Federal Democratic Republic of Ethiopia

OCCUPATIONAL STANDARD

PHARMACEUTICALS

MANUFACTURING MANAGEMENT

NTQF Level V

Ministry of Education
June 2013

Introduction

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

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

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

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

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

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

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

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

UNIT OF COMPETENCE CHART

Occupational Standard: Pharmaceuticals Manufacturing Management		
Occupational Code: **IND PHR**		

NTQF Level V

IND PHR5 01 0613 Prepare and Review Workplace Documentation to Support GMP	IND PHR5 02 0613 Develop a Documentation Control Strategy for a Manufacturing Enterprise	IND PHR5 03 0613 Manage People Performance
IND PHR5 04 0613 Manage Operational Plan	IND PHR5 05 0613 Develop Quick Changeover Procedures	IND PHR5 06 0613 Schedule and Manage Production
IND PHR5 07 0613 Adapt a Proactive Maintenance Strategy for a Seasonal or Cyclical Manufacturing Operation	IND PHR5 08 0613 Develop Processes for the Management of Breaches in Compliance Requirements	IND PHR5 09 0613 Perform Basic Statistical Quality Control
IND PHR5 10 0613 Develop a Communications Strategy to Support Production	IND PHR5 11 0613 Facilitate the Use of Planning Software Systems in Manufacturing	IND PHR5 12 0613 Develop a Balanced Score Card for Use in Competitive Manufacturing
IND PHR5 13 0613 Manage OHS processes	IND PHR5 14 0613 Manage project quality	IND PHR5 15 0613 Facilitate and capitalize on change and innovation
IND PHR5 16 0613 Establish and Conduct Business Relationships	IND PHR5 17 0613 Manage Continuous Improvement Process (Kaizen)	

Occupational Standard: Pharmaceuticals Manufacturing Management Level V	
Unit Title	**Prepare and Review Workplace Documentation to Support GMP**
Unit Code	**IND PHR5 01 0613**
Unit Descriptor	This unit of competency covers the skills and knowledge required by production/packaging line managers or supervisors to develop review and manage workplace documentation to support Good Manufacturing Practice (GMP).

Elements	Performance Criteria
1. Develop and/or review workplace documentation to meet GMP requirements	1.1 Policies and master plans are identified to determine work area requirements.
	1.2 **Workplace documentation** is identified and reviewed to confirm GMP requirements are met.
	1.3 Procedures and records are developed and/or reviewed to confirm GMP requirements are met.
	1.4 Improvements to workplace documentation are identified and reported.
	1.5 Procedures to alter workplace documents are followed.
2. Facilitate development and communication of workplace documentation	2.1 Workplace documentation is developed in consultation with relevant **stakeholders** to support GMP.
	2.2 **Documentation** is made available and clearly explained to relevant stakeholders.
	2.3 Training requirements are identified and addressed within level of responsibility.

Variable	Range
Workplace documentation	May include but is not limited to: • policies and master plans • quality manual • specifications • certificates • manufacturing formula • processing and packaging instructions • procedures • records • protocols (validation) • reports

Stakeholders	Refer to process and technical experts and may include but are not limited to: • operators • engineering department • quality assurance • quality control • area managers • related functions/personnel
Documentation	May include but is not limited to: • written descriptions • graphic display of information, including diagrams and photos • flow charts • log and work sheet • data recording (usage, batch recordings) • Information is typically stored and accessed electronically
Information covered by procedures	May include but is not limited to: • receipt of starting and packaging material • sampling • testing • release and rejection procedures • validation • equipment assembly and calibration • maintenance, cleaning and sanitation • personnel matters, including training and personal hygiene • environmental monitoring • pest control • complaints • recalls • returns • equipment operation
Records	May include but is not limited to: • batch records • equipment recording (as appropriate) • validations • calibrations • maintenance • cleaning or repair work, including details of when/who • operating log sheets • complaints
Version control	May include but is not limited to: • the maintenance of workplace documents to meet company and regulatory requirements

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • Review workplace documentation to confirm that it meets GMP requirements. Documentation may relate to a specific work area (rather than the whole plant). The candidate is required to document their findings • Develop, design or amend documentation to support GMP. For example, this could require the development of operating procedures. It may include reviewing and updating existing documentation or developing new documentation within required formats. The candidate must demonstrate application of document control procedures to submit or amend documents. They must also demonstrate that appropriate consultation was undertaken in the development process and the document changes are effectively communicated. This includes demonstrating an awareness of the link to related documents. Where training needs arise from the change, these must be identified together with recommendations for how they can be addressed • Review completed GMP-related documents and records to ensure that GMP requirements are met.
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • documentation requirements (as outlined in Code of Good Manufacturing Practice for Medicinal Products) • document authorization requirements and procedures and legal responsibilities of signatory • document types to support workplace systems and related development and control systems, roles and responsibilities, including an understanding of system security and access levels • procedures and responsibilities for altering documents and managing version control • systems, methods and procedures for recording and storing data and authorized levels of access (to electronic systems) • use of documentation including an understanding of the documents that can be used as evidence in audit processes • recording and reporting requirements • training and assessment arrangements and responsibilities
Underpinning Skills	Must demonstrate skills to: • use workplace documentation, recording and reporting formats and software

	• 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 Management Level V	
Unit Title	**Develop a Documentation Control Strategy for a Manufacturing Enterprise**
Unit Code	**IND PHR5 02 0613**
Unit Descriptor	This unit of competency covers the skills and knowledge required to develop and implement a documentation control strategy for an organization implementing a competitive systems and practices strategy or which is part of the value stream for such an organization. The documentation control strategy might be needed to comply with ISO9000 or other reasons.

Elements	Performance Criteria
1. Identify and obtain agreement to document management procedures and standards	1.1 An appropriate working group of stakeholders is established.
	1.2 Purpose and scope of *document* management standards, including interaction with production, maintenance, logistics, sales and marketing systems are agreed upon.
	1.3 Any relevant external standards, requirements and conventions are identified.
	1.4 Document control, tracking, updating and storage processes are agreed.
	1.5 Document management processes and standards are prepared and circulated to relevant stakeholders.
	1.6 Any variations are negotiated.
2. Determine document style and establish standards and conventions	2.1 Potential document styles are considered.
	2.2 Document conventions and layout are agreed.
	2.3 Standard symbols, abbreviations and similar are agreed.
	2.4 A style sheet, document model or template, as appropriate is produced.
	2.5 Document style conforms to document management standards are checked.
	2.6 Documents are circulated to relevant stakeholders and any variations are negotiated.
3. Implement document control strategy	3.1 A document control strategy and procedures, including arrangements for ongoing review of strategy is developed.

	3.2 Mechanisms are established to check documents conform to the control strategy.
	3.3 Appropriate staff development is arranged.
	3.4 Implementation of **document control strategy** is monitored.
	3.5 Improvements to the documentation control strategy, as appropriate are made.

Variable	Range
Documents	May include but not limited to: • hard copies of documentation, such as correspondence, procedures, contracts, agreements, specifications, production and other records, manuals and other reference materials • computer files, including word processed files and spreadsheets • technical drawings both hard copy or CAD files
The document control strategy	May include but not limited to: • authoring control • version control • access and distribution • review and revision • storage and archiving • access and security • approval for and means of destruction
Archiving of documentation	• may be required to comply with legislative or regulatory requirements, and/or with organizational policy • should include an indexing system that specifies the period for which the document is to be retained • should comply with relevant requirements regarding physical storage and security
Distribution control	May include a listing of recipients of each type of document and, where required, a document tracking system
External standards, requirements and conventions	May include but not limited to: • ISO900 requirements • engineering and other technical standards • drawing standards • organizational style/marketing guides • documentation requirements of suppliers, customers and regulatory agencies
Competitive systems and practices	May include but 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) - take time - process mapping - problem solving - run charts - standard procedures and 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

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: - identify and establish organization goals and requirements for document control - access and use relevant external standards, requirements and conventions to determine implications for document control strategy produce document control guidelines and procedures and verify for accuracy and suitability for application across organization.
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: - needs of the organization and its' individuals - word processing, spreadsheet and other software capable of producing files and documentation - types of documentation used in organizations

	• version and distribution control systems • archiving systems • document destruction systems • legislative and regulatory requirements associated with documentation relevant to the organization

Underpinning Skills	Must demonstrate skills in:
	• leading and motivating a working group
	• analyzing scope and purpose of an organization and matching to document control needs
	• preparing briefings and arranging training for employees in document control strategy
	• determining file management strategy for files from relevant computer applications which may include:
	    ➢ word processing
	    ➢ spreadsheets
	    ➢ databases
	    ➢ drawing and drawing linked applications e.g. Computer Aided Drafting (CAD)/Computer Aided Manufacturing (CAM)
	• researching style manuals and other style reference materials for possible application to organization style templates and guidelines
	• using oral and written communication to convey broad and specialized information in a variety of media and 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.

Occupational Standard: Pharmaceuticals Manufacturing Management Level V	
Unit Title	**Manage People Performance**
Unit Code	**IND PHR5 03 0613**
Unit Descriptor	This unit describes the performance outcomes, skills and knowledge required to manage the performance of staff who report to them directly. Development of key result areas and key performance indicators and standards, coupled with regular and timely coaching and feedback, provide the basis for performance management.

Elements	Performance Criteria
1. Allocate work	1.1 Relevant groups and individuals are consulted on work to be allocated and resources available.
	1.2 Work plans are developed in accordance with operational plans.
	1.3 Work in a way that is efficient, cost effective and outcome focused are allocated.
	1.4 *Performance standards*, *Code of Conduct* and work outputs are confirmed with relevant teams and individuals.
	1.5 *Performance indicators* are developed and agreed with relevant staff prior to commencement of work.
	1.6 *Risk analysis* in accordance with the organizational risk management plan and legal requirements are conducted.
2. Assess performance	2.1 *Performance management* is designed and processes are reviewed to ensure consistency with organizational objectives and policies.
	2.2 Participants are trained in the performance management and review process.
	2.3 Performance management is conducted in accordance with organizational protocols and time lines.
	2.4 Performance is monitored and evaluated on a continuous basis.
3. Provide feedback	3.1 Informal feedback is provided to staff on a regular basis.
	3.2 A relevant person where there is poor performance is advised and necessary actions are taken.

	3.3 On-the-job coaching when necessary is provided to improve performance and **excellence in performance** is confirmed.
	3.4 Performance in accordance with the organizational performance management system is documented.
	3.5 Formal structured feedback sessions as necessary and in accordance with organizational policy are conducted.
4. Manage follow up	4.1 Performance improvement and development plans in accordance with organizational policies are written and agreed.
	4.2 Assistance is sought from human resources specialists where appropriate.
	4.3 Excellence in performance through recognition and continuous feedback is reinforced.
	4.4 Individuals with poor performance are monitored and coached.
	4.5 Support services where necessary is provided.
	4.6 Individuals who continue to perform below expectations are counseled and the disciplinary process if necessary is implemented.
	4.7 Staff in accordance with legal and organizational requirements where serious misconduct occurs or ongoing poor-performance continues is **terminated**.

