



Australian Government

FBPPHM2001 Follow work procedures to maintain Good Manufacturing Practice requirements

Release: 2

FBPPHM2001 Follow work procedures to maintain Good Manufacturing Practice requirements

Modification History

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.

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
<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 in the workplace 1.2 Identify GMP requirements for pharmaceutical manufacture tasks

Elements	Performance Criteria
<i>Elements describe the essential outcomes.</i>	<i>Performance criteria describe the performance needed to demonstrate achievement of the element.</i>
	1.3 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

Unit Mapping Information

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

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 FBPPHM2001 Follow work procedures to maintain 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 followed work procedures to maintain Good Manufacturing Practice (GMP) and demonstrated each of the following points at least once:

- located and followed workplace information relating to GMP responsibilities
- maintained good personal hygiene consistent with GMP requirements, including:
 - making team leader or supervisor aware of reportable illness
 - removal of jewellery
 - removal of makeup
- used personal protective equipment and contamination prevention clothing according to workplace procedures
- used and stored personal clothing and footwear consistent with GMP requirements and workplace procedures
- followed workplace procedures when moving around the workplace to maintain GMP
- followed GMP requirements when carrying out work functions
- identified and responded to performance that fails to meet GMP requirements, including:
 - making adjustments
 - reporting to relevant personnel
- handled and disposed of materials that are contaminated or non-conforming
- identified and reported a situation that could compromise GMP requirements
- maintained work area in a clean and tidy state
- followed workplace procedures for documentation and recording.

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:

- sources of advice on GMP requirements in relation to own work
- the role of GMP in preventing contamination and potential implications of non-compliance
- 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
- personal protective equipment and contamination prevention clothing requirements
- personal clothing and footwear use, storage and disposal requirements
- storage and handling requirements for raw materials, product and packaging components relevant to work role
- common types and sources of contamination in the work area including pest infestation
- control methods and procedures used in the work area to maintain GMP, including:
 - the purpose of control
 - the consequences of lack of control
 - control monitoring
- performance that is unacceptable or fails to meet specifications
- actions required in response to non-conformance
- workplace environmental procedures
- workplace procedures for reporting and recording information.

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
 - commercial pharmaceutical production and packaging equipment
- specifications:
 - GMP information relating to the workplace
 - reporting and monitoring systems
 - workplace instructions and procedures
- relationships:
 - supervisor.

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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