



Australian Government

FBPPHM4003 Facilitate contamination control

Release: 2

FBPPHM4003 Facilitate contamination control

Modification History

Release	Comments
Release 2	This version released with FBP Food, Beverage and Pharmaceutical Training Package Version 5.0.
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 identify and implement contamination control measures in a pharmaceutical manufacturing facility.

The unit applies to individuals with specialised skills and knowledge of Good Manufacturing Practice (GMP) requirements who are responsible for overseeing the implementation of contamination control programs within 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 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. Review contamination risks and related control measures to meet GMP requirements	1.1 Identify hazards that could present contamination risks by type, origin and product association 1.2 Review hazards and risk control measures to confirm they meet

Elements	Performance Criteria
<i>Elements describe the essential outcomes.</i>	<i>Performance criteria describe the performance needed to demonstrate achievement of the element.</i>
	GMP requirements 1.3 Conduct risk assessment according to GMP requirements and workplace procedures 1.4 Confirm control measures
2. Implement procedures used to control risk of cross contamination	2.1 Identify effective barriers and control systems to minimise risk of contamination according to GMP requirements and workplace procedures 2.2 Conduct in-process and environmental monitoring according to GMP requirements and workplace procedures 2.3 Validate cleaning processes according to workplace procedures 2.4 Confirm line clearance procedures 2.5 Ensure personal hygiene and conduct of personnel in work area meets GMP requirements 2.6 Ensure operators have the skills and knowledge required to apply contamination control measures

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 from in-process and environmental monitoring test results - Interpret key information about GMP requirements in workplace procedures relevant to facilitating contamination control
Writing	Record contamination information in document management systems
Oral communication	Use appropriate language and communication skills to ensure that contamination management procedures are understood and implemented
Numeracy	Monitor data to determine instances of contamination according to GMP requirements

Unit Mapping Information

Code and title current version	Code and title previous version	Comments	Equivalence status
FBPPHM4003 Facilitate contamination control Release 2	FBPPHM4003 Facilitate contamination control Release 1	Foundation skills table updated Minor changes to performance evidence and knowledge evidence for clarity	Equivalent

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 FBPPHM4003 Facilitate contamination control

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Performance Evidence

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

There must be evidence that the individual has facilitated contamination control in at least one process, including:

- identified and investigated occurrences that could present contamination hazards and risks by:
 - type
 - origin
 - product association
- confirmed contamination control measures, including:
 - critical limits
 - monitoring and recording requirements
- interpreted Good Manufacturing Practice (GMP) requirements and workplace procedures related to contamination control
- used document management systems to:
 - access and review documents including the Contamination Control Strategy
 - monitor and record data according to GMP requirements
 - ensure procedures are understood and implemented
- reviewed workplace documents to determine contamination control measures, including:
 - equipment drawings
 - piping and instrumentation diagrams
 - process flow charting
- monitored gowning, cleaning, access and refresher training according to workplace procedures

- provided training and support to others in work area to implement contamination control 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:

- types of contamination, including:
 - microbiological
 - chemical
 - physical
 - product cross-contamination
- microbiological limits as per GMP Guide, monitoring methods and reporting and recording formats and requirements
- non-viable particle limits as per GMP Guide, monitoring methods and reporting and recording formats and requirements
- line clearance procedures, roles and responsibilities
- personal hygiene and clothing requirements, including:
 - informing team leader or supervisor of reportable illness
 - removal of jewellery
 - removal of makeup
 - personal clothing use, storage and disposal
 - personal clothing and footwear requirements for working in and moving between work areas
 - decontamination
 - laundering requirements
- GMP requirements and workplace procedures relevant to contamination control
- environmental issues and workplace controls relevant to contamination control, including:
 - the principles of workflow design to minimise risk of contamination
 - ventilation system requirements
 - production facility segregation requirements
 - storage requirements of raw materials prior to their use in manufacture
 - time limits and conditions for storing finished products prior to packaging
 - requirements relevant to product range
- workplace cleaning standards and responsibilities, including:
 - types of cleaning agents and what they do
 - waste collection
 - recycling, safe handling and disposal of different types of waste
 - safe handling and disposal of hazardous waste
- requirements for completion of workplace documentation
- active air samplers and particle counters used in environmental monitoring cleanrooms.

Assessment Conditions

Assessment of the skills in this unit of competency 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:
 - document management system
 - equipment drawings, piping and instrumentation diagrams and process flow charts
- specifications:
 - recording requirements and procedures
 - workplace procedures related to contamination control
 - GMP requirements related to contamination control
 - workplace cleaning procedures
- 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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