Variable	Range
Performance standards	May mean: • level of performance sought from an individual or group which may be expressed either quantitatively or qualitatively
Code of Conduct	May mean: • agreed (or decreed) set of rules relating to employee behaviour/conduct with other employees or an agreed (or decreed) set of rules relating to employee behaviour/conduct with other employees or customers
Performance indicators	May mean measures against which performance outcomes are gauged
Risk analysis	May mean determination of the likelihood of a negative event preventing the organization meeting its objectives and the likely consequences of such an event on organizational performance

Performance management	May mean: • in accordance with relevant industrial agreements • process or set of processes for establishing a shared understanding of what an individual or group is to achieve, and managing and developing individuals in a way which increases the probability it will be achieved in both the short- and long-term
Excellence in performance	May mean: • regularly and consistently exceeding the performance targets established while meeting the organization's performance standards
Termination	May mean: • cessation of the contract of employment between an employer and an employee, at the initiative of the employer within relevant industrial agreements

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills of: • documented performance indicators and a critical description and analysis of performance management system from the workplace • techniques in providing feedback and coaching for improvement in performance • Knowledge of relevant awards and certified agreements.
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • relevant legislation from all levels of government that affects business operation, especially in regard to occupational health and safety and environmental issues, equal opportunity, industrial relations and anti-discrimination • relevant awards and certified agreements • performance measurement systems utilized within the organization • unlawful dismissal rules and due process staff development options and information.
Underpinning Skills	Must demonstrate skills of: • communication skills to articulate expected standards of performance, to provide effective feedback and to coach staff who need development • risk management skills to analyze, identify and develop mitigation strategies for identified risks planning and organization skills to ensure a planned and objective approach to the performance management system.

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 Management Level V	
Unit Title	**Manage Operational Plan**
Unit Code	**IND PHR5 04 0613**
Unit Descriptor	This unit applies to people who manage the work of others and operate within the parameters of a broader strategic and/or business plan. The task of the manager at this level is to develop and implement an operational plan to ensure that the objectives and strategies outlined in the strategic and/or business plan are met by work teams. However in some larger organizations operational plans may be developed by a strategic planning unit. At this level work will normally be carried out within complex and diverse methods and procedures, which require the exercise of considerable discretion and judgment, using a range of problem solving and decision making strategies.

Elements	Performance Criteria
1. Develop operational plan	1.1 **Resource requirements** are researched, analyzed and documented and an operational plan in consultation with **relevant personnel**, **colleagues and specialist resource managers** is developed. 1.2 **Consultation processes** as an integral part of the operational planning process is developed and/or implemented. 1.3 Details of the operational plan including the development of **key performance indicators** are ensured to measure organizational performance. 1.4 **Contingency plans** are developed and implemented at appropriate stages of operational planning. 1.5 The development and presentation of proposals for resource requirements is ensured and supported by a variety of information sources and specialist advice is sought as required. 1.6 Approval for plan from relevant parties is obtained and understanding among work teams involved is ensured.
2. Plan and manage resource acquisition	2.1 Strategies are developed and implemented to ensure that employees are recruited and/or inducted within the organization's human resources management policies and practices.

	2.2 Strategies are developed and implemented to ensure that physical resources and services are acquired in accordance with the *organization's policies*, *practices and procedures*.
3. Monitor and review operational performance	3.1 Performance systems and processes are developed, monitored and reviewed to assess progress in achieving profit and productivity plans and targets.
	3.2 Budget and actual financial information is analyzed and interpreted to monitor and review profit and productivity performance.
	3.3 Areas of underperformance, recommend solutions are identified, and prompt action is taken to rectify the situation.
	3.4 Systems are planned and implemented to ensure that mentoring and coaching are provided to support individuals and teams to effectively, economically and safely use resources.
	3.5 Recommendations for variations are negotiated to operational plans and gain approval from *designated persons*/*groups*.
	3.6 Systems are developed and implemented to ensure that procedures and records associated with documenting performance are managed in accordance with organizational requirements.

Variable	Range
Resource requirements	May include: • goods and services to be purchased and ordered • human, physical and financial resources - both current and projected • stock requirements and requisitions
Relevant personnel, colleagues and specialist resource managers	May include: • employees at the same level or more senior managers • managers • occupational health and safety committee/s and other people with specialist responsibilities • supervisors and union or employee representatives
Consultation processes	May refer to: • email/intranet communications, newsletters or other processes and devices which ensure that all employees have the opportunity to contribute to team and individual operational plans

	• mechanisms used to provide feedback to the work team in relation to outcomes of consultation • meetings, interviews, brainstorming sessions
Operational plans	May also be termed: • action plans • annual plans • management and tactical plans
Key performance indicators	May refer to: • measures for monitoring or evaluating the efficiency or effectiveness of a system which may be used to demonstrate accountability and to identify areas for improvements
Contingency plans	May include: • contracting out or outsourcing human resources and other functions or tasks • diversification of outcomes • finding cheaper or lower quality raw materials and consumables • increasing sales or production • recycling and re-using • rental, hire purchase or alternative means of procurement of required materials, equipment and stock • restructuring of organization to reduce labour costs • risk identification, assessment and management processes • seeking further funding • strategies for reducing costs, wastage, stock or consumables • succession planning
Organization's policies, practices and procedures	May include: • organizational culture • organizational guidelines which govern and prescribe operational functions, such as the acquisition and management of human and physical resources • Standard Operating Procedures(SOPs) • undocumented practices in line with organizational operations
Designated persons/groups	May include: • groups designated in workplace policies and procedures • managers or supervisors whose roles and responsibilities include decision making on operations • other stakeholders such as Board members • other work groups or teams whose work will be affected by recommendations for variations

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills in: • development of an operational plan with details of how it will be implemented and monitored • Knowledge of models and methods for operational plans.
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • models and methods for operational plans • budgeting processes • alternative approaches to improving resource usage and eliminating resource inefficiencies and waste
Underpinning Skills	Must demonstrate skills in: • literacy skills to access and use workplace information and to write a succinct and practical plan • technology skills to use software to produce and monitor the plan against performance indicators • planning and organizational skills • coaching skills to work with people with poor performance • numeracy skills to allocate and manage financial resources
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 Management Level V	
Unit Title	**Develop Quick Changeover Procedures**
Unit Code	**IND PHR5 05 0613**
Unit Descriptor	This unit of competency covers the skills and knowledge required to develop/improve changeovers for equipment, processes or operations. It includes critically analyzing existing changeovers, applying quick changeover principles, and developing improved changeover procedures.

Elements	Performance Criteria
1. Analyse changeover	1.1 Observe changeover process is critically observed.
	1.2 Steps in changeover are identified.
	1.3 Start situation and required finish situation for changeover is identified.
2. Apply quick changeover principles	2.1 Changes are identified to the start situation and required finish situation which are possible.
	2.2 Internal and external **changeover activities** are identified.
	2.3 Activities which could be improved/eliminated are identified.
	2.4 Adjustments required after changeover are eliminated/reduced.
	2.5 Improved changeover process and recommendations for implementation procedure are developed.
	2.6 Relevant people are liaised with to validate recommendations.
3. Assess and minimise risks in changeover	3.1 **Hazards and risks** from all steps in changeover are analyzed.
	3.2 Ergonomic principles and hierarchy of control are applied to each equipment and manual hazard.
	3.3 Any regulatory risk in changeover is assessed.
	3.4 Hazards during changeover are minimized ensuring final risk profile is acceptable.
4. Implement improved changeover	4.1 Any required resources and approvals are acquired.
	4.2 Trials of improved changeover are organized.
	4.3 Trial is monitored.

| | 4.4 Adjustments to changeover process are made. |
| | 4.5 Improved changeover process is implemented. |

Variable	Range
Changeover	May refer to: • equipment exchanges, such as an exchange of punch, pin, dies/tools (traditional) • change between batches • change between campaigns (process manufacturing) • quantum equipment/process change to produce a different product
Quick changeover	May be known by a number of alternative titles depending on the industry sector. In manufacturing quick changeovers may be referred to as: • Single Minute Exchange of Die (SMED) • single-digit set-up – performing a set-up activity in a single-digit number of minutes (i.e. fewer than ten) • One Touch Exchange of Die (OTED) – literally, changing a die with one physical motion, such as pushing a button – broadly, an extremely simple procedure for performing a set-up activity • While the term die is the traditional term, organizations that require changeovers using other equipment are also covered by this unit. • This unit may not be applicable to a totally continuous operation producing only the one product, or simultaneous range of products. This is not applicable to a maintenance/Pressure Vessel Inspection (PVI) shutdown as experienced by the continuous process manufacturers. However, where there are continuous operations on a campaign basis, it may be applied to the development of changeover procedures between campaigns or similar changeovers
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) • 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
Set-up work	Is the work required to change over a machine or process from one item or operation to the next item or operation. It can be divided into two types: • internal set-up work that can be done only when the machine or process is not actively engaged • external set-up work that can be done concurrently with the machine or process performing productive duties
The principles of quick changeover	May include: • the principles of efficient movement as well as an understanding of equipment features and aids, including jigs, fixtures, locating devices and mechanical aids which will reduce human effort and time required
Activities which should be improved/eliminated	May include: • those which take time or are unreliable in terms of outcome • those which are difficult to do or have adverse OHS implications (e.g. repetitive strain injury, back injury and finger injuries)
Hazards and risks	May include: • OHS • regulatory compliance • environment • commercial and contractual obligations

	• An acceptable risk profile for changeovers is one which, at the minimum, meets regulatory and organization requirements and does not increase the current risk profile
Procedures	May include: • work instructions • standard operating procedures • formulas/recipes • batch recordings • temporary instructions and similar instructions provided for the smooth running of the plan • good operating practice as may be defined by industry codes of practice (e.g. good manufacturing practice (GMP) and responsible care) • government regulations Procedures may be: • written, verbal, computer-based or in some other format

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • observe and analyze steps in an existing changeover • manage risks in adjusting changeover procedures • develop changeover adjustments that deliver the greatest overall benefit • supervise changeover procedure trials.
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • principles of quick changeover • equipment and operating environment of activities subject to quick changeover • regulatory and commercial obligations and risk environment for operations subject to quick changeover analysis • safe movement and other relevant Occupational Health and Safety (OHS) principles • relevant procedures • purposes/requirements of changeover • sourcing of resources • trialling procedures
Underpinning Skills	Must demonstrate skills in: • critically analyzing an existing changeover, including a detailed examination of all actions and delays and the times taken • determining key steps in changeover • identifying regulatory implications and other risks changes to procedures

	- differentiating between habitual practice and necessary activity - identifying opportunities to maximize external set up work - communicating with others to explain and supervise changed procedures
Resources Implication	Access is required to real or appropriately simulated situations, including work areas, materials and equipment, and to information on workplace practices and OHS practices.
Methods of Assessment	Competence may be assessed through: - Interview / Written Test - Observation / Demonstration with Oral Questioning
Context of Assessment	Competence may be assessed in the work place or in a simulated work place setting.

