



**Australian Government**

# **Assessment Requirements for FBPPHM4003 Facilitate contamination control**

**Release: 2**

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## 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.

## 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.

## Links

Companion Volume Implementation Guides are found in VETNet: -

<https://vetnet.gov.au/Pages/TrainingDocs.aspx?q=78b15323-cd38-483e-aad7-1159b570a5c4>