



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>