



Australian Government

FBPPHM3003 Work in a controlled environment

Release: 1

FBPPHM3003 Work in a controlled environment

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 prepare to enter, work and exit a controlled environment in a pharmaceutical manufacturing facility.

The unit applies to individuals who apply Good Manufacturing Practice (GMP) requirements and operating principles to working in a controlled environment. Individuals work under broad direction and take responsibility for their own work.

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. Prepare to enter a controlled environment	1.1 Obtain workplace information, including workplace procedures related to working in a controlled environment 1.2 Remove jewellery and makeup according to workplace procedures 1.3 Wash hands according to workplace procedures 1.4 Source and fit personal protective equipment (PPE) and contamination prevention clothing prior to entering controlled environment

Elements	Performance Criteria
<i>Elements describe the essential outcomes.</i>	<i>Performance criteria describe the performance needed to demonstrate achievement of the element.</i>
	1.5 Check controlled environment operating conditions prior to entry
2. Work in a controlled environment	2.1 Enter controlled environment according to workplace procedures 2.2 Take commodity items into the controlled environment according to workplace procedures 2.3 Conduct work activities to minimise risk of contamination
3. Maintain a controlled environment	3.1 Identify controlled environment contamination risks 3.2 Control environmental contamination according to GMP requirements and workplace procedures 3.3 Maintain controlled environment work area according to workplace cleaning standards and environmental requirements 3.4 Report practices inconsistent with GMP according to workplace procedures
4. Exit a controlled environment	4.1 Follow workplace procedures to exit a controlled environment 4.2 Remove PPE and contamination prevention clothing according to workplace procedures 4.3 De-gown according to workplace procedures 4.4 Check, store and dispose of PPE according to manufacturer specifications, environmental and work health and safety 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 signs, symbols, checklists, production schedules, cleaning schedules and other technical information relevant to working in controlled environments - Access and interpret GMP information relevant to working in controlled environments
Writing	Complete workplace documentation using appropriate language and in required format

Skill	Description
Interact with others	Report GMP concerns to relevant personnel using required communication method
Navigate the world of work	Recognise and follow workplace requirements, including safety requirements and GMP, associated with own role and area of responsibility

Range of Conditions

This section specifies different work environments and conditions that may affect performance. Essential operating conditions that may be present (depending on the work situation, needs of the candidate, accessibility of the item, and local industry and regional contexts) are included.

Controlled environment must include at least one of the following:	- controlled, non-classified environment - cleanrooms that are controlled environments that have been certified as meeting an internationally recognised standard.
Contamination prevention clothing must include at least one of the following:	- facility suits for controlled, non-classified environment - disposable and reusable garments for controlled, classified cleanroom environments.

Unit Mapping Information

Code and title current version	Code and title previous version	Comments	Equivalence status
FBPPHM3003 Work in a controlled environment	Not applicable	New unit	No equivalent unit

Links

Companion Volume Implementation Guides are found in VETNet: -

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