
Interview situations	May include but is not limited to: • Establish rapport • obtain facts and information • Facilitate resolution of issues

	• Develop action plans • Diffuse potentially difficult situation
Types of Interview	May include but is not limited to: • Related to staff issues • Routine • Confidential • Evidential • Non-disclosure • Disclosure

Evidence Guide	
Critical Aspects of Competence	Demonstrates skills and knowledge to: • Demonstrate effective communication skills with clients and work colleagues accessing service • Adopt relevant communication techniques and strategies to meet client particular needs and difficulties
Underpinning Knowledge and Values	Demonstrates knowledge of: • communication process • dynamics of groups and different styles of group leadership • communication skills relevant to client groups
Underpinning Skills	Demonstrates skills of: • full range of communication techniques including: ➢ active listening ➢ feedback ➢ interpretation ➢ role boundaries setting ➢ negotiation ➢ establishing empathy ➢ communication strategies • communicate to fulfil job roles as specified by the organization
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: Pharmaceutical Manufacturing Supervision Level IV	
Unit Title	**Manage and Maintain Small/Medium Business Operations**
Unit Code	**IND PHR4 23 0613**
Unit Descriptor	This unit covers the operation of day-to-day business activities in a micro or small business. The strategies involve developing, monitoring and managing work activities and financial information, developing effective work habits, and adjusting work schedules as needed.

Elements	Performance Criteria
1. Identify daily work requirements	1.1 Work requirements for a given time period are identified taking into consideration ***resources*** and constraints. 1.2 Work activities are prioritized based on business needs, requirements and deadlines. 1.3 If appropriate, work is allocated to relevant staff or contractors to optimize efficiency.
2. Monitor and manage work	2.1 People, resources and/or equipment are coordinated to provide optimum results. 2.2 Staff, clients and/or contractors are communicated within a clear and regular manner, to monitor work in relation to ***business goals*** or timelines. 2.3 ***Problem solving techniques*** are applied to work situations to overcome difficulties and achieve positive outcomes.
3. Develop effective work habits	3.1 Work and personal priorities are identified and a balance is achieved between competing priorities using appropriate ***time management strategies***. 3.2 Input from ***internal and external sources*** is sought and used to develop and refine new ideas and approaches. 3.3 Business or inquiries are responded to promptly and effectively. 3.4 Information is presented in a format appropriate to the industry and audience.
4. Interpret financial information	4.1 Relevant documents and reports are identified. 4.2 Documents and reports are read and understood and any implications discussed with appropriate persons. 4.3 Data and numerical calculations are analyzed, checked, evaluated, organized and reconciled. 4.4 Daily financial records and cash flow are maintained correctly and in accordance with legal and accounting requirements.

	4.5 Invoices and payments are prepared and distributed in a timely manner and in accordance with legal requirements. 4.6 Outstanding accounts are collected or followed-up.
5. Evaluate work performance	5.1 Opportunities for improvements are monitored according to business demands. 5.2 Work schedules are adjusted to incorporate necessary modifications to existing work and routines or changing needs and requirements. 5.3 Proposed changes are clearly communicated and recorded to aid in future planning and evaluation. 5.4 Relevant codes of practice are used to guide an ethical approach to workplace practices and decisions.

Variable	Range
Resources	May include but is not limited to: • staff • money • time • equipment and space
Business goals	May include but is not limited to: • sales targets • budgetary targets • team and individual goals • production targets • reporting deadlines
Problem solving techniques	May include but is not limited to: • gaining additional research and information to make better informed decisions • looking for patterns • considering related problems or those from the past and how they were handled • eliminating possibilities • identifying and attempting sub-tasks • collaborating and asking for advice or help from additional sources
Time management strategies	May include but is not limited to: • prioritizing and anticipating • short term and long term planning and scheduling • creating a positive and organized work environment • clear timelines and goal setting that is regularly reviewed and adjusted as necessary • breaking large tasks into smaller tasks • getting additional support if identified and necessary

Internal and external sources	May include but is not limited to: • staff and colleagues • management, supervisors, advisors or head office • relevant professionals such as lawyers, accountants, management consultants • professional associations

Evidence Guide	
Critical Aspects of Competence	A person must be able to demonstrate: • ability to identify daily work requirements and allocate work appropriately • ability to interpret financial documents in accordance with legal requirements
Underpinning Knowledge and Attitudes	Demonstrate knowledge of: • Federal and Local Government legislative requirements affecting business operations, especially in regard to Occupational Health and Safety (OHS), equal employment opportunity, industrial relations and anti-discrimination • technical or specialist skills relevant to the business operation • relevant industry code of practice • planning techniques to establish realistic timelines and priorities • identification of relevant performance measures • quality assurance principles and methods • relevant marketing, management, sales and financial concepts • methods for monitoring performance and implementing improvements • structured approaches to problem solving, idea management and time management
Underpinning Skills	Demonstrate skills to: • interpret legal requirements, company policies and procedures and immediate, day-to-day demands • communicate using questioning, clarifying, reporting, and giving and receiving constructive feedback • numeracy skills for performance information, setting targets and interpreting financial documents and reports • technical and analytical skills to interpret business document, reports and financial statements and projections • relate to people from a range of social, cultural and ethnic backgrounds and physical and mental abilities • solve problem and develop contingency plans • using computers and software packages to record and manage data and to produce reports • evaluate using assessment work and outcomes • observe 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: Pharmaceutical Manufacturing Supervision Level IV	
Unit Title	**Apply Problem Solving Techniques and Tools**
Unit Code	**IND PHR4 24 0613**
Unit Descriptor	This unit of competency covers the knowledge, skills and attitude required to apply scientific problem solving techniques and tools to enhance quality, productivity and other kaizen elements on continual basis.

