Australian Government

Department of Education, Employment and Workplace Relations

HLTOPT405B Monitor implementation of good manufacturing practice in the ophthalmic industry

Release: 1

HLTOPT405B Monitor implementation of good manufacturing practice in the ophthalmic industry

Modification History

Not Applicable

Unit Descriptor

Descriptor	This unit of competency describes the skills and knowledge required to provide a supervision and leadership role in the implementation of Good Manufacturing Practices (GMP) for the manufacturing of optical appliances

Application of the Unit

Application	The application of knowledge and skills described in this competency unit related to functions necessary for working within the ophthalmic industry Workers at this level can be expected to have formal responsibility for others and required to model workplace policies and practices They may or may not have a formal supervision or management role

Licensing/Regulatory Information

Not Applicable

Pre-Requisites

Not Applicable

Employability Skills Information

Employability Skills This unit contains Employability Skills

Elements and Performance Criteria Pre-Content

Elements define the essential outcomes of a unit of competency.

The Performance Criteria specify the level of performance required to demonstrate achievement of the Element. Terms in italics are elaborated in the Range Statement.

Elements and Performance Criteria

ELEMENT	PERFORMANCE CRITERIA
1. Ensure others in the work area are able to meet *GMP requirements*	1.1 Ensure relevant clothing and equipment appropriate to work requirements is available, functional and correctly fitted 1.2 Ensure advice on GMP responsibilities and procedures is accessible and clearly explained 1.3 Ensure that GMP control measures used in the work area can be identified by others 1.4 Provide mentoring and support to individuals/groups to implement GMP and related procedures
2. Monitor personal hygiene and conduct of team members in the work area	2.1 Ensure personal hygiene of team members meets GMP requirements 2.2 Prepare, order use, handle store and dispose of PPE (personal protective equipment) according to GMP and organisational policies and procedures 2.3 Ensure personal movement around the workplace complies with safety requirements and company procedures and policies

ELEMENT	PERFORMANCE CRITERIA
3. Monitor the implementation of GMP requirements	3.1 Define, document and follow GMP procedures 3.2 Report non-compliance from identified procedures and address within level of responsibility 3.3 Ensure personal behaviour is consistent with GMP and organisation policies and procedure 3.4 Follow organisation procedures to control resource allocation and process to meet GMP requirements 3.5 Identify and report GMP non-conformance in accordance with organisation policies and procedures 3.6 Document GMP information in line with organisation reporting requirements 3.7 Ensure the workplace is maintained in a clean and tidy order to meet GMP housekeeping standards
4. Contribute to validation processes	4.1 Review validation practices and procedures in consultation with relevant personnel. 4.2 Identify validation results and issues and take corrective action within level of responsibility 4.3 Document GMP validation information in line with GMP code and organisation reporting requirements
5. Take corrective action in response to GMP non-compliance	5.1 Identify and report processes, practices and conditions which could result in non-compliance with GMP in accordance with organisation requirements 5.2 Take corrective action in accordance with level of responsibility 5.3 Raise GMP issues with designated personnel
6. Maintain and improve GMP in the workplace	6.1 Identify, report and correct processes or conditions which could result in non-conformance with GMP 6.2 Ensure matters raised relating to GMP are promptly resolved and/or referred to appropriate personnel 6.3 Monitor effectiveness of control measures within level of responsibility 6.4 Advise others in the workplace of GMP matters relevant to work role 6.5 Propose changes to documentation in line with organisation requirements to maintain GMP

ELEMENT	PERFORMANCE CRITERIA
	6.6 Conduct GMP audits to meet organisation and legislative requirements 6.7 Take action to respond to audit recommendations within level of responsibility.

Required Skills and Knowledge

REQUIRED SKILLS AND KNOWLEDGE

This describes the essential skills and knowledge and their level required for this unit.

Essential knowledge:
The candidate must be able to demonstrate essential knowledge required to effectively do the task outlined in elements and performance criteria of this unit, manage the task and manage contingencies in the context of the identified work role
This includes knowledge of:

- Auditing arrangements, roles and responsibilities as they relate to own work responsibilities, which may include understanding of the purpose and process for internal and external audit processes
- Basic concepts of quality assurance including quality specifications, operating parameters, validation procedures and control methods including understanding of related documentation including Standard Operating procedures
- Clothing and footwear requirements for working in and/or moving between work areas
- Control methods and procedures used in the work area to maintain GMP including:
  - identifying variances to the manufacturing process
  - understanding of the methods used to monitor process control
  - understanding of the purpose of control, the consequence if not controlled; and the method of control where relevant

It may also include:

  - corrected use and supply of quality manufacturing aids
  - purpose and requirements of validation procedures
  - purpose of equipment calibration
  - understanding of methods used to monitor process control
- Current technical and process knowledge required to monitor GMP and participate in investigating GMP non-compliance within level of responsibility, including:
  - conditions under which types of contamination are likely to occur

REQUIRED SKILLS AND KNOWLEDGE

- related control methods and validation procedures and responsibilities
- understanding of common micro-biological, physical and chemical contaminants
- Documentation systems and procedures, including record keeping to meet both organisation and legal requirements, procedures for developing and/or reviewing workplace procedures and document control systems used in the workplace
- GMP arrangements in the workplace, including awareness of relevant GMP codes of practice and related workplace policies and procedures to implement these responsibilities
- GMP responsibilities and requirements relating to the work area
- Housekeeping requirements and responsibilities relating to own work (where relevant this includes use and storage of housekeeping/cleaning equipment)

continued ...

