



Australian Government

Department of Education, Employment and Workplace Relations

FDFPH4002A Facilitate and monitor Good Manufacturing Practice

Revision Number: 1

FDFPH4002A Facilitate and monitor Good Manufacturing Practice

Modification History

Not applicable.

Unit Descriptor

Unit descriptor	This unit of competency targets content outlined in Chapter 4 of the Australian Code of Good Manufacturing Practice for Medicinal Products and should be read in conjunction with this document. It covers the skills and knowledge required to facilitate and monitor Good Manufacturing Practice (GMP) in a production/packaging work area.
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Application of the Unit

Application of the unit	This unit applies to people working in supervisory or line management production/packaging roles. This person would typically work within defined GMP programs and procedures. They contribute to the development of these programs as a team member and are responsible to oversee implementation in their work area.
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Licensing/Regulatory Information

Not applicable.

Pre-Requisites

Prerequisite units		

Employability Skills Information

Employability skills	This unit contains employability skills.
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Elements and Performance Criteria Pre-Content

Elements describe the essential outcomes of a unit of competency.	Performance criteria describe the performance needed to demonstrate achievement of the element. Where bold italicised text is used, further information is detailed in the required skills and knowledge section and the range statement. Assessment of performance is to be consistent with the evidence guide.
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Elements and Performance Criteria

ELEMENT	PERFORMANCE CRITERIA
1. Prepare to meet GMP requirements in the work area	1.1.Regulations, codes and guides relevant to the work area are identified 1.2.Workplace documentation relevant to work area activities is identified and reviewed to confirm that GMP requirements are met 1.3.The required facilities, materials, storage, equipment and personnel are confirmed and available 1.4.Operators who have the required competence to perform production/packaging activities to company and GMP standards are identified 1.5.Line clearance procedures are carried out 1.6.Critical processes are validated according to validation requirements 1.7.Procedures to eliminate or control the risk of cross-contamination are followed
2. Monitor the observance of GMP in the work area	2.1.Work practices conform to GMP requirements 2.2.In-process and environmental monitoring is carried out and recorded as required by GMP 2.3.Personal hygiene and conduct of personnel in the work area meets GMP requirements 2.4.Personnel movement between work areas complies with entry and exit procedures 2.5.GMP-related data is recorded to meet workplace reporting requirements
3. Respond to failures or non-conformances	3.1.The scope of failures or non-conformances are defined 3.2.Procedures to follow in the event of a failure are documented 3.3.Failures are investigated to determine root causes 3.4.Risk assessment is conducted 3.5.Findings are reported to meet GMP requirements 3.6.Procedures are followed to implement and monitor corrective and preventative action
4. Complete work to meet GMP requirements	4.1.Processes are reviewed to ensure all procedures are complete 4.2.Line logs are reviewed to ensure documentation is complete 4.3.End-of-batch procedures are followed

Required Skills and Knowledge

REQUIRED SKILLS AND KNOWLEDGE

This section describes the skills and knowledge required for this unit.

Required skills

Ability to:

- locate regulations, codes, guides and internal company documentation relevant to GMP and products/processes used in the work area
- use communication and document management systems to access and review relevant documents
- ensure that operators have the
- use communication skills to interpret and complete work information to support operations of work team or area
- demonstrate and support cooperative work practices within a culturally diverse workforce

Required knowledge

Knowledge of:

- legislative framework and structure, including the role of regulations, codes and guides
- corporate and personal responsibility and liability for maintaining GMP in the workplace
- the Pharmaceutical Inspection Co-operation Scheme (PICS) and related cross-recognition agreements
- the content covered by the Therapeutic Goods Act, relevant codes and guides
- sources of technical advice on test methods and critical limits
- regulatory mechanisms including audit processes
- the principles of quality management, quality assurance and quality control and the role of these activities in supporting GMP
- principles of risk management and related procedures
- system for raising and managing corrective and preventative actions
- specific requirements to be met by manufacturing and/or packaging activities in the work area to meet GMP requirements
- calibration programs and responsibilities
- procedures for reconciling materials and consumables and investigating discrepancies
- training system, including assessment methods and documentation
- purpose, procedure and responsibility for specific systems, programs and procedures to support GMP
- root cause analysis techniques
- workplace documentation and authorisation procedures

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, range statement and the Assessment Guidelines for the Training Package.

Overview of assessment

Assessment may occur in a real or simulated pharmaceutical or complementary medicine manufacturing workplace where the assessment environment provides access to workplace documentation and document management systems related to GMP that are typical of commercial manufacturing businesses and meet the requirements of the Therapeutic Goods Act. It will also provide a range of commercial production/packaging equipment and activities typically used in a commercial manufacturing environment.

Critical aspects for assessment and evidence required to demonstrate competency in this unit

Evidence of participation in a project team to develop or review systems and procedures to support GMP in a work area. This includes providing evidence that the candidate:

- provides documented evidence through use of workplace documentation and records to show that the work preparation, processing and completion meet GMP requirements
- leads response to a failure or non-conformance in the work area. This must include conducting risk assessment, analysing root cause analysis, identifying corrective and preventive action and monitoring implementation. This aspect of assessment may be undertaken as part of a team.

Context of and specific resources for assessment

Assessors must be satisfied that the person can consistently perform the unit as a whole, including all elements, performance criteria, and required skills and knowledge. A holistic approach should be taken to the assessment.

Assessment of this unit would typically involve responding to 'what if' scenarios, answering questions and conducting workplace projects.

Method of assessment

This unit is a core requirement for all pharmaceutical operators at AQF 4 and 5. It could be assessed concurrently with other units relating to problem solving

EVIDENCE GUIDE	
	and process improvement. Examples could be: • FDFOP2015A Apply principles of statistical process control • FDFPH4001A Prepare and review workplace documentation to support Good Manufacturing Practice • FDFPH4003A Facilitate contamination control • FDFPH4004A Participate in change control procedures • FDFPH4005A Participate in validation processes • MSACMT450A Undertake process capability improvements.
Guidance information for assessment	To ensure consistency in one's performance, competency should be demonstrated on more than one occasion over a period of time in order to cover a variety of circumstances, cases and responsibilities, and where possible, over a number of assessment activities.

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. Bold italicised wording, if used in the performance criteria, is detailed below. 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) may also be included.

Regulations, codes and guides

Relevant regulations, codes and guides include:

- Therapeutic Goods Act
- Therapeutic Goods Regulations
- Australian Code of Good Manufacturing Practice for Medicinal Products
- Therapeutic Goods Act guides to interpretation of legal requirements
- regulations, codes and guides related to other relevant international legislation (appropriate to product and market)
- company policies and guidelines

Workplace documentation

Workplace documentation relevant to work area activities includes:

- company policies and guidelines
- specifications
- manufacturing formulae
- processing and packaging instructions
- batch production and packaging records
- standard operating procedures (SOPs)
- occupational health and safety (OHS) information, including material safety data sheets (MSDS)

Work practices

Work is carried out according to:

- company policies and procedures
- legislative and licensing requirements, including therapeutic goods legislation, weights and measures and legislation relating to OHS, environmental management, equal opportunity and affirmative action, industrial awards and agreements

Sources of technical advice

Sources of technical advice include but are not limited to:

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

Unit Sector(s)

Unit sector	Pharmaceutical manufacturing
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Competency field

Competency field	
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Co-requisite units

Co-requisite units		

