



Australian Government

FBPPHM3001 Apply Good Manufacturing Practice requirements

Release: 1

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Modification History

Release	Comments
Release 1	This version released with FBP Food, Beverage and Pharmaceutical Training Package Version 2.0.

Application

This unit of competency describes the skills and knowledge required to comply with relevant Good Manufacturing Practice (GMP) requirements and workplace quality standards in a pharmaceutical manufacturing facility.

The unit applies to individuals who apply GMP requirements to undertake pharmaceutical manufacture work. Individuals work under broad direction and take responsibility for their own work.

No occupational licensing, legislative or certification requirements apply to this unit at the time of publication.

Pre-requisite Unit

Nil

Unit Sector

Pharmaceutical (PHM)

Elements and Performance Criteria

Elements	Performance Criteria
<i>Elements describe the essential outcomes.</i>	<i>Performance criteria describe the performance needed to demonstrate achievement of the element.</i>
1. Identify GMP as a regulatory concept	1.1 Locate sources of information relevant to work role from current Australian and other applicable regulatory frameworks for manufacturing pharmaceuticals 1.2 Locate sources of information relevant to work role relating to current global harmonisation of GMP compliance and product registrations
2. Identify requirements	2.1 Locate sources of information on GMP requirements in the

Elements	Performance Criteria
<i>Elements describe the essential outcomes.</i>	<i>Performance criteria describe the performance needed to demonstrate achievement of the element.</i>
of GMP related to own work	workplace 2.2 Identify GMP requirements for pharmaceutical manufacture tasks 2.3 Confirm specific GMP requirements for own work 2.4 Identify GMP non-compliant situations and risks to product quality 2.5 Alert relevant personnel and take appropriate action according to GMP requirements and workplace procedures
3. Complete workplace documentation to support GMP	3.1 Use workplace procedures to identify GMP requirements for documentation 3.2 Record information, including calculations and test results according to workplace reporting procedures and GMP requirements 3.3 Certify records, including electronic records, according to GMP requirements
4. Identify and follow biosecurity requirements	4.1 Identify information appropriate to work role relating to biosecurity requirements 4.2 Follow workplace biosecurity requirements and responsibilities related to work role
5. Apply GMP requirements when carrying out work activities	5.1 Identify common forms of contamination 5.2 Conduct work according to workplace environmental procedures 5.3 Maintain workplace cleanliness and tidiness to meet GMP requirements 5.4 Identify and report signs of unacceptable plant or equipment condition, including calibration status 5.5 Identify GMP requirements for routinely monitoring work area, materials, equipment and product 5.6 Complete documentation according to workplace procedures
6. Ensure personal hygiene and conduct meet GMP requirements	6.1 Maintain personal hygiene to meet GMP requirements 6.2 Carry out hand washing according to best practice hygiene standards 6.3 Prepare, use, store and dispose of personal protective equipment and contamination prevention clothing according to GMP requirements and workplace procedures 6.4 Comply with area entry and exit procedures when moving around the workplace

Elements	Performance Criteria
<i>Elements describe the essential outcomes.</i>	<i>Performance criteria describe the performance needed to demonstrate achievement of the element.</i>
7. Participate in improving GMP	7.1 Identify processes, practices or conditions which are inconsistent with GMP requirements and report according to workplace procedures 7.2 Identify elements of GMP that help improve products and processes 7.3 Implement corrective action within level of responsibility

Foundation Skills

This section describes those language, literacy, numeracy and employment skills that are essential for performance in this unit of competency but are not explicit in the performance criteria.

Skill	Description
Reading	Interpret information about GMP compliance requirements in workplace documentation
Writing	Record workplace information using appropriate language and in required format
Navigate the world of work	- Apply workplace procedures to own role and responsibilities - Understand main tasks, responsibilities and boundaries of own role
Interact with others	Report operational and safety information to relevant personnel using required communication method
Get the work done	Use problem-solving techniques to address routine issues within level of responsibility

Unit Mapping Information

Code and title current version	Code and title previous version	Comments	Equivalence status
FBPPHM3001 Apply Good Manufacturing Practice requirements	FDFPH2001A Apply Good Manufacturing Practice procedures	Updated to meet Standards for Training Packages Additional elements and performance	No equivalent unit

		criteria Code changed to reflect AQF alignment	
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Links

Companion Volume Implementation Guides are found in VETNet: -

<https://vetnet.gov.au/Pages/TrainingDocs.aspx?q=78b15323-cd38-483e-aad7-1159b570a5c4>

Assessment Requirements for FBPPHM3001 Apply Good Manufacturing Practice requirements

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Performance Evidence

An individual demonstrating competency must satisfy all of the elements and performance criteria in this unit.

