



Australian Government

Assessment Requirements for FBPPHM4004 Participate in change control procedures

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.

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 change control procedures in at least one pharmaceutical manufacturing facility, including:

- identified situations requiring change control according to change proposal
- participated in developing a change management plan
- led the implementation of change in a work area
- communicated information on change requirements to others in the work area, including demonstrating:
 - two-way communication
 - active listening
 - responses to feedback
- accessed and used document management systems
- implemented training to support others in the work area to implement responsibilities according to change management plan
- interpreted Good Manufacturing Practice (GMP) requirements and workplace procedures related to change control
- documented change according to GMP requirements and workplace change control 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:

- principles of risk management and related procedures
- documentary evidence required to support change requests
- workplace change control procedures, including:
 - evaluation criteria

- change classification
- authorisation requirements
- document control
- roles and responsibilities
- workplace training systems and responsibilities
- GMP requirements and workplace procedures relevant to change control
- 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:
 - change proposal
 - document management system
- specifications:
 - workplace change control procedures
 - workplace documentation relating to change control procedures
 - GMP requirements related to change control
- 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>