![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
Elements describe the essential outcomes.	*Performance criteria describe the performance needed to demonstrate achievement of the element.*
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
Elements describe the essential outcomes.	*Performance criteria describe the performance needed to demonstrate achievement of the element.*
	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