Elements	Performance criteria
1. Identify and select theme/problem.	1.1***Safety requirements*** are followed in accordance with safety plans and procedures. 1.2All possible problems related to the process /Kaizen elements are listed using ***statistical tools and techniques***. 1.3All possible problems related to kaizen elements are identified and listed on Visual Management Board/Kaizen Board. 1.4 Problems are classified based on obviousness of cause and action. 1.5Critical factors like the number of customers affected, Potentials for bottlenecks, and number of complaints etc… is selected. 1.6Problems related to priorities of ***Kaizen Elements*** are given due emphasis and selected.
2. Grasp current status and set goal.	2.1The extent of the problem is defined. 2.2Appropriate and achievable goal is set.
3. Establish activity plan.	3.1The problem is confirmed. 3.2 High priority problem is selected. 3.3The extent of the problem is defined. 3.4Activity plan is established as per ***5W1H***.
4. Analyze causes of a problem.	4.1All possible causes of a problem are listed. 4.2Cause relationships are analyzed using***4M1E***. 4.3Causes of the problems are identified. 4.4Root causes are selected. 4.5The root cause which is most directly related to the problem is selected. 4.6All possible ways are listed using ***creative idea generation*** to eliminate the most critical root cause.

	4.7 The suggested solutions are carefully tested and evaluated for potential complications. 4.8 Detailed summaries of the action plan are prepared to implement the suggested solution.
5. Examine countermeasures and their implementation.	5.1 Action plan is implemented by ***medium KPT*** members. 5.2 Implementation is monitored according to the agreed procedure and activities are checked with preset plan.
6. Assess effectiveness of the solution.	6.1 ***Tangible and intangible results*** are identified. 6.2 The results are verified over time. 6.3 Tangible results are compared with targets using ***various types of diagram***.
7. Standardize and sustain operation.	7.1 If the goal is achieved, the new procedures are standardized and made part of daily activities. 7.2 All employees are trained on the new ***Standard Operating Procedures (SOPs)***. 7.3 SOP is verified and followed by all employees. 7.4 The next problem is selected to be tackled by the team.

Variable	**Range**
Safety requirements	may include but not limited to: • OHS requirements include legislation, material safety, managements system, hazardous substances and dangerous goods code and local safe operating procedures • Work is carried out in accordance with legislative obligations, environmental legislations, relevant health regulation, manual handling procedure and organization insurance requirements
Statistical tools and techniques	may include but not limited to: • 7 QC tools may include: ➢ Stratification ➢ Pareto Diagram ➢ Cause and Effect Diagram ➢ Check Sheet ➢ Control Chart/Graph ➢ Histogram ➢ Scatter Diagram • QC techniques may include: ➢ Brain storming ➢ Why analysis ➢ What if analysis ➢ 5W1H

