



Australian Government

FBPPHM3008 Operate an aseptic fill and seal process

Release: 2

FBPPHM3008 Operate an aseptic fill and seal process

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 set up, operate, monitor, adjust and shut down an aseptic fill and seal process within a graded cleanroom environment in a pharmaceutical manufacturing facility.

The unit applies to individuals who apply Good Manufacturing Practice (GMP) requirements and operation principles to the aseptic fill and seal process. Individuals work under broad direction and take responsibility for their own work.

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. Set up filling and sealing process	1.1 Identify production requirements from workplace documentation 1.2 Confirm materials, packaging components and consumables are available to meet batch and production requirements 1.3 Confirm required facilities and equipment are available

Elements	Performance Criteria
<i>Elements describe the essential outcomes.</i>	<i>Performance criteria describe the performance needed to demonstrate achievement of the element.</i>
	<p>1.4 Source and fit cleanroom garments and personal protective equipment according to gowning Standard Operating Procedures (SOP)</p> <p>1.5 Maintain sterile quality of the gown according to workplace gowning SOP</p> <p>1.6 Fit and adjust machine components and attachments according to production requirements and equipment operation and maintenance manual</p> <p>1.7 Enter processing and operating parameters according to safety and production requirements</p> <p>1.8 Check and adjust equipment performance according to equipment operating procedures</p> <p>1.9 Conduct pre-start checks according to workplace procedures</p>
2. Operate and monitor a filling and sealing process	<p>2.1 Start up and monitor aseptic fill and seal process to confirm products are within required limits</p> <p>2.2 Monitor packaging quality and seal integrity to confirm that specifications are met</p> <p>2.3 Identify and report out of limit products or processes according to workplace procedures</p> <p>2.4 Maintain work area according to workplace cleaning standards</p> <p>2.5 Maintain consistent aseptic techniques</p> <p>2.6 Conduct process and sampling according to safety requirements and environmental monitoring procedures</p> <p>2.7 Contain, remove and report spillages according to procedures</p> <p>2.8 Complete documentation according to workplace requirements</p>
3. Shut down filling and sealing process	<p>3.1 Confirm the workplace procedures for shutting down the process</p> <p>3.2 Complete end-of-batch procedures according to batch instructions</p> <p>3.3 Safely shut down the process</p> <p>3.4 Clean sealing equipment according to workplace procedures</p> <p>3.5 De-gown according to workplace gowning SOP</p> <p>3.6 Complete records according to workplace procedures</p>

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">Identify relevant information from workplace documentation, SOP and batch instructions and interpret requirements for the aseptic fill and seal process
Writing	<ul style="list-style-type: none">Complete workplace documentation using appropriate language and in required format
Numeracy	<ul style="list-style-type: none">Confirm process specifications for flow rates, temperature, fill levels, weights and volumes

Unit Mapping Information

Code and title current version	Code and title previous version	Comments	Equivalence status
FBPPHM3008 Operate an aseptic fill and seal process Release 2	FBPPHM3008 Operate an aseptic fill and seal process Release 1	Foundation skills table updated Range of conditions deleted to remove duplication Minor changes to assessment requirements and assessment conditions 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>