FBPPHM3020 Apply 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 7.0.

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 apply GMP requirements to undertake pharmaceutical manufacture work. Individuals work under broad direction and take responsibility for their own work.

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
Elements describe the essential outcomes.	*Performance criteria describe the performance needed to demonstrate achievement of the element.*
1. Identify requirements of GMP related to own work	1.1 Locate sources of information on GMP requirements and regulatory obligations of employees relevant to work role from current Australian and other applicable regulatory frameworks for manufacturing pharmaceuticals

1.2 Identify GMP requirements for pharmaceutical manufacture tasks

1.3 Confirm specific GMP requirements for own work

1.4 Identify GMP non-compliant situations and risks to product |

Elements	Performance Criteria
Elements describe the essential outcomes.	*Performance criteria describe the performance needed to demonstrate achievement of the element.*
	quality 1.5 Alert relevant personnel and take appropriate action according to GMP requirements and workplace procedures
2. Complete workplace documentation to support GMP	2.1 Use workplace procedures to identify GMP requirements for documentation 2.2 Record required information, calculations and test results according to workplace reporting procedures and GMP requirements 2.3 Certify records according to GMP requirements
3. Identify and follow biosecurity requirements	3.1 Identify information appropriate to work role relating to biosecurity requirements 3.2 Follow workplace biosecurity requirements and responsibilities related to work role
4. Apply GMP requirements when carrying out work activities	4.1 Identify common forms of contamination relevant to own work activities 4.2 Conduct work according to workplace environmental procedures 4.3 Maintain workplace cleanliness and tidiness to meet GMP requirements 4.4 Identify and report signs of unacceptable plant, equipment condition or calibration status 4.5 Identify GMP requirements for routinely monitoring work area, materials, equipment and product 4.6 Complete documentation according to workplace procedures
5. Apply hygiene and entry and exit procedures to meet GMP requirements	5.1 Maintain personal hygiene to meet GMP requirements 5.2 Carry out hand washing according to best practice hygiene standards 5.3 Prepare, use, store and dispose of personal protective equipment and contamination prevention clothing according to GMP requirements and workplace procedures 5.4 Comply with area entry and exit procedures when moving around the workplace
6. Participate in improving GMP	6.1 Identify processes, practices or conditions which are inconsistent with GMP requirements and report according to workplace procedures 6.2 Identify elements of GMP that help improve products and

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Elements	Performance Criteria
Elements describe the essential outcomes.	*Performance criteria describe the performance needed to demonstrate achievement of the element.*
	processes
	6.3 Implement corrective action within level of responsibility

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 information about GMP compliance requirements in workplace documentation
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
FBPPHM3020 Apply Good Manufacturing Practice requirements	FBPPHM3001 Apply Good Manufacturing Practice requirements	Element removed Changes to Element, Performance Criteria, Foundation Skills, Performance Evidence, Knowledge Evidence and Assessment Conditions	Not equivalent

Links

Companion Volumes, including Implementation Guides, are available at VETNet: - https://vetnet.gov.au/Pages/TrainingDocs.aspx?q=78b15323-cd38-483e-aad7-1159b570a5c4