Occupational Standard: Pharmaceuticals Manufacturing Management Level V	
Unit Title	**Schedule and Manage Production**
Unit Code	**IND PHR5 06 0613**
Unit Descriptor	This unit of competency covers the skills and knowledge required to plan, monitor and adjust schedules to meet operational requirements.

Elements	Performance Criteria
1. Identify production requirements	1.1 Forecast and sales information is used to identify production requirements. 1.2 Production priorities are identified to satisfy demand.
2. Identify resource requirements to meet production requirements	2.1 Stock levels of raw materials/ingredients, packaging components and consumables are confirmed against production requirements. 2.2 Equipment capacity and status and human resources are confirmed against production requirements.
3. Develop and communicate the production schedule	3.1 The production *schedule* is developed to meet demand and delivery timelines within production capacity and budget. 3.2 The production schedule takes account of stock levels, storage capacity, equipment capacity and product mix to minimize stock and product holdings and maximize production efficiency. 3.3 The production schedule is recorded in the appropriate workplace format. 3.4 The production schedule is made available to relevant personnel in a timely manner.
4. Monitor actual against scheduled production	4.1 Production is monitored to identify actual and potential barriers to achieving the schedule. 4.2 Resource usage rates are monitored to identify potential shortages. 4.3 Unplanned events that could affect the schedule are identified, assessed and addressed.
5. Adjust production schedules	5.1 Production schedules are adjusted to take account of changed conditions. 5.2 Changes to the production schedule are negotiated and communicated to relevant personnel in a timely manner.

	5.3 Resource implications of amended schedules are identified and resources are accessed to meet requirements.
	5.4 Potential failure to meet delivery deadlines are identified and communicated to relevant personnel in a timely manner.
	5.5 Schedule documentation is amended as required to meet workplace reporting requirements.
6. Review production schedule development process	6.1 The production scheduling process is reviewed to identify opportunities for improvement.
	6.2 Variances in production against schedule are identified, investigated and reported.
	6.3 Personnel responsible for implementing the schedule are consulted to identify improvement opportunities.
	6.4 The scheduling process is revised to reflect improvements.

Variable	Range
Scheduling	May involve: • the use of planning and systems control software, such as SAP and MRPII
Schedules	May be based on customer orders and/or market forecasts
Policies and procedures	Production scheduling is 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 of scheduling arrangements

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • confirm production requirements and resource implications • establish and document production schedule • coordinate implementation of schedule • ensure production schedule is communicated and reported to all appropriate personnel • manage unplanned production issues • assess production outcomes against schedule and make required adjustments.
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • the role and scope of the scheduling function, including flow of information to and from the scheduling process and the impact of scheduling for related planning, purchasing, production and dispatch processes

	- factors to be taken into account in planning the schedule, including the inter-relationships between factors, such as - use-by codes - production capacity and availability - labor requirements and availability - product compatibility - capacity of related processes and/or storage facilities - consequences of failing to meet delivery timelines - the characteristics of raw materials/ingredients, packaging components and consumables and production process to determine the most efficient plan to meet production requirements, including stock shelf-life, product compatibility (with the exception of dedicated product lines) and changeover procedures - equipment capacity to ensure that production quantities and timelines are achievable - methods used to monitor actual to planned production, such as use of systems software and Key Performance Indicators (KPIs) where these are collected on a real time basis - relevant personnel and departments to be consulted/notified of production schedule and related amendments, including the information relevant to each group/person - awareness of conditions that can affect achievement of schedule, including conditions that are unusual or unplanned and related options for response - options for maximizing resource utilization and minimizing waste, including options for alternate resource allocation in response to unplanned events - recording systems and requirements - process improvement procedures - supplier capacity and timeframes where relevant - competencies required by the work process and competencies held by the work team where relevant
Underpinning Skills	Must demonstrate skills to: - identify and confirm resource requirements to meet the schedule, such as stock levels, equipment availability and capacity, personnel, storage capacity, and transport, and where required, identify alternate sources of supply for resources in short supply - develop a schedule to match production priorities to available resources, such as consulting relevant personnel to confirm schedule feasibility, and notifying relevant

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<tr><td></td><td>personnel of any possibility that demand cannot be met within required timeframe</td></tr>
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	- record and communicate the schedule in appropriate formats, such as use of software and communicating information to meet workplace and audience requirements - monitor actual production and materials usage levels against production plan to identify variances and take appropriate corrective action, including assessing the consequences of any adjustments to the schedule for the customer, the company and resource availability - adjust the schedule in response to typical and atypical variables affecting achievement of schedule - respond to unplanned events to minimize disruption and optimize efficiency - confirm that resources and personnel are available to meet amended schedule and, if not, take action to secure requirements - communicate schedule changes to affected personnel - track and investigate variance to identify cause - follow review procedures to identify opportunities to improve scheduling process - follow procedures to adopt and communicate improvements to the scheduling process - use planning and systems control software according to enterprise procedures - match work allocation to competencies available in the work team according to enterprise procedures - use communication skills to interpret and complete work information to support operations of work team or area - use communication skills to consult and communicate with relevant personnel - 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 Management Level V	
Unit Title	**Adapt a Proactive Maintenance Strategy for a Seasonal or Cyclical Manufacturing**
Unit Code	**IND PHR5 07 0613**
Unit Descriptor	This unit of competency covers the skills and knowledge required to develop a standard proactive maintenance strategy for a seasonal or cyclical operational processes or similar. This unit applies to an individual responsible for developing a proactive maintenance strategy for an organization that operates seasonal/cyclical plant and also adopts proactive maintenance strategies. The organization will also usually be implementing other competitive systems and practices. The unit covers changing the normal priority of some of the choices which need to be made in implementing a proactive maintenance strategy. The unit applies to the selection of appropriate strategies, initial development and implementation will need to be managed as well as application of the strategies to new areas and the improvement of operation in existing areas. This unit requires the application of skills associated with problem solving, initiative, enterprise, planning and organizing in order to adapt a proactive maintenance strategy to meet seasonal or cyclical needs of the enterprise. This work is done in the context of using computer technology and also requires aspects of self-management and learning to ensure improvement of own performance.

Elements	Performance Criteria
1. Interpret proactive maintenance strategy	1.1 Proactive maintenance strategy is analyzed.
	1.2 Areas which may conflict with cyclical requirements are identified.
	1.3 *Critical conditions* which must be met in order to maintain plant reliability until season end are identified.
	1.4 Cycle requirements are compiled for proactive maintenance strategy.
2. Identify cyclical requirements of the process	2.1 When the season finishes and the expected cycle duration, the requirements are established.
	2.2 Plant items and maintenance activities which production imperatives dictate can only be completed after season end are identified.

	2.3 Critical conditions which must be met in order to maintain plant reliability until season end is identified.	
	2.4 Cycle requirements are compiled for proactive maintenance strategy.	
3. Identify maintenance requirements of ancillary equipment	3.1 Proactive maintenance requirements of ancillary equipment are identified.	
	3.2 Maintenance which can only be done at season end is identified.	
	3.3 *Ancillary equipment* requirements for proactive maintenance strategy are compiled.	
4. Identify maintenance requirements during season	4.1 A critical maintenance activity which must be done during season is identified.	
	4.2 Conflicts are negotiated with seasonal or cyclical processing requirements.	
	4.3 Proactive maintenance strategy requirements during season are compiled.	
5. Adapt proactive maintenance strategy	5.1 Identified requirements are compared to the proactive maintenance strategy	
	5.2 A proactive maintenance strategy which meets these requirements is negotiated.	
	5.3 Team members are involved in relating identified problems and opportunities for improvement to the maintenance strategy, and involved them in developing any required changes to ensure awareness, learning and commitment.	
	5.4 The implementation of the strategy is monitored to ensure the identified requirements are met.	
	5.5 Required adjustments are made and review schedule are arranged.	

Variable	Range
Critical conditions	Are those factors which must be undertaken to maintain plant reliability during processing season. These may include: • maximum load factors • lubrication schedules • correct operating temperatures • cleaning and waste removal schedules • equipment inspection and test schedules • development of standard operating procedures and training of operators

Ancillary equipment	May include other plant, such as:
	• boilers
	• utilities
	• plants
	• waste treatment and hazard control equipment (e.g. fire ring mains, fire monitors, steam curtains, gas (or other loss of containment) monitors, blast protection and flare stacks)
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
TPM	TPM refers to:
	• an application of total quality management to maintenance with the intention of increasing reliability, getting it right first time and increasing OEE

RCM	RCM includes: • moving maintenance from reactive, or even planned/programmed towards a focus on uptime and OEE
RCA	• RCA is a structured problem solving technique. Typically 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.
MBTF	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 MBTF is reducing, then it is an indicator that the maintenance regime is failing.
FMEA	Is a systematic approach that identifies potential failure modes in a system, product, or operations/assembly operation caused by either design or operations/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 Hazard and Operability Studies (HAZOP) for design and modification.
Uptime	Refers to the overall availability of the plant (it is the inverse of downtime) or the unavailability of the plant. Ideal uptime is 100%
overall equipment effectiveness(OEE)	Is the combination of the main factors causing loss of productive capacity from equipment/plant and is where: • OEE = availability x performance x quality rate • 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 losses due to rejects, reworks and start-up waste
Condition monitoring	involves often quite sophisticated monitoring of equipment, including such things as: • vibration monitoring • instrumental analysis of lubricating oil, and so on, to determine the current state of the equipment, monitor the change in this condition and predict when it needs servicing/maintenance to maintain reliability

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.

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • analyze the equipment availability requirements of a seasonal or cyclical operation • consider a variety of proactive maintenance strategies for suitability to a seasonal or cyclical operation • consult operators, maintenance, management and other stakeholders in decisions on proactive maintenance strategies • monitor the implementation of selected proactive maintenance strategies and make required adjustments.

Underpinning Knowledge and Attitudes	Must demonstrate knowledge of:
	• processing equipment and products of the organization
	• start-up, shutdown and isolation considerations for the organization
	• skills required by operators and maintenance personnel to achieve effective proactive maintenance strategy implementation
	• characteristics and strengths of different types of strategies, techniques and tools, such as:
	  ➢ Total Productive Maintenance (TPM)
	  ➢ Reliability Centered Maintenance (RCM)
	  ➢ Mean Time Between Failure (MBTF
	  ➢ Failure Mode Effects Analysis (FMEA)
	  ➢ condition monitoring
	  ➢ Root Cause Analysis (RCA)
	• holistic costs of different strategies combining cost of maintenance with costs of lost production, sales, and so on, as relevant to the organization
	• business goals sufficient to match the strategy to the business needs
	• strategic thinking and its application to proactive maintenance
	• principles of process equipment and how to improve its reliability
	• resources required and how to obtain them

Underpinning Skills	Must demonstrate skills in: • considering the impact of seasonal and cyclical production requirements on equipment availability requirements • prioritizing maintenance activities critical to production

	• communicating with others using a variety of media and techniques
	• adapting personal communication strategy to different levels of literacy and numeracy in target individuals and groups
	• working in a team
	• analyzing quantitative and qualitative information to determine proactive maintenance strategy options
	• solving problems to root cause
	• applying basic arithmetic and statistical techniques
	• planning complex strategies, including consideration of timelines, resources, benefit/cost, implementation requirements, and monitoring and adjustment considerations
	• reading and interpreting engineering specifications, drawings and charts
	• using information system terminals and computers
	• prioritizing options, including reasons and recommendations
	• 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 Management Level V	
Unit Title	**Develop Processes for the Management of Breaches in Compliance Requirements**
Unit Code	**IND PHR5 08 0613**
Unit Descriptor	This unit describes the performance outcomes, skills and knowledge required to develop and monitor the processes for managing identified breaches in the fulfillment of compliance requirements within an organization. This unit has been designed to be consistent with Compliance programs. This unit applies to individuals working as a chief executive or manager in a small organization (where it would be part of their broad role), or as a compliance officer or senior manager within a larger organization with responsibility for identifying, classifying, investigating, rectifying and reporting breaches in compliance requirements.

