



Australian Government

FBPPHM4001 Monitor and maintain Good Manufacturing Practice requirements

Release: 2

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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 provide a leadership role in the day-to-day monitoring and maintenance of Good Manufacturing Practice (GMP) in a pharmaceutical manufacturing facility.

The unit applies to individuals with specialised skills and knowledge of GMP requirements who communicate workplace policies and procedures relevant to pharmaceutical manufacturing operations and have responsibility for the output of others. This includes applying and communicating non-routine technical solutions to predictable and unpredictable problems.

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. Empower team members	1.1 Ensure personal protective equipment and contamination

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to identify GMP requirements	prevention clothing used by team members is serviceable and fitted correctly according to work health and safety requirements 1.2 Ensure GMP requirements and workplace procedures are available 1.3 Identify and address training needs according to team member's level of responsibility 1.4 Provide training and coaching to support individuals and groups to implement GMP requirements and related workplace procedures 1.5 Demonstrate personal hygiene to others to support implementation of GMP requirements and workplace procedures 1.6 Monitor and control resource allocation according to workplace procedures and GMP requirements 1.7 Ensure GMP control measures used in the work area are identifiable by workers
2. Monitor personal hygiene and conduct of team members	2.1 Ensure personal hygiene of work team 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 Ensure personal movements within workplace comply with area entry and exit procedures
3. Monitor implementation of GMP requirements	3.1 Clearly define, document and follow GMP requirements in work area 3.2 Participate in a root cause analysis (RCA) as part of a cross-functional team and report non-compliance(s) from workplace procedures 3.3 Identify and report GMP non-conformance(s) and signs of unacceptable plant or equipment condition 3.4 Put in place quality approved corrective action or preventative action (CAPA) 3.5 Record information according to workplace reporting procedures and to meet GMP requirements 3.6 Ensure team members maintain work area according to workplace cleaning standards

Elements	Performance Criteria
<i>Elements describe the essential outcomes.</i>	<i>Performance criteria describe the performance needed to demonstrate achievement of the element.</i>
4. Maintain and facilitate continuous improvement of GMP	4.1 Identify, report and correct processes or conditions which could result in GMP non-conformance according to individual level of responsibility 4.2 Promptly resolve matters relating to GMP or refer them to appropriate personnel 4.3 Monitor effectiveness of CAPA and control measures according to level of responsibility 4.4 Advise others in the work area of GMP matters relevant to their work role 4.5 Maintain workplace records and documents according to workplace procedures and GMP requirements

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 key information about GMP requirements in workplace procedures
Writing	Prepare GMP training documentation using structure, technical language and format appropriate for purpose and audience
Numeracy	Analyse and interpret numerical performance indicators for workplace reporting related to GMP requirements
Oral Communication	Demonstrate two-way communication including active listening and confirming instructions when explaining GMP requirements to team members

Range of Conditions

This section specifies different work environments and conditions that may affect performance. Essential operating conditions that may be present (depending on the work situation, needs of the candidate, accessibility of the item, and local industry and regional contexts) are included.

Personal hygiene must include:	• informing team leader or supervisor of any reportable illnesses • removal of jewellery, including: • rings • watches • bracelets • removal of makeup.
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Unit Mapping Information

Code and title current version	Code and title previous version	Comments	Equivalence status
FBPPHM4001 Monitor and maintain Good Manufacturing Practice requirements Release 2	FBPPHM4001 Monitor and maintain Good Manufacturing Practice requirements Release 1	Minor word change in Knowledge Evidence 3.2 Removal of Foundation Skills Interact with others and Get the work done Minor changes in Performance Evidence	Equivalent

Links

Companion Volume Implementation Guides are found in VETNet: -

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