

**Modification history**

Release	Comments
Release 2	This version released with FBP Food, Beverage and Pharmaceutical Training Package Version 3.0.
Release 1	This version released with FBP Food, Beverage and Pharmaceutical Training Package Version 2.0.

FBPPHM3008	Operate an aseptic fill and seal process
<b>Application</b>	<p>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.</p> <p>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.</p> <p>No occupational licensing, legislative or certification requirements apply to this unit at the time of publication. <b>Error! Use the Home tab to apply AFSA AR Code to the text that you want to appear here.</b></p>
<b>Prerequisite Unit</b>	Nil
<b>Unit Sector</b>	Pharmaceutical (PHM)

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 1.4 Source and fit cleanroom garments and personal protective equipment according to workplace gowning standard operating procedures (SOP) 1.5 Maintain sterile quality of the gown according to workplace gowning SOP 1.6 Fit and adjust machine components and attachments according to production requirements and equipment operation and maintenance manual 1.7 Enter processing and operating parameters according to safety and production requirements 1.8 Check and adjust equipment performance according to equipment operating procedures 1.9 Conduct pre-start checks according to workplace procedures
2. Operate and monitor a filling and sealing process	2.1 Start up and monitor aseptic fill and seal process to confirm products are within required limits 2.2 Monitor packaging quality and seal integrity to confirm that specifications are met 2.3 Identify and report out of limit products or processes according to workplace procedures 2.4 Maintain work area according to workplace cleaning standards 2.5 Maintain consistent aseptic techniques 2.6 Conduct process and sampling according to safety requirements and environmental monitoring procedures 2.7 Contain, remove and report spillages according to procedures 2.8 Complete documentation according to workplace requirements

<b>Elements</b>	<b>Performance Criteria</b>
<i>Elements describe the essential outcomes.</i>	<i>Performance criteria describe the performance needed to demonstrate achievement of the element.</i>
3. Shut down filling and sealing process	3.1 Confirm the workplace procedures for shutting down the process 3.2 Complete end-of-batch procedures according to batch instructions 3.3 Safely shut down the process 3.4 Clean sealing equipment according to workplace procedures 3.5 De-gown according to workplace gowning SOP 3.6 Complete records according to workplace procedures

<b>Foundation Skills</b>	
<i>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.</i>	
<b>Skill</b>	<b>Description</b>
Reading	<ul style="list-style-type: none"> <li>Identify relevant information from workplace documentation, standard operating procedures and batch instructions and interpret requirements for the aseptic fill and seal process</li> </ul>
Writing	<ul style="list-style-type: none"> <li>Complete workplace documentation using appropriate language and in required format</li> </ul>
Numeracy	<ul style="list-style-type: none"> <li>Confirm process specifications for flow rates, temperature, fill levels, weights and volumes</li> </ul>

<b>Range of Conditions</b>	
<i>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.</i>	
Cleanroom garments and personal protective equipment must include:	<ul style="list-style-type: none"> <li>coverall</li> <li>disposable and/or reusable: <ul style="list-style-type: none"> <li>surgical or elastic gloves</li> <li>face masks</li> <li>hair nets and hoods</li> <li>beard/moustache covers</li> <li>goggles or glasses</li> <li>overshoes or cleanroom boots and/or shoe covers.</li> </ul> </li> </ul>
Pre-start checks must include:	<ul style="list-style-type: none"> <li>carrying out required area or line clearances</li> <li>inspecting equipment condition to identify signs of wear</li> <li>confirming all safety equipment is in place and operational confirming that equipment is clean or sanitised</li> <li>confirming that equipment is correctly configured for processing requirements.</li> </ul>

<b>Unit Mapping Information</b>			
<b>Code and title current version</b>	<b>Code and title previous version</b>	<b>Comments</b>	<b>Equivalence status</b>
FBPPHM3008 Operate an aseptic fill and seal process Release 2	FBPPHM3008 Operate an aseptic fill and seal process Release 1	Foundation skills amended Assessment Conditions updated	Equivalent unit

<b>Links</b>	Companion Volumes, including Implementation Guides, are available at VETNet <a href="https://vetnet.gov.au/Pages/TrainingDocs.aspx?q=78b15323-cd38-483e-aad7-1159b570a5c4">https://vetnet.gov.au/Pages/TrainingDocs.aspx?q=78b15323-cd38-483e-aad7-1159b570a5c4</a>
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<p><b>TITLE</b></p>	<p><b>Assessment requirements for</b> Error! Use the Home tab to apply AFSA Unit Code to the text that you want to appear here. Error! Use the Home tab to apply AFSA Unit Title to the text that you want to appear here.</p>
<p><b>Performance Evidence</b></p>	
<p>An individual demonstrating competency in this unit must satisfy all the elements and performance criteria of this unit.</p> <p>There must be evidence that the individual has operated at least one aseptic fill and seal process, including:</p> <ul style="list-style-type: none"> <li>• accessed workplace information to confirm production requirements for the aseptic fill and seal process</li> <li>• confirmed supply of necessary materials, packaging components and consumables for the aseptic fill and seal process</li> <li>• selected, fitted and used cleanroom garments and personal protective equipment including gowning and de-gowning</li> <li>• maintained the sterile quality of the gown after performance of gowning procedures and aseptic process by microbiological surface sampling of several locations on gown</li> <li>• followed required work area entry and exit procedures and moved around the work area in a manner that does not generate additional contaminants</li> <li>• conducted pre-start checks required for the safe operation of the aseptic fill and seal process, including:             <ul style="list-style-type: none"> <li>• carrying out required area or line clearances</li> <li>• inspecting equipment condition to identify signs of wear</li> <li>• confirming all safety equipment is in place and operational</li> <li>• confirming that equipment is clean or sanitised</li> <li>• confirming that equipment is correctly configured for processing requirements</li> </ul> </li> <li>• started, operated, monitored and adjusted aseptic fill and seal process equipment to achieve required outcomes, including:             <ul style="list-style-type: none"> <li>• supply and flow of materials to and from process</li> <li>• flow rates</li> <li>• weights and volumes</li> <li>• fill levels</li> <li>• temperature, including materials and sealing temperatures</li> <li>• supply of packaging components and consumables</li> <li>• container closure integrity</li> </ul> </li> <li>• conducted in-process control checks to confirm the process remains within limits</li> <li>• inspected units for defects</li> <li>• taken corrective action in response to a non-conformance</li> <li>• maintained consistent aseptic techniques</li> <li>• followed end-of-batch procedures, including:             <ul style="list-style-type: none"> <li>• line clearance and cleaning</li> <li>• yield calculation</li> <li>• materials reconciliation</li> <li>• product labelling</li> </ul> </li> <li>• safely shut down the process according to workplace procedures</li> <li>• cleaned and maintained work area to meet workplace cleaning standards and environmental requirements</li> <li>• completed records according to workplace procedures.</li> </ul>	

