



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>