



Australian Government

FBPPHM4001 Monitor and maintain Good Manufacturing Practice requirements

Release: 2

FBPPHM4001 Monitor and 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 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>

Assessment Requirements for FBPPHM4001 Monitor and 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 monitored and maintained Good Manufacturing Practice (GMP) requirements of one or more work teams, including:

- communicated information on GMP requirements to others in the work area, including demonstrating:
 - two-way communication
 - active listening
 - constructive responses to feedback
- accessed and used document management systems
- demonstrated personal hygiene according to GMP requirements and workplace procedures
- monitored recorded data to meet GMP recording requirements according to workplace procedures
- documented GMP requirements for a specific work area
- provided training and support to others in the work area to implement responsibilities according to GMP requirements and to workplace procedures
- determined actions required to respond to GMP non-compliance according to workplace procedures
- participated in improvement processes, including investigating actual and potential GMP non-compliance
- participated in, or reviewed, practices and procedures to prevent or minimise the likelihood of unacceptable performance.

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:

- the role of GMP in preventing contamination, including:
 - its relationship to legal requirements of pharmaceutical manufacturers
 - potential implications of non-compliance
- GMP requirements, including:
 - relevant GMP codes of practice
 - related workplace procedures
 - organisational structures for implementing these requirements
 - quality assurance
- principles and process of effective communication and consultation
- workplace training and coaching system and responsibilities
- personal clothing use, storage and disposal requirements and hygiene requirements, including:
 - making team leader or supervisor aware of reportable illness
 - removal of jewellery
 - removal of makeup
- personal clothing and footwear requirements for working in and moving between work areas
- current technical and process knowledge required to monitor and maintain GMP and participate in investigating GMP non-compliance including:
 - common microbiological, physical and chemical contaminants
 - conditions under which types of contamination, including cross-contamination are likely to occur
 - purpose of equipment calibration
 - control methods and procedures, including the purpose of control and the consequences if not controlled
- recall and traceability procedures relevant to the work area, including:
 - reconciliation
 - line clearance
 - stored versus dedicated
- procedures followed to investigate contamination events and performance improvement processes, including:
 - root cause analysis (RCA)
 - corrective action or preventive action (CAPA)
- documentation systems and procedures, including:
 - record keeping to meet both company and legal requirements
 - responding to out-of-specification, or unacceptable, performance and outcomes
 - procedures for identifying and isolating, or quarantining, materials or products of unacceptable quality

- processes for developing or reviewing workplace procedures
- document control systems used in the workplace
- responsibilities for reporting and recording information
- 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.

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
 - document management system
- specifications:
 - GMP requirements
 - workplace cleaning standards
 - workplace reporting procedures
 - workplace procedures related to GMP
- relationships:
 - team members.

Assessors of this unit must satisfy the requirements for assessors in applicable vocational education and training legislation, frameworks and/or standards.

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