Essential knowledge (*contd*):

- Procedures followed to investigate contamination events and performance improvement processes
- Procedures for responding to out-of-specification or unacceptable performance/ outcomes, including procedures for identifying lens wastage that does not comply with relevant Australian Standards and manufacturing aids of unacceptable quality
- Properties, handling and storage requirements of raw materials, packaging components and final products
- Recall and traceability procedures relevant to work area
- Standards for materials and equipment used in the work area
- The relationship between GMP and the quality system, personnel responsible for designing and management GMP, personal role to maintain GMP, the role of internal and external auditors as appropriate
- The role of GMP in preventing lens waste
- Understanding of the properties, handling and storage requirements of manufacturing aids, raw materials, measuring and calibration devices and manufacturing related components and final products
- Waste collection, recycling, handling and disposal, which may include handling/ disposal requirements for different types of waste such as hazardous waste where relevant

Essential skills:
It is critical that the candidate demonstrate the ability to effectively do the task outlined in elements and performance criteria of this unit, manage the task and manage contingencies in the context of the identified work role
This includes the ability to:

- Communicate information about GMP requirements and related procedures to others in

REQUIRED SKILLS AND KNOWLEDGE

the work area, which requires demonstration of two-way communicate including active listening and constructive response to feedback

- Determine action required to respond to GMP non-compliance within level of responsibility
- Ensure that appropriate and timely action is taken in response to the non-compliance
- Ensure that housekeeping standards are maintained and that equipment is in operational order, which may include participating in the management of equipment calibration
- Identify control points in a work area and demonstrate monitoring techniques used
- Model personal conduct and work activities to meet requirements of GMP
- Monitor the recording of GMP information to confirm that records accurately reflect performance and meet the requirements of the workplace and legislation
- Participate in and/or review practices and procedures to prevent or minimise the likelihood of unacceptable performance, production aides, raw materials, calibration devices and manufacturing related components and final products
- Participate in consultation processes to improve GMP which may include investigating actual and potential GMP non-compliance
- Provide access to GMP documentation
- Support others to follow GMP procedures, which includes validation procedures within level of responsibility
- Support others to identify control points and demonstrate monitoring and control methods
- Take into account opportunities to address waste minimisation, environmental responsibility and sustainable practice issues

Evidence Guide

EVIDENCE GUIDE

The evidence guide provides advice on assessment and must be read in conjunction with the Performance Criteria, Required Skills and Knowledge, the Range Statement and the Assessment Guidelines for this Training Package.

Critical aspects for assessment and evidence required to demonstrate this competency unit:	• The individual being assessed must provide evidence of specified essential knowledge as well as skills • Observation of actual or simulated workplace performance is essential for assessment of this unit • Consistency of performance should be demonstrated over the required range of situations relevant to the workplace

EVIDENCE GUIDE

	• Where, for reasons of safety, space, or access to equipment and resources, assessment takes place away from the workplace, the assessment environment should represent workplace conditions as closely as possible
Context of and specific resources for assessment:	• Resources essential for assessment include: • Access to an optical appliance manufacturing workplace
Method of assessment:	• Observation in the work place • Written assignments/projects or questioning should be used to assess knowledge • Case study and scenario as a basis for discussion of issues and strategies to contribute to best practice • Role play simulation
Access and equity considerations:	• All workers in the health industry should be aware of access and equity issues in relation to their own area of work • All workers should develop their ability to work in a culturally diverse environment • In recognition of particular health issues facing Aboriginal and Torres Strait Islander communities, workers should be aware of cultural, historical and current issues impacting on health of Aboriginal and Torres Strait Islander people • Assessors and trainers must take into account relevant access and equity issues, in particular relating to factors impacting on health of Aboriginal and/or Torres Strait Islander clients and communities

Range Statement

RANGE STATEMENT

The Range Statement relates to the unit of competency as a whole. It allows for different work environments and situations that may affect performance. Add any essential operating conditions that may be present with training and assessment depending on the work situation, needs of the candidate, accessibility of the item, and local industry and regional contexts.

GMP requirements include:	• Legislative requirements relevant to Good Manufacturing practice including
	  • Good Manufacturing Practice codes
	  • the Therapeutic Goods Act and/or other relevant legislation
	  • legislation covering environmental management. occupational health and safety, anti-discrimination and equal opportunity

Reporting systems include:	• Electronic data recording • Manual recording • Storage and filing systems
Products/materials stored may include:	• Raw materials • Packaging components • Consumables • Part-processed products • Finished products • Cleaning materials

Unit Sector(s)

Not Applicable