## 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:

- stages of the aseptic fill and seal process, including:
  - the purpose, methods and outcomes of each stage
  - control points
- how the flow of an aseptic fill and seal process affects outputs on downstream processes
- quality characteristics to be achieved by the aseptic fill and seal process, including:
  - quality requirements of packaging components and consumables
  - sterilisation requirements and procedures
  - fill volume by levels and weights
  - requirements of seal formation and integrity
  - importance of maintaining sterile product
  - integrity testing procedures
- principles of filling and sealing, including properties of packaging materials used
- principles of heat sterilisation
- the effect of heat sterilisation on microbiological characteristics of product, packaging materials, and a filling process
- aseptic container preparation, handling and loading
- functions and limitations of cleanroom garments and personal protective clothing and equipment
- gowning and de-gowning techniques
- cleanroom behaviour and hygiene
- aseptic techniques
- microbiology applicable to aseptic fill and seal process
- basic operating principles, requirements and parameters of aseptic filling and sealing equipment, including:
  - main equipment components, operating capacities and applications
  - typical faults and related causes, including signs and symptoms of faulty equipment and early warning signs of potential problems
  - status and purpose of guards
  - the purpose and location of sensors and related feedback instrumentation
  - corrective actions taken where operation is outside specified operating parameters
- operating principles of process control, including the relationship between control panels, systems and physical equipment
- pre-start checks requirements, including:
  - carrying out required area or line clearances
  - inspecting equipment condition to identify signs of wear
  - confirming all safety equipment is in place and operational
  - confirming that equipment is clean or sanitised
  - confirming that equipment is correctly configured for processing requirements
- methods used to monitor an aseptic fill and seal process, including:
  - inspecting
  - measuring
  - testing
  - product, packaging and process changeover procedures and responsibilities
- common causes of out-of-specification product or process and corrective actions required, including the effect of variations in both product and packaging components or consumables on filling and sealing performance
- end-of-batch procedures, including:
  - calculating yield
  - materials reconciliation
  - product labelling
  - actions required if yield or reconciliation is not within prescribed limits
- requirements of different shutdowns, including:
  - emergency and routine shutdowns
  - procedures to follow in the event of a power outage
- line clearance procedures, including cleaning and sanitation procedures

<p><b>Knowledge Evidence</b></p> <ul style="list-style-type: none"> <li>• isolation, lock out and tag out procedures and responsibilities</li> <li>• Good Manufacturing Practice (GMP) requirements associated with aseptic fill and seal process and related control measures</li> <li>• environmental issues and controls relevant to the aseptic fill and seal process, including waste collection and handling procedures</li> <li>• requirements for completion of workplace documentation.</li> </ul>
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<p><b>Assessment Conditions</b></p> <p>Assessment of skills must take place under the following conditions:</p> <ul style="list-style-type: none"> <li>• physical conditions:             <ul style="list-style-type: none"> <li>• a pharmaceutical workplace or an environment that accurately represents workplace conditions</li> </ul> </li> <li>• resources, equipment and materials:             <ul style="list-style-type: none"> <li>• cleanroom garments and personal protective equipment</li> <li>• aseptic fill and seal process equipment</li> <li>• materials, packaging components and consumables for an aseptic fill and seal process</li> <li>• microbiological surface sampling tools (touch plates)</li> <li>• microbiological growth medium for process simulation (media fill)</li> <li>• environmental monitoring equipment</li> <li>• cleaning materials and equipment associated with aseptic fill and seal process</li> <li>• record keeping system</li> </ul> </li> <li>• specifications:             <ul style="list-style-type: none"> <li>• batch instructions including product specifications, control points and processing parameters</li> <li>• recording requirements and procedures according to Good Documentation Practice</li> <li>• workplace documentation relating to aseptic fill and seal process and procedures that comply with GMP requirements</li> <li>• information on equipment capacity and operating parameters</li> <li>• microbiological surface sampling limits for gown locations</li> <li>• cleaning and environmental monitoring procedures associated with aseptic fill and seal process.</li> </ul> </li> </ul> <p>Assessors of this unit must satisfy the requirements for assessors in applicable vocational education and training legislation, frameworks and/or standards.</p>
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<p><b>Links</b></p>	<p>Companion Volumes, including Implementation Guides, are available at VETNet <a href="https://vetnet.gov.au/Pages/TrainingDocs.aspx?q=78b15323-cd38-483e-aad7-1159b570a5c4">https://vetnet.gov.au/Pages/TrainingDocs.aspx?q=78b15323-cd38-483e-aad7-1159b570a5c4</a></p>
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