Australian Government

Department of Education, Employment and Workplace Relations

HLTOPT404C Implement good manufacturing processes in the ophthalmic industry

Release: 1

HLTOPT404C Implement good manufacturing processes in the ophthalmic industry

Modification History

HLT07 Version 4	HLT07 Version 5	Comments
HLTOPT404B Implement good manufacturing processes in the ophthalmic industry	HLTOPT404C - Implement good manufacturing processes in the ophthalmic industry	Unit updated in V5. ISC upgrade changes to remove references to old OHS legislation and replace with references to new WHS legislation. No change to competency outcome.

Unit Descriptor

Descriptor

This unit of competency describes the skills and knowledge required to comply with relevant Good Manufacturing Practice (GMP) codes 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

Work at this level may be undertaken independently or under guidance and/or supervision

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. Identify requirements of GMP as related to the optical industry	1.1 Identify and locate sources of information on GMP 1.2 Identify requirements and responsibilities related to own work
2. Observe personal hygiene requirements of GMP	2.1 Ensure personal hygiene meets *GMP requirements* 2.2 Prepare, order, use, handle, store and dispose of PPE (personal protective equipment) according to GMP and workplace requirements 2.3 Ensure personal movement around workplace complies with safety requirements, company procedures and policies

ELEMENT	PERFORMANCE CRITERIA
3. Implement GMP requirements	3.1 Identify GMP requirements 3.2 Routinely monitor work area, work flow, materials. equipment and products to ensure compliance with GMP requirements 3.3 Ensure production aids, measuring and calibration devices and manufacturing related products are handled according to GMP and workplace requirements 3.4 Follow workplace procedures to control resource allocation and process in accordance with GMP requirements 3.5 Identify common forms of contamination that contributes to lens wastage and implement appropriate control measures in accordance with GMP requirements 3.6 Ensure work and use of resources meets current legislation, approved codes of practice and organisation requirements 3.7 Maintain the workplace in accordance with GMP requirements 3.8 Identify and implement correct handling practices for lens materials during the manufacturing process 3.9 Identify and implement correct handling practices and procedures for gauges, instruments, machinery and other manufacturing correctly
4. Participate in improving GMP	4.1 Recognise and correct existing and potential disruptions to the workflow 4.2 Identify and report processes, practices or conditions which are not compliant with GMP in accordance with organisation policies and procedures 4.3 Implement corrective action in line with organisation policies and procedures and own level of responsibility 4.4 Raise GMP issues with supervisor or designated personal in accordance with organisation policies and procedures

ELEMENT	PERFORMANCE CRITERIA
5. Participate in quality and validation processes	5.1 Follow validation processes to GMP requirements 5.2 Raise issues identified in validation processes with supervisor or designated personal in accordance with *organisation policies and procedures* 5.3 Document validation procedures in line with GMP and in accordance with organisation policies and procedures 5.4 Information is recorded in line with GMP and organisation reporting requirements
6. Apply stock control procedures	6.1 Maintain stock of machinery parts, preventive maintenance parts and accessories and manufacturing consumables 6.2 Reduce shrinkage with effective and efficient procedures and processes 6.3 Recognise and apply stock-on-hand practices to maintain adequate stock levels

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:

- Awareness of manufacturing contaminants relevant to the manufacture of optical appliances including
  - control methods to prevent occurrence
  - possible consequences and
  - the conditions under which they occur
  - the types of contamination likely to occur
- Basic concepts of quality assurance including:

- control methods
- operating parameters
- quality specifications
- validation procedures
- understanding of related documentation including Standard Operating Procedures

- Basic understanding of the properties, handling and storage requirements of manufacturing aids, raw materials, measuring and calibration devices and manufacturing related components and final products
- Control methods and procedures used in the manufacture of optical appliances to maintain GMP which includes:
  - an understanding of the purpose of control
  - identifying variances to the manufacturing process
  - the consequences if not controlled and
  - the method of control if 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,

- GMP responsibilities and requirements relating to work role
- GMP arrangements in the workplace including an awareness of relevant GMP codes of practice and related organisation policies and procedures
- Housekeeping requirements and responsibilities relating to own work (where relevant this may include use and storage of housekeeping/cleaning equipment)
- Organisation policies and procedures to investigate manufacturing contamination events and performance improvement processes

continued ,,,

Essential knowledge continued:

- Personal clothing/footwear requirements, ordering, use, storage and disposal
- Procedures for responding to unacceptable outcomes which include procedures for identifying lens wastage that does not comply with relevant Australian Standards and manufacturing aids of unacceptable quality
- Production processing aids and their relationship to legislative responsibilities and potential implications of non-compliance
- Recall and traceability procedures relevant to work role
- Responsibilities for reporting and recording manufacturing quality information
- Standards for materials and equipment used
- The relationship between GMP and the quality system, personnel responsible for designing and managing GMP, personal role in maintaining GMP and external auditors

as appropriate
- The role of GMP in preventing lens wastage
- Understanding of the purpose of keeping records and the recording requirement of GMP, which includes an understanding of recording lens wastage, and the manufacturing aids, products and materials traceability procedures
- Waste collection, recycling and handling procedures relevant to own work responsibilities

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:

- Apply appropriate control measures
- Apply appropriate variation identification procedures
- Follow validation procedures within level of responsibility
- Follow workplace procedures when moving around the workplace or from one task to another
- Handle and/or dispose of out of specification production aids, raw materials, measuring and calibration devices and manufacturing related components and final products in accordance with GMP and organisation policies and procedures
- Handle, clean and store equipment, production aids, raw materials, measuring and calibration devices and manufacturing related components and final products in accordance with GMP and organisation policies and procedures
- Identify and report situations which do/could compromise GMP
- Identify and respond to unacceptable production aids, raw materials, measuring and calibration devices and manufacturing related components and final products within level of responsibility
- Locate and follow workplace information relating to GMP responsibilities
- Maintain GMP for own work
- Maintain personal hygiene consistent with GMP requirements
- Maintain records as requirement by GMP
- Maintain work area in a clean and tidy state
- Order, use, handle, store and dispose of appropriate clothing/footwear as requirement by work tasks and GMP requirements
- Record results of monitoring
- 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 • 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 (if possible) • 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 • Questioning • Role play simulation

EVIDENCE GUIDE

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

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.work health and safety (WHS), occupational health and safety, anti-discrimination and equal opportunity
- Requirements to comply with Standards Australia

Common forms of manufacturing contamination may include but are not limited to:	• Fining emery contamination • Poor quality surfacing pads • Polishing compound contamination via foreign matter not conducive to polishing surfaces • Poor or inadequate machinery maintenance • Poor or inadequate calibration of equipment
Variations to lens quality may include but is not limited to:	• Non compliance to Australian Standards • Non compliance to prescription/order
Reporting systems may include:	• electronic data recording • manual data recording • storage and filing systems
Organisation requirements and procedures may include:	• Goals, objectives, plans, systems and processes • Legal and organisation policy/guidelines and requirements • WHS policies, procedures and programs • Business and performance plans • Anti-discrimination and related policy • Access and equity principles and practice • Ethical standards • Quality and continuous improvement processes and standards • Defined resource parameters and financial/administrative procedures • Reporting procedures

Unit Sector(s)

Not Applicable