



Australian Government

Assessment Requirements for FBPPHM4005 Participate in validation of pharmaceutical manufacturing processes

Release: 1

Assessment Requirements for 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.

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

Companion Volume Implementation Guides are found in VETNet: -

<https://vetnet.gov.au/Pages/TrainingDocs.aspx?q=78b15323-cd38-483e-aad7-1159b570a5c4>