There must be evidence that the individual has applied Good Manufacturing Practice (GMP) requirements, and demonstrated each of the following points at least once:

- read and interpreted relevant instructions and labels applicable to GMP operations, including pictorial and written signs and instructions
- followed workplace information relating to GMP responsibilities
- completed forms and reports according to GMP requirements and workplace procedures
- recorded calculations and test results
- identified and responded to:
 - out-of-calibration equipment
 - out-of-specification or unacceptable raw materials, packaging components, final or part processed product
- maintained workplace cleanliness and tidiness to meet GMP requirements
- maintained personal hygiene consistent with GMP requirements, including:
 - making team leader or supervisor aware of reportable illness
 - removal of jewellery
 - removal of makeup
- cleaned and sanitised hands using recognised procedures for:
 - washing with soap and water
 - rubbing with an alcohol-based formulation
- used personal protective clothing and equipment and contamination prevention clothing according to GMP requirements
- provided accurate verbal and written descriptions of incidents or situations that did or could have:
 - compromised GMP compliance or product quality
 - provided the potential for product contamination.

Knowledge Evidence

An individual must be able to demonstrate the knowledge required to perform the tasks outlined in the elements and performance criteria of this unit. This includes knowledge of:

- GMP as a regulatory concept, including regulatory obligations of employees, and the potential implications of non-compliance
- sections of Australian and other applicable regulatory frameworks relevant to pharmaceutical manufacturing:
 - National Medicines Policy
 - Therapeutic Goods Act (TGA)
 - Therapeutic Goods Regulations
 - Manufacturing Principles
 - Therapeutic Goods Orders
 - GMP code of practice
 - other TGA guidelines relevant to product and market
 - state or territory regulations or legislation relating to environmental manufacturing and health and safety in the workplace
 - United States Food, Drug and Cosmetic Act and associated Codes of Federal Regulations and guidance
 - European directives and legislation of European Union member states applicable to pharmaceutical manufacturing.
- drivers of global harmonisation initiatives, including risks in the supply chain when operating in a global environment, including the following:
 - Pharmaceutical Inspection Co-operation Scheme (PIC/S) background and guidance
 - The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) background and guidance
 - World Health Organization (WHO) background and guidance
- the relationship between GMP and the quality system, including:
 - personnel responsible for designing and managing GMP
 - personal role to maintain GMP
 - the role of internal and external auditors
 - quality procedures
 - quality assurance
 - quality control
 - risk management procedures
- personal clothing use, storage and disposal requirements and hygiene requirements, including:
 - informing team leader or supervisor of reportable illness
 - removal of jewellery
 - removal of makeup
- personal clothing and footwear requirements for working in and moving between work areas

- workplace cleaning standards and responsibilities relating to own work, including:
 - waste collection
 - recycling, safe handling and disposal for different types of waste
 - safe handling and disposal of hazardous waste
- sections of the following Acts and Regulations related to biosecurity requirements of pharmaceutical manufacturing:
 - the Gene Technology Act 2000
 - Biosecurity Act 2015
 - Export Control Act 1982
 - Imported Food Control Act 1992
 - regulatory requirements which apply to the supply of materials which are genetically modified organisms
 - regulatory requirements relating to quarantining and use of materials and products
- awareness of common contaminants relevant to the work process, including:
 - microbiological, from materials, equipment, environment and personnel
 - physical, from equipment, environment and personnel
 - chemical, from other products or materials, including cleaning agents
- quality control methods and procedures, including the purpose of control and the consequence if not controlled
- properties, handling and storage requirements of raw materials, packaging components and final product
- GMP requirements for maintaining plant and process equipment
- GMP requirements for transferring of equipment and material between areas
- GMP requirements for equipment status labelling
- documentation systems and procedures, including:
 - recordkeeping to meet both workplace and legal requirements
 - responsibilities for reporting and recording information
 - batch documentation
 - cleaning records
 - training records
 - product and materials traceability procedures
 - controls and methods for ensuring electronic data integrity and paper data integrity
 - significance of certifying and verifying GMP records
- procedures for responding to out-of-specification or unacceptable process performance or outcomes
- awareness of controls to protect personnel and the environment from contamination by products and materials.

Assessment Conditions

Assessment of skills must take place under the following conditions:

- physical conditions:
 - a pharmaceutical manufacturing workplace or an environment that accurately represents workplace conditions
- resources, equipment and materials:
 - personal protective equipment and contamination prevention clothing
 - alcohol based hand cleanser
 - soap and water
 - commercial pharmaceutical production and packaging equipment
- specifications:
 - GMP requirements
 - workplace reporting procedures
 - workplace procedures related to GMP
 - workplace biosecurity requirements
 - workplace environmental procedures.

Assessors of this unit must satisfy the requirements for assessors in applicable vocational education and training legislation, frameworks and/or standards.

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