



Australian Government

FBPPHM3020 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 7.0.

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 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 requirements of GMP related to own work	1.1 Locate sources of information on GMP requirements and regulatory obligations of employees relevant to work role from current Australian and other applicable regulatory frameworks for manufacturing pharmaceuticals 1.2 Identify GMP requirements for pharmaceutical manufacture tasks 1.3 Confirm specific GMP requirements for own work 1.4 Identify GMP non-compliant situations and risks to product

Elements	Performance Criteria
<i>Elements describe the essential outcomes.</i>	<i>Performance criteria describe the performance needed to demonstrate achievement of the element.</i>
	quality 1.5 Alert relevant personnel and take appropriate action according to GMP requirements and workplace procedures
2. Complete workplace documentation to support GMP	2.1 Use workplace procedures to identify GMP requirements for documentation 2.2 Record required information, calculations and test results according to workplace reporting procedures and GMP requirements 2.3 Certify records according to GMP requirements
3. Identify and follow biosecurity requirements	3.1 Identify information appropriate to work role relating to biosecurity requirements 3.2 Follow workplace biosecurity requirements and responsibilities related to work role
4. Apply GMP requirements when carrying out work activities	4.1 Identify common forms of contamination relevant to own work activities 4.2 Conduct work according to workplace environmental procedures 4.3 Maintain workplace cleanliness and tidiness to meet GMP requirements 4.4 Identify and report signs of unacceptable plant, equipment condition or calibration status 4.5 Identify GMP requirements for routinely monitoring work area, materials, equipment and product 4.6 Complete documentation according to workplace procedures
5. Apply hygiene and entry and exit procedures to meet GMP requirements	5.1 Maintain personal hygiene to meet GMP requirements 5.2 Carry out hand washing according to best practice hygiene standards 5.3 Prepare, use, store and dispose of personal protective equipment and contamination prevention clothing according to GMP requirements and workplace procedures 5.4 Comply with area entry and exit procedures when moving around the workplace
6. Participate in improving GMP	6.1 Identify processes, practices or conditions which are inconsistent with GMP requirements and report according to workplace procedures 6.2 Identify elements of GMP that help improve products and

Elements	Performance Criteria
<i>Elements describe the essential outcomes.</i>	<i>Performance criteria describe the performance needed to demonstrate achievement of the element.</i>
	processes 6.3 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

Unit Mapping Information

Code and title current version	Code and title previous version	Comments	Equivalence status
FBPPHM3020 Apply Good Manufacturing Practice requirements	FBPPHM3001 Apply Good Manufacturing Practice requirements	Element removed Changes to Element, Performance Criteria, Foundation Skills, Performance Evidence, Knowledge Evidence and Assessment Conditions	Not equivalent

Links

Companion Volumes, including Implementation Guides, are available at VETNet: - <https://vetnet.gov.au/Pages/TrainingDocs.aspx?q=78b15323-cd38-483e-aad7-1159b570a5c4>

Assessment Requirements for FBPPHM3020 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 **on one or more occasions**:

- 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
- applicable sections of Australian and other applicable regulatory frameworks relevant to pharmaceutical manufacturing:
 - Therapeutic Goods Act (TGA)
 - Manufacturing Principles
 - Guide to GMP
- 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
- 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 the skills in this unit of competency 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
 - 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.

Links

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