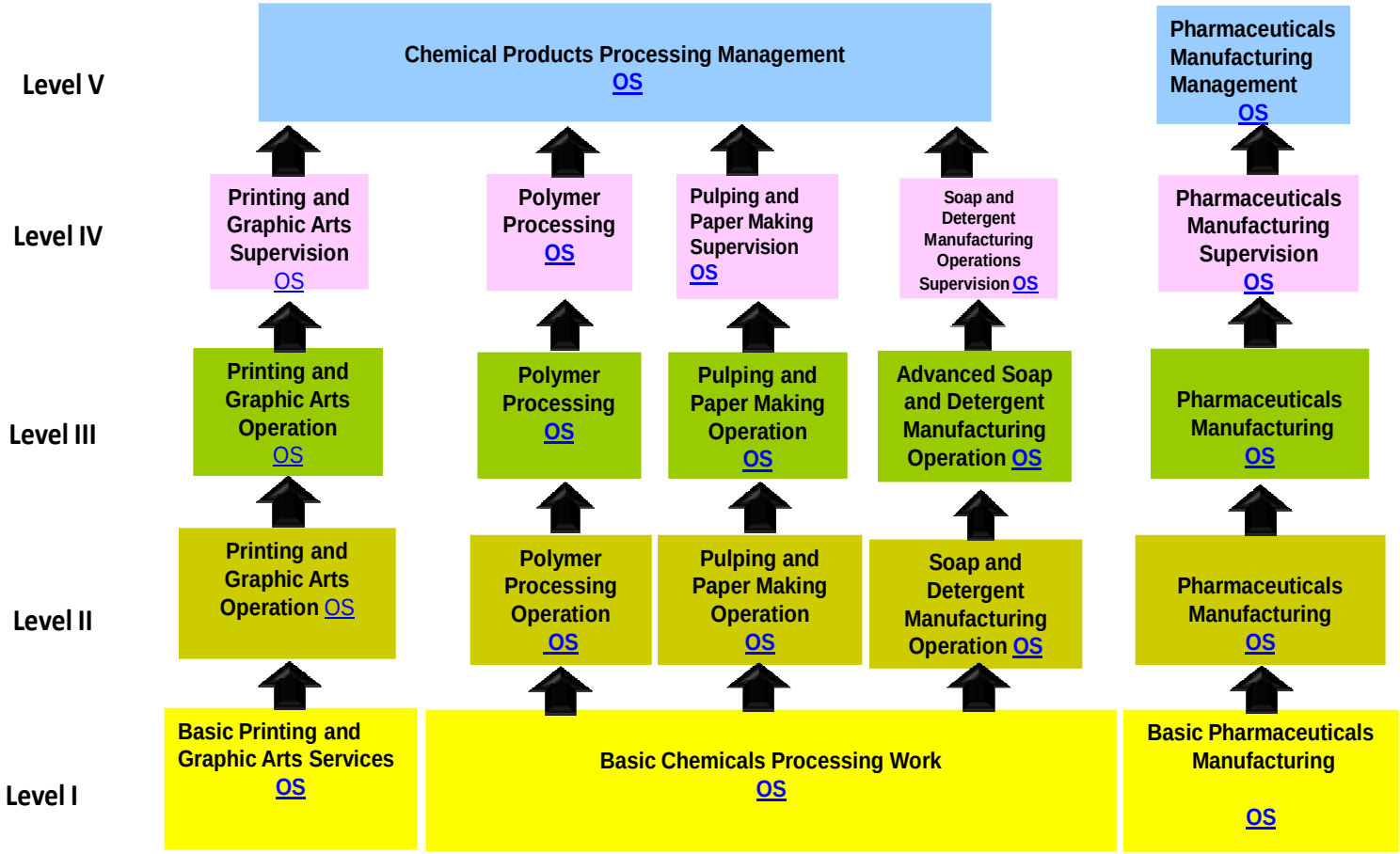
Kaizen Elements	may include but not limited to: • Quality • Cost • Productivity • Delivery • Safety • Moral • Environment • Gender equality
5W1H	may include but not limited to: • Who: person in charge • Why: objective • What: item to be implemented • Where: location • When: time frame • How: method
4M1E	may include but not limited to: • Man • Machine • Method • Material and • Environment
Creative idea generation	may include but not limited to: • Brainstorming • Exploring and examining ideas in varied ways • Elaborating and extrapolating • Conceptualizing
Medium KPT	may include but not limited to: • 5S • 4M (machine, method, material and man) • 4P (Policy, procedures, People and Plant) • PDCA cycle • Basics of IE tools and techniques
Tangible and intangible results	may include but not limited to: • Tangible result may include: ➢ Quantifiable data • Intangible result may include: ➢ Qualitative data
Various types of diagram	may include but not limited to: • Line graph • Bar graph • Pie-chart • Scatter diagram • Affinity diagram

Standard Operating Procedures (SOPs)	may include but not limited to: • The customer demand • The most efficient work routine (steps) • The cycle times required to complete work elements • All process quality checks required to minimize defects/errors • The exact amount of work in process required

Evidence Guide	
Critical Aspects of Assessment	Demonstrates skills and knowledge competencies to: • Apply all relevant procedures and regulatory requirements to ensure quality and productivity of an organization. • Detect non-conforming products/services in the work area • Apply effective problem solving approaches/strategies. • Implement and monitor improved practices and procedures • Apply statistical quality control tools and techniques.
Underpinning Knowledge and Attitude	Demonstrates knowledge of: • QC story/PDCA cycle/ • QC story/ Problem solving steps • QCC techniques • 7 QC tools • Basic IE tools and techniques. • SOP • Quality requirements associated with the individual's job function and/or work area • Workplace procedures associated with the candidate's regular technical duties • Relevant health, safety and environment requirements • organizational structure of the enterprise • Lines of communication • Methods of making/recommending improvements. • Reporting procedures
Underpinning Skills	Demonstrates skills to: • Apply problem solving techniques and tools • Apply statistical analysis tools • Apply Visual Management Board/Kaizen Board. • Detect non-conforming products or services in the work area • Document and report information about quality, productivity and other kaizen elements. • Contribute effectively within a team to recognize and recommend improvements in quality, productivity and other kaizen elements. • Implement and monitor improved practices and procedures. • Organize and prioritize activities and items. • Read and interpret documents describing procedures

	• Record activities and results against templates and other prescribed 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.

COMMENT TEMPLATE

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