Elements	Performance Criteria
1. Develop procedures for responding to breaches in internal and external compliance requirements	1.1 Information on current ***compliance requirements*** applicable to the organization is obtained and interpreted. 1.2 Each area of compliance requirement is reviewed to establish potential breaches. 1.3 Appropriate procedures for identifying, classifying, investigating, rectifying and reporting breaches in compliance requirements are developed and documented.
2. Monitor adherence to compliance requirements	2.1 Organization operations are monitored and evaluated to identify incidences of breaches in compliance requirements. 2.2 Complaints and other ***sources of information on potential breaches in compliance requirements*** are reviewed and evaluated. 2.3 Compliance management information system is interrogated to identify any indication of breaches in compliance requirements.
3. Manage the identification and rectification of breaches in compliance	3.1 Appropriate staff is assigned to take the required action to identify, classify, investigate and rectify breaches in compliance requirements. 3.2 Senior management team within the organization is ensured if informed of all breaches in compliance requirements.

4. Liaise with relevant personnel and organizations during breach management	4.1 Liaison is maintained with *relevant regulatory authorities and other organizations with an interest in compliance* in regard to breaches in requirements and related action being taken.
	4.2 Advice is taken from *relevant internal and external personnel* on the management of breaches in compliance requirements and act upon this advice appropriately.
5. Evaluate the response to and rectification of, breaches in compliance	5.1 Action taken is monitored to manage and rectify an identified breach in compliance requirements in terms of the organization's compliance policy.
	5.2 Success in rectification of compliance breaches is confirmed and relevant internal and external personnel are notified.
	5.3 Problems in the rectification of compliance breaches are recognized and initiated appropriate action to ensure that management of the breach is maintained.
	5.4 Reports of systemic and recurring problems of non-compliance are referred to those with sufficient authority to correct them.
6. Document and disseminate the breach management activities and outcomes	6.1 Identified breaches in compliance requirements in accordance with relevant internal and external requirements are documented and reported.
	6.2 Records of breaches in compliance requirements are maintained and stored.
	6.3 The action taken is reported to rectify identified breaches in compliance requirements and the outcomes of this action.
	6.4 Reports on breach management are disseminated to relevant internal and external personnel.

Variable	Range

Compliance requirements	May include:
	• different types of external and internal compliance requirements including:
	  ➢ accreditation requirements of an institute, professional organization or registration body
	  ➢ internal policies, procedures, standards or codes of practice of an organization
	  ➢ regulations of a state/territory, national or international regulatory authority

	> requirements for certification under statutory licensing systems and statutory standards or codes of practice
	• cross-industry, industry-specific and internal organizational compliance requirements in such areas as : > anti-discrimination (including discrimination by race, sex, disability, religion, etc.) > bankruptcy > chemical use, child protection, construction, conveyance/real estate, copyright, corporate governance, customs, credit > education, electricity, environmental protection, equal opportunity > financial services (including banking), fire, freedom of information, freight forwarding > gambling, gene technology > health, human rights > insurance, immigration, intellectual property > land management > pharmaceuticals, patents, privacy > quarantine > racing, rail transport, road transport > safety (including cross-industry generic regulations as well as industry, equipment or product-specific sub-categories e.g. marine safety, rail safety, aviation safety, road safety, dangerous goods, construction safety, mine safety, road safety, etc.), security, sewage, superannuation > taxation, telecommunications, tobacco, trade practices and consumer protection > water supply, workers compensation, workers rehabilitation
Sources of information on potential breaches in compliance requirements may include:	• external reviews of organization operations • feedback from clients, suppliers • feedback from organization managers and operations personnel • internal audit reports • reports from regulatory authorities and other organizations with an interest in compliance
Relevant regulatory authorities and other organizations with an interest in compliance	May include: • educational institutions and organizations • government departments • internal audit managers within the organization • professional associations and institutes • regulatory authorities

Relevant internal and external personnel	May include:
	• board of directors
	• chief executive officer
	• chief executives and managers in organizations with an interest in the compliance issues being researched
	• compliance management team (where relevant)
	• compliance specialists at the operational level
	• frontline managers
	• legal and business advisors and consultants with expertise and interest in compliance requirements and related management systems
	• representatives of professional associations and institutes relevant to the organization's operations and sphere of business
	• representatives of relevant authorities in pertinent compliance areas and senior management team

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills in:
	• development of processes for managing organizational compliance breaches
	• knowledge of compliance requirements applicable to the organization
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of:
	• analysis techniques relevant to the review and interpretation of an identified breach in compliance requirements
	• compliance requirements applicable to the organization
	• elements of compliance program/management system including:
	➢ documentation of compliance requirements relevant to the organization
	➢ specification of compliance management functions, accountabilities and responsibilities within the organization
	➢ compliance related management information systems
	➢ record keeping systems required for compliance management
	➢ liaison procedures with relevant internal and external personnel on compliance related matters
	➢ breach management policies and processes including the identification, classification, investigation, rectification and reporting of breaches in compliance requirements

	- compliance reporting procedures - corporate induction and training processes related to compliance management - processes for the internal and external promulgation and promotion of information on compliance requirements and compliance program/management system - compliance complaints handling systems - continuous improvement processes for compliance including monitoring, evaluation and review - strategies for developing a positive compliance culture within the organization - techniques and performance indicators for monitoring the operation of a compliance/program management system - internal and external personnel with an interest in compliance - organizational responsibilities for compliance - planning processes of the organization - potential breaches in compliance requirements - relevant organizational policies and procedures including: - procedures for breaches in compliance requirements - compliance plans and policies in various compliance areas - organizational standards for operations and ethics - reporting processes on compliance management including reports on breaches and rectification action - Sections of relevant Ethiopian and international standards dealing with aspects of breach management processes and responsibilities.
Underpinning Skills	Must demonstrate skills of: - interpersonal skills to contribute to a positive culture of compliance within an organization - investigative skills to gather information on how breaches in compliance requirements occurred - organizational skills to develop and monitor processes to manage breaches in compliance requirements, including: - determining compliance requirements applicable to the organization - sourcing information on breach management systems suitable for the organization - developing a breach management system and related procedures - managing other personnel dealing with identified breaches in compliance requirements

	➢ documenting breach management procedures
	➢ applying investigative skills to the level required
	• Communication and interpersonal skills to relate to internal and external personnel and in particular those representing relevant regulatory authorities, professional institutes and organizations, standards organizations, etc.
	• Technical skills to use communications technology effectively.
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 Management Level V	
Unit Title	**Perform Basic Statistical Quality Control**
Unit Code	**IND PHR5 09 0613**
Unit Descriptor	This unit covers taking samples and applying a statistical process to monitor production.

Elements	Performance Criteria
1. Take samples	1.1 Difference between population and sample is understood.
	1.2 Various **sampling schemes** are applied in accordance with standard operating procedures.
2. Apply statistical process to monitor production	2.1 Concept of variation in terms of average and spread is understood. Data is used to produce **relevant statistical information.**
	2.2 Data is interpreted accurately and information is presented to appropriate authority according to standard operating procedures.

Variable	Range
Sampling schemes	• Acceptable Quality Level (AQL) and Average Outgoing on Quality Level plans ,check physical parameters(weight, thickness etc), Six Sigma etc.
Relevant statistical information	Average, range and process control data and the plotting of charts such as line graphs, run charts, tally charts, histograms, control charts, random and assignable causes etc.

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • Perform all elements of the unit as specified by the criteria, including required knowledge, and be capable of applying the competency in new and different situations and contexts.
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • the difference between population and sample, and the concept of variation in terms of average and range, random and assignable causes • numerical operations and statistical calculations/formulae within the scope of this unit • statistical process control procedures, which may include Six Sigma etc. and the sampling procedures to be followed

	• the types of charts that can be produced to assist monitoring of products including run charts, tally charts, histograms, control charts • procedures for reporting sample data information • use and application of personal protective equipment safe work practices and procedures
Underpinning Skills	Must demonstrate skills in: • reading, interpreting and following information on written job instructions, standard operating procedures, charts, lists, drawings and other applicable reference documents • applying statistical process control procedures in accordance with instructions to a given production process • obtaining data from samples including average, range and random or assignable causes • producing tally, run or control charts from sampling data • reporting information from sampling data • checking and clarifying task-related information • completing proformas and standard workplace forms
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 Management Level V	
Unit Title	**Develop a Communications Strategy to Support Production**
Unit Code	**IND PHR5 10 0613**
Unit Descriptor	This unit of competency covers the skills and knowledge required to develop and implement a communications strategy to support employees in a production or operational environment where competitive systems and practices are being implemented.

Elements	Performance Criteria
1. Determine information needs of employees and production or operations systems	1.1 Competitive systems and practices strategy are examined and broad information framework is determined.
	1.2 The production or operational processes and their requirements are examined and the information needs of employees in these areas are determined.
	1.3 *Operational support areas* are examined and the information needs of employees are determined.
	1.4 Information used and desired with employees at all relevant levels are discussed, and team and other key personnel in strategy development are involved to ensure awareness, learning and commitment.
	1.5 Control systems are examined to determine their data needs.
2. Select communication strategy	2.1 Required information flows are analyzed.
	2.2 *Access requirements* by information users are determined.
	2.3 Suitability of communication media for required information flows and access are evaluated.
	2.4 Implications of contingencies and non-conformances for communication strategy are considered.
	2.5 Possible strategy is discussed with relevant stakeholders.
	2.6 An appropriate strategy or strategies is selected.
3. Implement strategy	3.1 A list of what needs to be achieved is developed.
	3.2 Resources required to implement strategy is determined.
	3.3 Authority for communication media to be developed

	3.4 Development of communication media is monitored and appropriate corrective action, as required is taken.
	3.5 Developed *communication media* is deployed.
4. Monitor ongoing situation	4.1 Relevant indicators for communication strategy are determined.
	4.2 Indicators are monitored.
	4.3 Communication needs on a regular basis are re-evaluated.
	4.4 Improvements are made to the communication strategy, as appropriate.

