

Australian Government

FBPPHM2001 Follow work procedures to maintain Good Manufacturing Practice requirements

Release: 2

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Release	Comments	
Release 2	This version released with FBP Food, Beverage and Pharmaceutical Training Package Version 7.0.	
Release 1	This version released with FBP Food, Beverage and Pharmaceutical Training Package Version 2.0.	

Modification History

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 follow GMP requirements to undertake routine pharmaceutical manufacture work as a junior operator, under supervision.

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	
Elements describe the essential outcomes.	Performance criteria describe the performance needed to demonstrate achievement of the element.	
1. Identify requirements of GMP related to own work	1.1 Locate sources of information on GMP requirements in the workplace1.2 Identify GMP requirements for pharmaceutical manufacture tasks	

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Elements	Performance Criteria		
Elements describe the essential outcomes.	Performance criteria describe the performance needed to demonstrate achievement of the element.		
	1.3 Confirm specific GMP requirements for own work		
2. Prepare for work	2.1 Confirm personal hygiene meets GMP requirements		
	2.2 Prepare, use, store and dispose of personal protective equipment and contamination prevention clothing according to GMP requirements and workplace procedures		
	2.3 Comply with area entry and exit procedures when moving around the workplace		
3. Follow GMP requirements when carrying out work activities	3.1 Routinely monitor work area, materials and equipment to ensure compliance with GMP requirements		
	3.2 Handle raw materials, product and packaging components according to GMP requirements and workplace procedures		
	3.3 Identify contamination and follow appropriate control measures relating to work responsibilities and GMP requirements		
	3.4 Identify processes, practices or conditions which are inconsistent with GMP requirements and report according to workplace procedures		
	3.5 Maintain workplace cleanliness and tidiness to meet GMP requirements		
	3.6 Conduct work according to workplace environmental procedures		
	3.7 Complete documentation according to workplace procedures		

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	• Identify and comprehend information about GMP requirements	
Writing	• Record workplace information using appropriate language and in required format	

Code and title current version	Code and title previous version	Comments	Equivalence status
FBPPHM2001 Follow work procedures to maintain Good Manufacturing Practice requirements Release 2	FBPPHM2001 Follow work procedures to maintain Good Manufacturing Practice requirements Release 1	Removed Foundation Skills Navigate the world of work and Interact with others Minor updates to Knowledge Evidence	Equivalent

Unit Mapping Information

Links

Companion Volume Implementation Guides are found in VETNet: https://vetnet.gov.au/Pages/TrainingDocs.aspx?q=78b15323-cd38-483e-aad7-1159b570a5c4