



Australian Government

FBPPHM4004 Participate in change control procedures

Release: 1

FBPPHM4004 Participate in change control procedures

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 participate in planning and implementing change control procedures 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 contribute to the development of defined change management programs and procedures 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. Participate in planning change	1.1 Interpret change proposal to identify impact of change on the workplace 1.2 Interpret workplace procedures and GMP requirements for managing change 1.3 Conduct risk assessment for change implementation in the

Elements	Performance Criteria
<i>Elements describe the essential outcomes.</i>	<i>Performance criteria describe the performance needed to demonstrate achievement of the element.</i>
	workplace 1.4 Undertake planning of change management 1.5 Identify workplace procedures affected by change management plan and allocate responsibilities for review 1.6 Identify training needs arising from change and determine delivery methods and responsibilities 1.7 Apply authorisation requirements according to workplace change control procedures 1.8 Finalise change management plan according to workplace procedures and GMP requirements
2. Participate in implementing change	2.1 Communicate change to all affected personnel 2.2 Implement training to support affected individuals and groups according to workplace procedures 2.3 Revise workplace procedures to reflect change requirements 2.4 Monitor and evaluate change according to workplace change control procedures 2.5 Implement adjustments to change according to workplace change control procedures 2.6 Maintain workplace records and documents according to workplace change control 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 change proposal and workplace change control procedures - Interpret key information in GMP requirements and workplace procedures relevant to change control
Writing	Document change management plan in required workplace format

Skill	Description
Oral Communication	• Demonstrate two-way communication including active listening and questioning skills when explaining change management plan to team members • Use appropriate vocabulary, including technical language directly relevant to role
Interact with others	• Use appropriate techniques negotiation and conflict resolution techniques
Get the work done	• Access and use electronic document management system

Unit Mapping Information

Code and title current version	Code and title previous version	Comments	Equivalence status
FBPPHM4004 Participate in change control procedures	FDFPH4004A Participate in change control procedures	Updated to meet Standards for Training Packages Changes to 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 FBPPHM4004 Participate in change control procedures

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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 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.

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