



Australian Government

FBPPHM4005 Participate in validation of pharmaceutical manufacturing processes

Release: 1

FBPPHM4005 Participate in validation of pharmaceutical manufacturing processes

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 use qualification and validation processes to meet Good Manufacturing Practice (GMP) requirements in a pharmaceutical manufacturing facility.

The unit applies to individuals with specialised skills and knowledge of GMP requirements who participate in validation process relevant to pharmaceutical manufacturing operations as part of a multi-disciplinary team 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. Participate in qualification processes for facilities, systems or equipment	1.1 Identify procedures for developing and implementing qualification processes 1.2 Develop and review qualification processes and documentation according to workplace procedures

Elements	Performance Criteria
<i>Elements describe the essential outcomes.</i>	<i>Performance criteria describe the performance needed to demonstrate achievement of the element.</i>
	1.3 Implement qualification process training needs
2. Participate in validation processes for facilities, systems or equipment	2.1 Identify validation requirements according to workplace procedures and GMP requirements 2.2 Follow validation protocol to support validation activities in the work area 2.3 Evaluate and document deviations and exceptions from protocol 2.4 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 in GMP requirements and workplace procedures relevant to qualification and validation processes
Writing	Create qualification procedures and validation reports using relevant technical terminology and format to suit regulatory requirements
Oral Communication	- Demonstrate two-way communication, including active listening and confirming instructions, when explaining qualification processes to team members - Use appropriate vocabulary, including technical language to explain processes
Get the work done	Access and use electronic document management systems

Unit Mapping Information

Code and title current	Code and title	Comments	Equivalence
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version	previous version		status
FBPPHM4005 Participate in validation of pharmaceutical manufacturing processes	FDFPH4005A Participate in validation processes	Updated to meet Standards for Training Packages Changes to the unit title and performance criteria for clarity	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 FBPPHM4005 Participate in validation of pharmaceutical manufacturing processes

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Performance Evidence

An individual demonstrating competency in this unit must satisfy all the elements and performance criteria of this unit.

There must be evidence that the individual has participated in the validation processes of at least one workplace, including:

- identified procedures for developing and implementing qualification processes for a:
 - design qualification
 - installation qualification
 - operational qualification, and
 - performance qualification
- applied principles of risk management to identify critical facilities, systems and equipment
- communicated information on qualification process requirements to others in the work area, including demonstrating:
 - two-way communication
 - active listening
 - constructive responses to feedback
- implemented training to support others in the work area to implement responsibilities according to qualification process requirements
- interpreted Good Manufacturing Practice (GMP) requirements and workplace procedures related to qualification and validation requirements
- managed the impact of qualification and validation procedures on:
 - related processes
 - work areas
 - personnel
- developed workplace procedures to support qualification and validation according to GMP requirements and workplace procedures
- documented qualification and validation processes according to GMP requirements and workplace procedures.

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 procedures for developing and implementing qualification processes
- types of qualification processes, including:
 - design
 - installation
 - operational
 - performance
- validation objectives and procedures, including:
 - prospective validation
 - concurrent validation
 - re-validation
 - circumstances that justify not undertaking a validation process prior to commencing production
 - procedure updates and sampling requirements
- workplace training systems and responsibilities
- GMP requirements and workplace procedures relevant to qualification and validation processes
- documentation systems and procedures, including:
 - record keeping to meet both company and legal requirements
 - processes for developing or reviewing workplace procedures
 - document control systems used in the workplace
 - responsibilities for reporting and recording information.

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:
 - qualification and validation process documentation
- specifications:
 - workplace procedures relating to validation
 - GMP requirements related to validation
- relationships:
 - team members.

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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