Variable	Range
Operations support areas	Refers to areas other than production and may be located in the organization or be in an external organization that provides support services as part of its business. Examples include: • office • logistics • sales • marketing • insurance • legal • training and utilities providers
Information access requirements	May include: • timing of access (e.g. occasional, periodic and continual) • method of access (e.g. visual/auditory/tactile access) • online/hard copy access • access locations
Communication media	May include: • terminals, computers, and so on, with built in memory • internet • hard copy manuals, such as standard operating procedures, Occupational Health and Safety (OHS) and training manuals • verbal briefings and informal conversations • circulars and letters • signage • instruction displays • tags and isolations/lockouts • permits to work/clearances • visual factory type displays and painted walkways
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 and 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
Stakeholders may include:	• team members • personnel officers • industrial officers • union delegates • production and operations management • human relations management • financial management and engineering/technical personnel

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • analyze competitive systems and practices implementation and determine information flow requirements • communicate information verbally and in writing across different levels of complexity using a variety of methods and mediums

	• monitor outcomes of communication strategies against KPIs • plan and implement strategies to make gains from competitive systems and practices apparent and easily understood to different audiences • determine communication needs during contingencies and non-conformances.
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • strategic requirements of own organization • common techniques used in competitive systems and practices and key concepts required to be communicated to employees • communication media, relevant software and standard formats
Underpinning Skills	Must demonstrate skills of: • identifying the competitive systems and practices strategies being implemented in the organization and stage of implementation • using formal problem solving procedures, such as Root Cause Analysis (RCA) • analyzing and planning for communication needs of production and operations employees • developing formal and informal communication procedures with employees in production and operational areas using a variety of media and formats • linking communication strategy Key Performance Indicators (KPIs) to KPIs for implementation of competitive systems and practices • establishing feedback, control and monitoring arrangements to gauge the success of communication strategies • briefing key personnel on the communication strategies • interpreting documents, procedures and instructions for others • giving presentations and briefings
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 Management Level V	
Unit Title	**Facilitate the Use of Planning Software Systems in Manufacturing**
Unit Code	**IND PHR5 11 0613**
Unit Descriptor	This unit of competency covers the skills and knowledge required to facilitate the use of planning software in an organisation in a person's work area or team. These systems are known by various generic names, such as Enterprise Resource Planning (ERP), Materials Resource Planning (MRPII, MRP III etc.) or by proprietary names. This unit primarily requires the application of skills associated with using communication technology and supporting team use of planning software. Problem solving, initiative and enterprise, and planning and organizational skills are required to ensure that planning software is used efficiently. This requires aspects of learning and self-management to ensure own performance and that of the team.

Elements	Performance Criteria
1. Identify scope of planning software	1.1 Categories of information held by ***planning software*** are identified. 1.2 Information categories relevant to team and area processes are identified. 1.3 Range of information able to be provided to planning software by team or work group is identified. 1.4 Range of information able to be provided to team or work group by planning software is identified.
2. Communicate using the planning software system	2.1 ***Information*** using planning software is sent and received. 2.2 ***Messages*** using planning software is sent and received.
3. Make decisions using planning software	3.1 The planning software system is interrogated to find required current, historical or predicted information. 3.2 Actions appropriate to the information are taken in accordance with procedures
4. Monitor the use of planning software	4.1 Planning software information is routinely monitored. 4.2 Performance and use of planning software with team is reviewed.

5. Support others to use planning software	5.1 Team or other work group members, both using planning software and face to face are regularly communicated with.
	5.2 Improvements required are identified.
	5.3 Appropriate actions are taken to implement improvements.

Variable	Range
Planning software	Is a general term applied to a number of software systems which integrate a range of business information, such as: • sales/order taking • finance/accounting • logistics • maintenance • human resources • production It is frequently referred to by names such as ERP or MRP/MRPII. In some cases it can be integrated with engineering applications, such as SCADA systems. In such cases the unit MSS402061A Use SCADA systems in operations may also be required
Information and messages	Able to be sent and received via the planning software will vary between programs and organizations. This unit assumes that a range of discretion is available to the team leader over the information and messages that can be sent or received. Examples of information and message categories include: • orders • production/operations processes • scheduling (e.g. daily/weekly) • finance and accounting • human resources (e.g. rosters, reserves, training completed and scheduled) • quality requirements • customers • suppliers
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, ERP systems, 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) • take 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
Value stream	Begins with the customer and includes all actions (both value-adding and non-value added) by both internal sections/departments and external organizations to meet a customer requirement. Depending on the operations and the customer requirement stages where value stream actions may occur include: • sales outlet/representative • information gathering, data analysis and research • product design • raw material sourcing • intermediate processing • final assembler/collation/preparation • support services (e.g. accounting, finance and legal) • storage and delivery to customer and after-market support

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • identify team or work group area information requirements and relate to planning software categories • lead and motivate others in using planning software • ensure information sent to planning software is accurate and appropriate

	• obtain regular and one-off information from planning software • make decisions using planning software generated information.
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • hierarchy of planning software system and operation • information available from/through the planning software system • query facilities and information analysis capabilities offered by planning software • support/training/skill development mechanisms available for access by team members
Underpinning Skills	Must demonstrate skills in: • entering and receiving information via planning software terminals • communicating with team and organization planning software support personnel • engaging and motivating team in use of planning software • identifying team or work group area information requirements • identifying scope of information relevant to team and area available in planning software by categories • planning and organizing improvements in team's use of planning software
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 Management Level V	
Unit Title	**Develop a Balanced Score Card for Use in Competitive Manufacturing**
Unit Code	**IND PHR5 12 0613**
Unit Descriptor	This unit of competency covers the skills and knowledge required to develop and use a Balanced Scorecard approach for reporting and improving operational performance. This unit covers the skills needed to develop or improve a Balanced Scorecard and facilitate its use for improving performance in an organization. The unit covers the development of Key Performance Indicators (KPIs) and type of metrics for a Balanced Scorecard but does not include the technical skills for related information technology (IT) skills. This unit has a strong emphasis on providing leadership in implementation, determining required performance measures and requires an ability to test the validity of performance measuring and reporting processes.

Elements	Performance Criteria
1. Develop strategy map for Balanced Scorecard operation	1.1 Strategic objectives of an *organization* in consultation with stakeholders are developed.
	1.2 Strategic goals and objectives include those which make the organization unique is checked.
	1.3 With employees and customers that strategic objectives address real issues and problems is checked.
	1.4 Strategic objectives are categorized into the major perspectives of financial, customer, process, innovation and learning, and growth.
	1.5 *Additional required perspectives* and associated strategic goals and objectives are added.
	1.6 Strategic objectives showing cause/effect flows are mapped.
	1.7 Strategy map with stakeholders is validated.
2. Develop KPIs	2.1 Possible KPIs for each strategic objective is identified.
	2.2 Appropriate metrics for each KPI is identified/developed.
	2.3 Target KPI levels is agreed.
	2.4 Measures and KPIs encourage the behaviors required are checked to meet the total performance goals and objectives.

3. Develop reporting systems	3.1 Strategic and operational drivers are identified.
	3.2 KPIs are aligned to strategic and operational drivers.
	3.3 Reporting structures which align responsibilities with reported information are developed.
	3.4 Data to be collected and **Balanced Scorecard** reports to be generated and distributed are arranged.
	3.5 Reporting against strategy map is arranged.
4. Implement a Balanced Scorecard strategy	4.1 Pattern of performance as revealed by strategy map is analyzed.
	4.2 Causes of poor performance as displayed by the Balanced Scorecard are determined.
	4.3 Appropriate action is taken to improve total performance.

Variable	Range
Organization	May include: • a whole organization • a discrete subsidiary, plant or division
Additional required perspectives	May include: • workforce • environment • Occupational Health and Safety (OHS)
Balanced Scorecard	• Is an approach to competitive systems and practices that sets out an organization'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, internal business process and learning and growth. For each perspective area the Balanced Scorecard emphasizes establishing and measuring performance (metrics)
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

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills to: • develop strategy for an enterprise • develop procedures for implementation of the Balanced Scorecard practices in an enterprise • identify and implement changes to operations flowing from the implementation of the Balanced Scorecard • lead the implementation of change across an enterprise.
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: • vision and mission of organization • strategic issues for the organization • Balanced Scorecard principles and components, including perspectives, feedback loops, metrics and reporting systems • Key KPI development principles • responsibilities of personnel at different organizational levels/within different organizational sections and functions
Underpinning Skills	Must demonstrate skills of: • developing KPIs and their application at the enterprise level • analyzing organization operations and determine strategy for implementation of Balanced Scorecard approach, including: ➢ required communication with others

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   ➢ negotiations if any, required with internal and external suppliers, customers and delegates
➢ analysis of any skill gaps in self and others
➢ required training
➢ measuring of KPIs
➢ data collection
➢ work organization and procedure changes
➢ risk identification and contingency measures
analyzing data, including competitive systems and practices indicators and verifying results with stakeholders
solving problems associated with implementing and gaining support for Balanced Scorecard implementation across the organization
negotiating with employees, suppliers and customers, where necessary, to achieve implementation of Balanced Scorecard
communicating and negotiating at all levels in the organization and value stream and with individuals of different levels of literacy and numeracy documenting

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<td>Methods of Assessment</td>
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Interview / Written Test
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Occupational Standard: Pharmaceuticals Manufacturing Management Level V	
Unit Title	**Manage OHS Processes**
Unit Code	**IND PHR5 13 0613**
Unit Descriptor	This unit of competency specifies the workplace performance required by an individual responsible for ongoing management of Occupational Health and Safety (OHS) within an area of management responsibility, where the OHS management processes have been set up by other persons, either internal or external to the organization.

Elements	Performance Criteria
1. Manage OHS information and records	1.1 Relevant **OHS legislation, standards**, **codes of practice/compliance codes, guidance material and other sources of OHS information** are identified and accessed and their relevance to the specific work context is evaluated.
	1.2 Information on OHS requirements, trends and **risk controls** is collected, collated and provided to others.
	1.3 Records and record keeping processes are reviewed to ensure that **legal requirements for OHS record keeping** are identified and addressed.
	1.4 Processes for ensuring that **OHS records** are accurately completed, collected and stored are implemented and monitored in accordance with legal requirements and workplace procedures.
2. Manage OHS participative processes	2.1 **Participative processes** are monitored to ensure compliance with legislative requirements and **organization policies and procedures**.
	2.2 Information provided to employees is evaluated to ensure it is in a readily accessible and understandable format.
	2.3 Processes for ensuring that workgroup members have an opportunity, either directly or through their representative, to contribute to decisions that may affect their health and safety are implemented and monitored.
	2.4 Processes for addressing OHS issues are evaluated to ensure issues raised through consultation are resolved promptly and in line with organization procedures and legislative requirements.

