



Australian Government

FBPPHM4002 Prepare and review workplace documentation to support 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 develop, review and communicate workplace operations documentation to support Good Manufacturing Practice (GMP) in a pharmaceutical manufacturing facility.

The unit applies to individuals with specialised skills and knowledge of GMP requirements who manage and maintain documentation 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. Review and draft workplace documentation to meet GMP requirements	1.1 Identify workplace documentation requiring development or review according to workplace documentation management process and GMP requirements 1.2 Initiate documentation changes according to change control process 1.3 Review workplace documentation in consultation with relevant

Elements	Performance Criteria
<i>Elements describe the essential outcomes.</i>	<i>Performance criteria describe the performance needed to demonstrate achievement of the element.</i>
	stakeholders to support GMP 1.4 Draft workplace documentation in consultation with relevant stakeholders to support GMP 1.5 Ensure workplace documentation explains complex information in a simple and clear manner
2. Finalise workplace documentation to meet GMP requirements	2.1 Complete final version of documentation according to documentation management process 2.2 Submit final version of documentation for approval according to change control process

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 in GMP requirements and workplace procedures - Review completed workplace documentation to ensure that GMP requirements are met
Writing	Prepare training documentation using structure, technical language and format appropriate for purpose and audience
Oral Communication	- Demonstrate two-way communication including active listening and confirming instructions when explaining workplace documentation to team members - Use appropriate vocabulary, including technical language directly relevant to role
Get the work done	Access and use electronic document management systems

Unit Mapping Information

Code and title	Code and title	Comments	Equivalence status
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current version	previous version		
FBPPHM4002 Prepare and review workplace documentation to support Good Manufacturing Practice requirements	FDFPH4001A Prepare and review workplace documentation to support Good Manufacturing Practice	Updated to meet Standards for Training Packages Change to unit title Changes to element 2 and its performance criteria to remove the identification of training requirements	Equivalent unit

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 FBPPHM4002 Prepare and review workplace documentation to support 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 reviewed and developed workplace documentation to support the Good Manufacturing Practice (GMP) requirement of at least one workplace, including:

- identified workplace documentation requiring development or review using workplace documentation management process
- reviewed and developed workplace documentation, suitable for purpose and audience, including:
 - ensuring compliance with workplace procedures and GMP requirements
 - reporting improvements
 - reviewing and updating existing documentation
 - developing new documentation
 - applying documentation control procedures when submitting or amending documents
- accessed and used document management systems
- consulted with relevant stakeholders in the preparation and review process and ensured changes are effectively communicated
- communicated information on documentation requirements to others in the work area, including demonstrating:
 - two-way communication
 - active listening
 - constructive responses to feedback.

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:

- workplace procedures and GMP requirements
- types of documentation requiring development or review, including:
 - procedures
 - instructions
 - records
- situations requiring documentation development or review, including:
 - general review
 - process change
 - inspection findings
 - deviations
- procedures and responsibilities for developing and altering documents, including:
 - version control
 - good documentation design and the use of templates
 - an understanding of system security and access levels
 - controls systems, including individual roles and responsibilities
 - document authorisation requirements and responsibilities of signatories
 - systems for recording and storing data and authorised levels of access to electronic systems
- use of documentation, including documents that can be used as evidence during audit processes
- requirements for completion of workplace documentation.

Assessment Conditions

Assessment of skills 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:
 - document management system
- specifications:
 - information about GMP requirements
 - workplace procedures related to GMP.

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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