



**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	<ul style="list-style-type: none"> <li>Interpret key information from in-process and environmental monitoring test results</li> <li>Interpret key information about GMP requirements in workplace procedures relevant to facilitating contamination control</li> </ul>
Writing	<ul style="list-style-type: none"> <li>Record contamination information in document management systems</li> </ul>
Oral communication	<ul style="list-style-type: none"> <li>Use appropriate language and communication skills to ensure that contamination management procedures are understood and implemented</li> </ul>
Numeracy	<ul style="list-style-type: none"> <li>Monitor data to determine instances of contamination according to GMP requirements</li> </ul>

## 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>