	2.5 Information about the outcomes of *consultation* is provided promptly in a format and medium that is readily accessible to employees.
3. Manage OHS risk management processes	3.1 Hazard, incident, and injury reporting and investigation processes are in place, to meet legislative requirements and to inform future prevention strategies.
	3.2 Processes are in place so that hazard identification and risk assessments occur according to organization procedures.
	3.3 Risk controls and hazard specific procedures are consistent with the hierarchy of control and are monitored to support compliance with legislative and regulatory requirements.
	3.4 Processes are in place to identify and address any OHS implications of either proposed or implemented changes to the workplace, work processes or organization of work
	3.5 Limits of own professional expertise are recognized and expert advisors consulted as required
4. Manage OHS training program	4.1 OHS training needs assessment is undertaken for workgroup members that takes account of legislative and regulatory requirements, internal policies and procedures, existing skills of work group members and risk control requirements.
	4.2 Training programs are implemented and monitored to ensure identified OHS training requirements are addressed.
	4.3 Processes to ensure that all new employees receive *OHS induction* are implemented and monitored.
	4.4 Relevant OHS and training specialists are accessed and consulted as required in the development and implementation of the OHS training program.
5. Manage OHS continuous improvement process	5.1 Input from individuals and workgroup is considered in identifying and implementing OHS improvement.
	5.2 OHS priorities are determined in consultation with appropriate managers and *stakeholders*.
	5.3 OHS action plans are developed taking account of priorities and training needs.
	5.4 Achievements against the *OHS plans* are monitored and updated accordingly.

Variable	Range
OHS legislation	May include: • commonwealth, state and territory OHS acts and regulations
Standards	May include: • documents produced by national bodies, OHS regulators or industry bodies, that prescribe preventative action to avert occupational deaths, injuries and diseases • standards are of an advisory nature only, except where a law adopts the standard and thus makes it mandatory • they may be called up as evidence in court or other enforcement action

Codes of practice/compliance codes	May include:
	• documents generally prepared to provide advice to employers and workers, of an acceptable way of achieving standards
	• codes of practice/compliance codes may:
	  ➢ be incorporated into regulations
	  ➢ not relate to a standard
	  ➢ be called up as evidence in court or other enforcement action

Guidance material	Guidance material: • is an advisory technical document, providing detailed information for use by unions, employers, management, health and safety committee members and representatives, safety officers and others requiring guidance • advises on 'what to do' and 'how to do it' • has no legal standing

Other sources of OHS information	Include persons, organizations and references where knowledge about OHS may be obtained. These sources may be:
	• internal, including:
	  ➢ hazard, incident and investigation reports
	  ➢ workplace inspections
	  ➢ incident investigations
	  ➢ minutes of meetings
	  ➢ job safety analyses and risk assessments
	  ➢ organization data such as insurance records, enforcement notices and actions, workers compensation data, OHS performance data
	  ➢ reports and audits
	  ➢ Material Safety Data Sheets (MSDS) and registers
	  ➢ employees handbooks
	  ➢ employees including questionnaire results

	➤ OHS advisors ➤ manufacturers' manuals and specifications - external, including: ➤ regulatory bodies and OHS Acts regulations, codes and guidance material ➤ other relevant legislation ➤ Databases, such as national and state injury data ➤ OHS specialists and consultants ➤ newspapers and journals, trade/industry publications ➤ internet sites ➤ industry networks and associations, including unions and employer groups ➤ OHS professional bodies ➤ specialist advisors ➤ research information
OHS information	May include: - requirements under OHS legislation, regulations, standards, codes of practice/compliance codes and guidelines - rights and responsibilities - information on hazards including MSDS - collated information on hazard incidents and injuries - investigation and audit reports - outcomes of hazard identifications and workplace inspections - risk assessments - risk controls - workplace OHS policies and procedures - work procedures - training records
Risk controls	May include: The devices and methods to, where practicable, eliminate the hazard or, where this is not practicable, minimize the risk associated with the hazard
Legal requirements for record keeping	Those specified under OHS legislation and regulations for: - serious incident and injury reporting - registered plant - hazardous substances and dangerous goods - environmental monitoring - health surveillance - Privacy legislation
OHS records	may include: - hazard, incident and investigation reports - workplace inspection reports

	• incident investigation reports • first aid records • minutes of meetings • job safety analyses and risk assessments • MSDS and registers • plant and equipment operation records including those relevant to registered plant • maintenance and testing reports • training records • environmental monitoring records • health surveillance records

Participative processes	May include:
	• processes that:
	   ➢ inform employees and other stakeholders of OHS matters
	   ➢ seek their input
	   ➢ offer opportunity for stakeholders to participate in decisions that may impact on their health and safety
	• participative processes may also be referred to as 'consultative processes', however 'participation' implies a higher level of involvement

Organization policies and procedures	May include policies and procedures underpinning the management of OHS, including: • hazard, incident and injury reporting • hazard identification, risk assessment and control • consultation and participation • incident investigation • quality system documentation
Consultation	May include: • seeking information or the opinions from one or more people prior to decision-making • consultation should particularly include those who may affect the outcomes or be affected by the decisions made but may also include specialist sources
Hazards	May include: • a source or situation with the potential for harm in terms of human injury or ill-health, damage to property, the environment, or a combination of these
Hazard identification	is the process of identifying sources of harm and may be required: • at design or pre purchase of equipment and materials • at commissioning or pre-implementation of new processes or practices

	• before new forms of work and organization of work are implemented • before changes are made to workplace, equipment, work processes or work arrangements • as part of planning major tasks or activities, such as equipment shutdowns • following an incident report • when new knowledge becomes available • at regular intervals during normal operations • prior to disposal of equipment, buildings or materials
Specific safety related hazards	May include but are not limited to: • chemicals, • bodily fluids • sharps • noise • manual handling • work posture • underfoot hazards • moving parts of machinery • cytotoxic medicines and waste
Other workplace hazards	May include: • occupational violence • stress • fatigue • bullying
Incident	May include: • any event that has caused or has the potential for injury, ill health or damage
Risks	in relation to any hazard, means: • the probability and consequences of injury, illness or damage resulting from exposure to a hazard
Risk assessments	Involve analyzing a hazard to: • identify factors influencing the risk and the range of potential consequences • effectiveness of existing controls • likelihood of each consequence considering exposure and hazard level • and combining these in some way to obtain a level of risk
Hierarchy of control	Is the preferred order of control measures for OHS risks: • elimination (e.g. controlling the hazard at the source) • substitution (e.g. replacing one substance or activity at the source) • engineering control (e.g. installing guards on machinery)

	• administration control (e.g. policies and procedures for safe work practices) • personal protective equipment (e.g. respirators and ear plugs)
Expert advisors	May include: • persons either internal or external to the organization including: ➢ safety professionals ➢ ergonomists ➢ occupational hygienists ➢ audiologists ➢ safety engineers ➢ toxicologists ➢ occupational health professionals • other persons providing specific technical knowledge or expertise in areas related to OHS, including: ➢ risk managers ➢ health professionals ➢ injury management advisors ➢ legal practitioners with experience in OHS ➢ engineers (e.g. design, acoustic, mechanical and civil) ➢ security and emergency response personnel ➢ workplace trainers and assessors ➢ maintenance and trade persons
OHS induction	May include the processes by which new employees are introduced to, and acquainted with their job and the new workplace, including familiarization with: • hazards and risks associated with the work, • risk control measures, • welfare facilities and • emergency response procedures
Stakeholders	Are those people or organizations who may be affected by, or perceive themselves to be affected by an activity or decision, including: • managers • supervisors • health and safety and other employee representatives • OHS committees • employees and contractors • the community
OHS action plans	May include: • documented plans developed within the workplace to implement a systematic approach to OHS management and contain:

	- actions that support an integrated strategy to address deficiencies, meet obligations or provide for improved outcomes - allocated responsibilities - timeframes

Evidence Guide	
Critical Aspects of Competence	Must demonstrate knowledge and skills in: - managing OHS processes for a small organization or a group(s) of persons undertaking a range of work - Evidence gathered by an assessor to determine competence will include: - written or verbal responses to scenarios and case studies - reports from persons who have been involved in the management processes - portfolio of workplace documents - Evidence of workplace performance over time must be obtained to inform a judgment of competence.
Underpinning Knowledge and Attitudes	Must demonstrate knowledge of: - the difference between hazard and risk - sources of OHS information both internal and external to the workplace - understanding of OHS legislation and regulatory requirements relevant to the particular industry/type of work site - the roles and responsibilities of employees, supervisors and managers in the workplace - legislative requirements for consultation - legal and practical requirements for OHS training - legal requirements for OHS record keeping and reporting - knowledge and understanding of guidance material, including codes of practice/compliance codes relevant to the particular industry/type of work site - risk assessment process, including: - hazard identification procedures - principles of risk assessment - the hierarchy of control and its application - legislative requirements for record keeping and reporting - systems for identifying skill needs, such as: - performance reviews - training needs analysis - identifying additional training needs of learners - workplace specific information, including:

	➢ hazards of the particular work environment and how they cause harm
	➢ hazard identification procedures relevant to the hazards in their workplace
	➢ designated person for raising OHS issues
	➢ organization procedures related to OHS, including hazard, incident and injury reporting, hazard identification, risk assessment and control, consultation and participation, incident investigation and record keeping
	➢ awards and enterprise agreements that impact on the particular workplace
	➢ the characteristics and composition of the workforce and how they may impact on the management of OHS
Underpinning Skills	Must demonstrate skills to:
	• use technical skills to access OHS information
	• use language, literacy and conceptual skills to analyze and evaluate OHS information
	• communicate with supervisors, other managers, staff, OHS inspectors and expert advisers in a range of contexts, and using a range of media and formats
	• conduct effective meetings
	• develop solutions to complex OHS problems, utilizing information from a range of sources
	• apply an action planning process
	• assimilate information from a range of sources to evaluate effectiveness of processes
	• relate to people from a range of social, cultural and ethic backgrounds and physical and mental abilities
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 Management Level V	
Unit Title	**Manage Project Quality**
Unit Code	**IND PHR5 14 0613**
Unit Descriptor	This unit specifies the outcomes required to manage quality within projects. It covers determining quality requirements, implementing quality assurance processes, and using review and evaluation to make quality improvements in current and future projects.

Elements	Performance Criteria
1. Determine quality requirements	1.1 **Quality objectives**, standards and levels are determined, with input from stakeholders and guidance of a higher project authority, to establish the basis for quality outcomes and a **quality management plan**.
	1.2 Established **quality management methods, techniques and tools** are selected and used to determine preferred mix of quality, capability, cost and time.
	1.3 Quality criteria are identified, agreed with a higher project authority and communicated to stakeholders to ensure clarity of understanding and achievement of quality and overall project objectives.
	1.4 Agreed quality requirements are included in the project plan and implemented as basis for performance measurement.
2. Implement quality assurance	2.1 Results of project activities and product performance are measured and documented throughout the project life cycle to determine compliance with agreed quality standards.
	2.2 Causes of unsatisfactory results are identified, in consultation with the client, and appropriate actions are recommended to a higher project authority to enable continuous improvement in quality outcomes.
	2.3 Inspections of quality processes and **quality control** results are conducted to determine compliance of quality standards to overall quality objectives.
	2.4 A quality management system is maintained to enable effective recording and communication of quality issues and outcomes to a higher project authority and stakeholders.
3. Implement project quality improvements	3.1 Processes are reviewed and agreed changes implemented continually throughout the project life cycle to ensure continuous improvement to quality.

	3.2 Project outcomes are reviewed against performance criteria to determine the effectiveness of quality management processes and procedures.
	3.3 Lessons learned and recommended *improvements* are identified, documented and passed on to a higher project authority for application in future projects.

Variable	Range
Quality objectives	May include but not limited to: • requirements from the client and other stakeholders • requirements from a higher project authority • negotiated trade-offs between cost, schedule and performance • those quality aspects which may impact on customer satisfaction
Quality management plan	May include but not limited to: • established processes • authorizations and responsibilities for quality control • quality assurance • continuous improvement
Quality management methods, techniques and tools	May include but not limited to: • brainstorming • benchmarking • charting processes • ranking candidates • defining control • undertaking benefit/cost analysis • processes that limit and/or indicate variation • control charts • flowcharts • histograms • pareto charts • scatter gram and run charts
Quality control	May include but not limited to: • monitoring conformance with specifications • recommending ways to eliminate causes of unsatisfactory • performance of products or processes • monitoring of regular inspections by internal or external agents
Improvements	May include but not limited to: • formal practices, such as total quality management or continuous improvement

	• improvement by less formal processes which enhance both the product quality and processes of the project, for example client surveys to determine client satisfaction with project team performance

Evidence Guide	
Critical Aspects of Competence	Demonstrates skills and knowledge in: • lists of quality objectives, standards, levels and measurement criteria • records of inspections, recommended rectification actions and quality outcomes • management of quality management system and quality management plans • application of quality control, quality assurance and continuous improvement processes • records of quality reviews • lists of lessons learned and recommended improvements • how quality requirements and outcomes were determined for projects • how quality tools were selected for use in projects • how team members were managed throughout projects with respect to quality within the project • how quality was managed throughout projects • how problems and issues with respect to quality and arising during projects were identified and addressed • how projects were reviewed with respect to quality management • how improvements to quality management of projects have been acted upon

Underpinning Knowledge and Attitudes	Demonstrates knowledge of:
	• the principles of project quality management and their application
	• acceptance of responsibilities for project quality management
	• use of quality management systems and standards
	• the place of quality management in the context of the project life cycle
	• appropriate project quality management methodologies; and their capabilities, limitations, applicability and contribution to project outcomes
	• attributes:
	   ➢ analytical
	   ➢ attention to detail
	   ➢ able to maintain an overview

	➢ communicative ➢ positive leadership
Underpinning Skills	Demonstrate skills of: • ability to relate to people from a range of social, cultural and ethnic backgrounds, and physical and mental abilities • project management • quality management • planning and organizing • communication and negotiation • problem-solving • leadership and personnel management • monitoring and review skills
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 Management Level V	
Unit Title	**Facilitate and Capitalize on Change and Innovation**
Unit Code	**IND PHR5 15 0613**
Unit Descriptor	This unit specifies the outcomes required to plan and manage the introduction and facilitation of change; particular emphasis is on the development of creative and flexible approaches, and on managing emerging opportunities and challenges.

Elements	Performance Criteria
1. Participate in planning the introduction and facilitation of change	1.1 *Manager* contributes effectively to the organization's planning processes to introduce and facilitate change. 1.2 Plans are made to introduce change in consultation with *appropriate stakeholders*. 1.3 Organization's objectives and plans are communicated effectively to introduce change to individuals and teams.
2. Develop creative and flexible approaches and solutions	2.1 Variety of approaches are identified and analyzed to manage workplace issues and problems. 2.2 *Risks* are identified and assessed, and action initiated to manage these to achieve a recognized benefit or advantage to the organization. 2.3 Workplace is managed in a way which promotes the development of innovative approaches and outcomes. 2.4 Creative and responsive approaches to resource management improve productivity and services, and/or reduce costs.
3. Manage emerging challenges and opportunities	3.1 Individuals and teams are supported to respond effectively and efficiently to changes in the organization's goals, plans and priorities. 3.2 Coaching and mentoring are made to assist individuals and teams to develop competencies to handle change efficiently and effectively. 3.3 Opportunities are identified and taken as appropriate, to make adjustments and to respond to the changing needs of customers and the organization. 3.4 *Information needs* of individuals and teams are anticipated and facilitated as part of change implementation and management.

	3.5 Recommendations for improving the methods and techniques to manage change are identified, evaluated and negotiated with appropriate individuals and groups.

Variables	Range
Manager	a person with frontline management roles and responsibilities, regardless of the title of their position
Appropriate stakeholders may include but not limited to:	• organization directors and other relevant managers • teams and individual employees who are both directly and indirectly involved in the proposed change • union/employee representatives or groups • OHS committees • other people with specialist responsibilities • external stakeholders where appropriate - such as clients, suppliers, industry associations, regulatory and licensing agencies
Risks	May include but not limited to: • any event, process or action that may result in goals and objectives of the organization not being met • any adverse impact on individuals or the organization • various risks identified in a risk management process
Information needs	May include but not limited to: • new and emerging workplace issues • implications for current work roles and practices including training and development • changes relative to workplace legislation, such as OHS, workplace data such as productivity, inputs/outputs and future projections • planning documents • reports • market trend data • scenario plans and customer/competitor data

Evidence Guide	
Critical Aspects of Competence	Demonstrates skills and knowledge in: • Planning the introduction and facilitation of change • Developing creative and flexible approaches and solutions • Managing emerging challenges and opportunities
Underpinning Knowledge and Attitudes	Demonstrate knowledge of: • Relevant legislation from all levels of government that affects business operation, especially in regard to occupational health and safety and environmental issues, equal opportunity, industrial relations and anti-discrimination

	• the principles and techniques involved in: • change and innovation management • development of strategies and procedures to implement and facilitate change and innovation • use of risk management strategies: identifying hazards, and assessing risks and implementing risk control measures • problem identification and resolution • leadership and mentoring techniques • management of quality customer service delivery • consultation and communication techniques • record keeping and management methods • the sources of change and how they impact • factors which lead/cause resistance to change • approaches to managing workplace issues
Underpinning Skills	Demonstrate skills on: • Communication skills • Planning work • Managing risk
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 Management Level V	
Unit Title	**Establish and Conduct Business Relationships**
Unit Code	**IND PHR5 16 0613**
Unit Descriptor	This unit covers the skills, attitudes and knowledge required to manage business relationship with customers.

Elements	Performance Criteria
1. Establish contact with customer	1.1 Welcoming customer environment is maintained.
	1.2 Customer is greeted warmly according to enterprise policies and procedures.
	1.3 Effective service environment is created through verbal and non-verbal presentation according to enterprise policies and procedures.
	1.4 Customer data is maintained to ensure database relevance and currency.
	1.5 Information on customers and service history is gathered for analysis.
	1.6 ***Opportunities*** to maintain regular contact with customers are identified and taken up.
2. Clarify needs of customer	2.1 Customer needs are determined through questioning and active listening.
	2.2 Customer needs are accurately assessed against the products/services of the enterprise.
	2.3 Customer details are documented clearly and accurately in required format.
	2.4 Negotiations are conducted in a business-like and professional manner.
	2.5 Maximize benefits for all parties in the negotiation through use of established ***negotiation techniques*** and in the context of establishing long term relationships.
	2.6 The results of negotiations are communicated to appropriate colleagues and stakeholders within appropriate timeframes.
3. Provide information and advice	3.1 Features and benefits of products/services provided by the enterprise are described / recommended to meet customer needs.
	3.2 Information is provided to satisfy customer needs.

	3.3 Alternative sources of information/advice are discussed with the customer.
4. Foster and maintain business relationships	4.1 Pro-actively seek, review and act upon information needed to maintain sound business relationships.
	4.2 Agreements are honored within the scope of individual responsibility.
	4.3 Adjustments to agreements are made in consultation with the customer and share information with appropriate colleagues.
	4.4 Nurture relationships through regular contact and use of effective interpersonal and communication styles.

Variables	Range
Opportunities to maintain regular contact with customers	May include but not limited to: • informal social occasions • industry functions • association membership • co-operative promotions • program of regular telephone contact
Negotiation techniques	May include but not limited to: • identification of goals, limits • clarification of needs of all parties • identifying points of agreement and points of difference • preparatory research of facts • active listening and questioning • non-verbal communication techniques • appropriate language • bargaining • developing options • confirming agreements and appropriate cultural behavior

Evidence Guide	
Critical Aspects of Competence	Demonstrates skills and knowledge in: • consistently applying enterprise policies and procedures and industry codes of practice in regard to customer service • providing a quality service environment by treating customers in a courteous and professional manner through all stages of the procedure • using effective questioning/active listening and observation skills to identify customer needs • communicating effectively with others involved in or affected by the work

	• maintaining relevant and current customer databases in accordance with enterprise policies and procedures • ability to build and maintain relationships to achieve successful business outcomes

Underpinning Knowledge and Attitudes	Demonstrate knowledge of:
	• Operational knowledge of enterprise policies and procedures in regard to:
	   ➢ customer service
	   ➢ dealing with difficult customers
	   ➢ maintenance of customer databases
	   ➢ allocated duties/responsibilities
	   ➢ General knowledge of the range of enterprise merchandise and services, location of telephone extensions and departments/sections
	• Basic operational knowledge of legislation and statutory requirements, including consumer law, trade practices and fair trading legislation
	• Basic operational knowledge of industry/workplace codes of practice in relation to customer service
	• negotiation and communication techniques appropriate to negotiations that may be of significant commercial value

Underpinning Skills	Demonstrate skills to: • Use workplace technology related to use of customer database • Collect, organize and understand information related to collating and analyzing customer information to identify needs • Communicate ideas and information • Plan and organize activities concerning information for database entries • Use mathematical ideas and techniques to plan database cells and size • Establish diagnostic processes which identify and recommend improvements to customer service
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 Management Level V	
Unit Title	Manage Continuous Improvement Process (Kaizen)
Unit Code	IND PHR5 17 0613
Unit Descriptor	This unit describes the performance, outcomes, knowledge, attitude and skills required to sustain and develop an environment in which continuous improvement, innovation and learning are promoted, rewarded and managed.

Elements	Performance criteria
1. Diagnose the current status.	1.1 **Parameters** used for study current situation are obtained.
	1.2 Internal and external environment is analyzed.
	1.3 Problems related to targeted environment is recognized and identified.
	1.4 Problems regarding to current situation are analyzed.
	1.5 Alternatives are generated.
	1.6 Best alternatives are selected.
2. Design an effective continuous improvement process (kaizen).	2.1 The values, mission and goals of kaizen management system are clarified.
	2.2 The **kaizen management template** and a visual management logo full of purpose and meaning are developed.
	2.3 A clear action strategy (master and detailed plans) is defined.
	2.4 The most effective and proven **kaizen tools** are chosen and applied.
	2.5 A practical way is identified to involve all employees in **Gemba activities** (top, middle and bottom).
3. Develop change capability.	3. 1. Kaizen Promotion Team Structure is developed.
	3. 2. The Kaizen Training Plan is defined and started.
	3. 3. Supervisors' kaizen capability and habits are developed.
	3. 4. Key people are developed in terms of **Individual leadership capability**.
4. Implement improved processes.	4.1 **Sustainability/continuous improvement** are promoted as an essential part of doing business.
	4.2 Impacts of change and consequences are addressed for people, and transition plans implemented.

	4.3 Objectives, time frames, measures and communication plans are ensured in place to manage implementation.
	4.4 Contingency plans are implemented in the event of non-performance.
	4.5 Failure is followed-up by prompt investigation and analysis of causes.
	4.6 Emerging challenges and opportunities are managed effectively.
	4.7 Continuous improvement systems and processes are evaluated regularly.
	4.8 Improvements are communicated to all relevant groups and individuals.
	4.9 Opportunities are explored for further development of value stream improvement processes.
5. Establish direction and control.	5.1 A *system audit tool* is defined and implemented.
	5.2 The kaizen management system is deployed across all company levels and functions.
	5.3 Results are checked and corrections made.
	5.4 *Standard operating procedures* are developed and maintained.
	5.5 The recruit, training and evaluation systems are improved and *HR practices* compensated.

Variable	Range

Parameters	May include but not limited to:
	• Working condition
	• Resources may include:
	  ➢ Human
	  ➢ Material
	  ➢ Machine
	• Kaizen elements

Kaizen management template	May include but not limited to:
	• Visual management board for:
	  ➢ displaying characteristic figures, data and graphics
	  ➢ depicting and controlling processes
	  ➢ identifying and marking sources of risks, setting and standards
	  ➢ displaying company's values and goals of kaizen

Kaizen tools	May include but not limited to: • 5S (a visual workplace management)

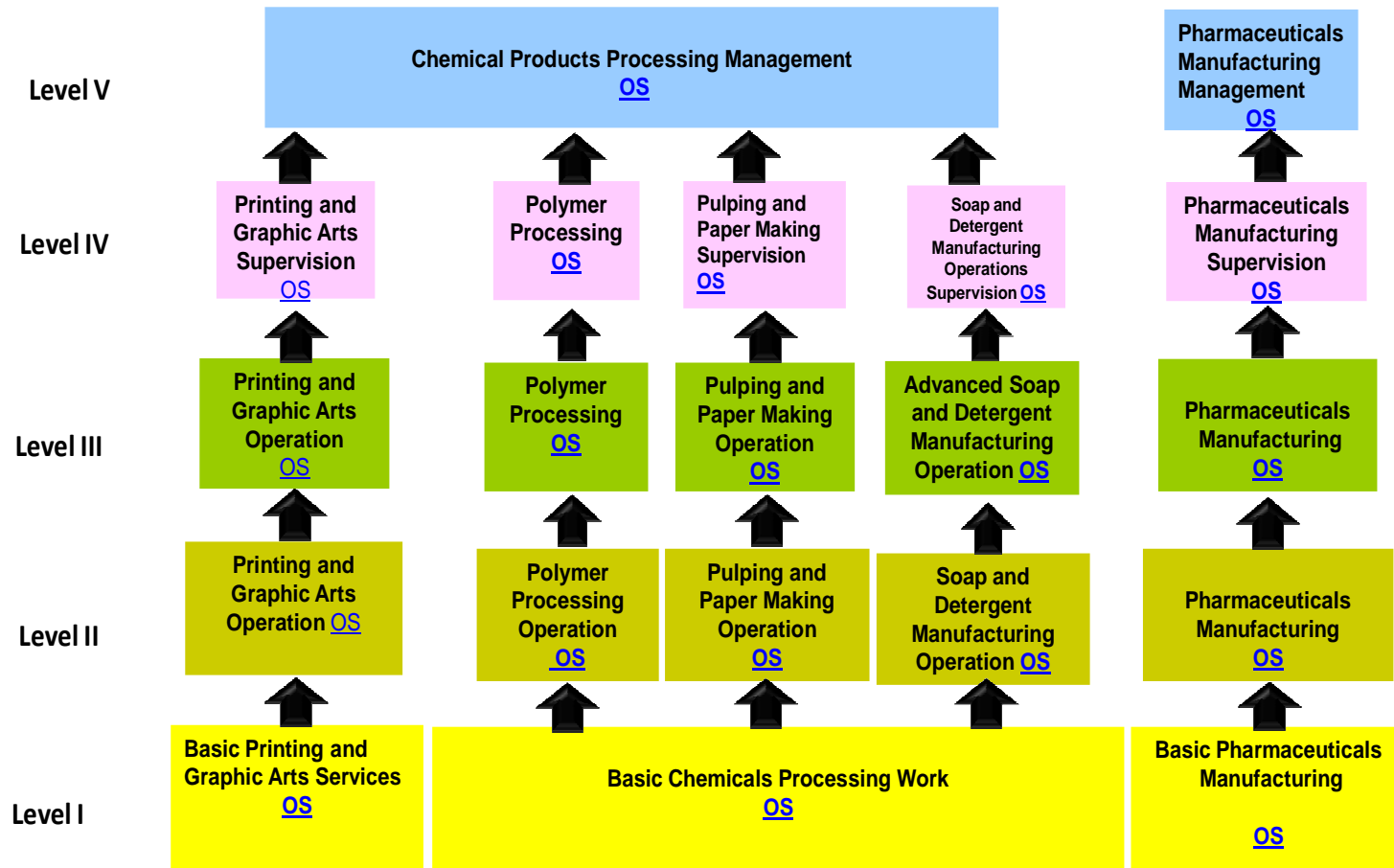|	
	• 7 QC tools(Cause and Effect Diagram, Check Sheet , Pareto Diagram , Histogram, Scatter Diagram, Control Chart and Flow Chart) • Brainstorming • Basic Industrial Engineering (IE) tools such as time study, motion study, line balancing, work sampling • JIT(JUST IN TIME principles) • MUDA identification and elimination tools • Kanban • Poka-yoke • Takt- time
Gemba activities	May include but not limited to: • Value-adding activities to satisfy the customer • Employee autonomous operations (participating in team to identify nonconformity, propose solutions and implement them autonomously)
Individual leadership capability	May include but not limited to: • Personal and interpersonal skills • Courage • Honour and integrity • Energy and drive • Strategic skills • Operating skills • Organizational positioning skills
Sustainability/continuous improvement	May include but not limited to: • Improvements made by following PDCA (Plan, Do, Check and Act) cycle for: ➢ Improvements in one's own work ➢ Saving in energy, material and other resources ➢ Improvements in the working environment ➢ Improvements in machines and processes ➢ Improvements in jigs and tools ➢ Improvement in office work ➢ Improvements in product quality ➢ Ideas for new products ➢ Customers services and customer relations
System audit tool	May include but not limited to: • 5S audit • Patrol system • Kaizen board • 5M check lists • Key Performance Indicators (KPIs)

Standard operating procedure	May include but not limited to:
	 • Administrative standards for:
	  ➢ Managing the business
	  ➢ Administration
	  ➢ Personnel Guidelines
	  ➢ Job Descriptions
	  ➢ Guidelines for preparing cost information
	 • Operation standards for:
	  ➢ Describing the way a job is done.
	  ➢ Help realising Quality, cost, delivery.
	  ➢ Addressing the need to satisfy customers.
	  ➢ Using the process that's the best.
	  ➢ Producing work in the most cost effective manner.
	  ➢ Assuring total quality for the customer.

HR practices	May include but not limited to:
	 • Resources may include:
	  ➢ Recruit and retain high quality people with innovative skills and a good track, record in innovation
	 • HR development is used for:
	  ➢ strategic capability and provide encouragement and facilities for enhancing innovating skills and enhancing the intellectual capital of the organization
	 • Reward will provide financial incentives and rewards and recognition for successful innovation

Evidence Guide	
Critical Aspects of Assessment	Demonstrates skills and knowledge competencies to: • Establish policy and cross-functional goals for kaizen • Deploy and implement goals as directed through policy deployment and cross-functional management. • Realize goals through deployment and audits. • Build systems, procedures, and structures conducive to kaizen. • Use kaizen in functional capabilities. • Introduce Kaizen as a corporate strategy • Provide support and direction between allocating resources • Establish, maintain and upgrade standards. • Make employees conscious through training programs. • Assist employees develop skills and tools for problem solving.
Underpinning Knowledge and Attitude	Demonstrates knowledge of: • Quality management and continuous improvement theories

	• creativity/innovation theories/concepts
	• competitive systems and practices tools, including:
	  ➢ 5S
	  ➢ JUST IN Time (JIT)
	  ➢ mistake proofing
	  ➢ process mapping
	  ➢ establishing customer pull
	  ➢ setting of KPIs/metrics
	  ➢ SOP
	  ➢ Kaizen elements/targets.
	  ➢ identification and elimination of waste/MUDA
	  ➢ continuous improvement processes including implementation, monitoring and evaluation strategies for a whole organization and its value stream
	  ➢ Difference between breakthrough improvement and continuous improvement
	  ➢ organizational goals, processes and structure
	  ➢ approval processes within organization
	  ➢ methods of determining the impact of a change
	  ➢ customer perception of value
	  ➢ Define, Measure, Analyze, Improve and Control (DMAIC) to sustain process

Underpinning Skills	Demonstrates Skills to: • Use leadership skills to foster a commitment to quality and openness to improvement. • Analyze training needs and implementing training programs • Prepare and maintain quality and audit documentation • Undertake self-directed problem solving and decision-making on issues of a broad and/or highly specialized nature and in highly varied and/or highly specialized contexts • Communicate at all levels in the organization and to audiences of different levels of literacy and numeracy • Analyze current state/situation of the organization. • Analyze individually and collectively the implementation of competitive systems and practices tools in the organization and determining strategies for improved implementation • Solve highly varied and highly specialized problems related to competitive systems and practices implementation and continuous improvement to root cause

	• Negotiate with stakeholders, where required, to obtain information required for implementation and refinement of continuous improvements, including management, unions, employees and members of the community.
	• Review relevant metrics, including all those measures which might be used to determine the performance of the improvement system, including:
	  ➢ Key Performance Indicators (KPIs) for existing processes
	  ➢ Quality statistics
	  ➢ Delivery timing and quantity statistics
	  ➢ Process/equipment reliability ('uptime')

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

Level V

Chemical Products Processing Management
OS

Pharmaceuticals Manufacturing Management
OS

Level IV

Printing and Graphic Arts Supervision
OS

Polymer Processing
OS

Pulping and Paper Making Supervision
OS

Soap and Detergent Manufacturing Operations Supervision **OS**

Pharmaceuticals Manufacturing Supervision
OS

Level III

Printing and Graphic Arts Operation
OS

Polymer Processing
OS

Pulping and Paper Making Operation
OS

Advanced Soap and Detergent Manufacturing Operation **OS**

Pharmaceuticals Manufacturing
OS

Level II

Printing and Graphic Arts Operation **OS**

Polymer Processing Operation
OS

Pulping and Paper Making Operation
OS

Soap and Detergent Manufacturing Operation **OS**

Pharmaceuticals Manufacturing
OS

Level I

Basic Printing and Graphic Arts Services
OS

Basic Chemicals Processing Work
OS

Basic Pharmaceuticals Manufacturing

OS

Acknowledgement

We wish to extend thanks and appreciation to the many representatives of business, industry, academe and government agencies who donated their time and expertise to the development of this occupational standard.

We would like also to express our appreciation to the Staff and Experts of Ethiopia Ministry of industry (MOI), Ministry of Education (MOE) who made the development of this occupational standard possible.

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

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