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.

FBPPHM3009	Operate an aseptic form, fill and seal process
Application	This unit of competency describes the skills and knowledge required to set up, operate, adjust and shut down an aseptic form, fill and seal process within a graded cleanroom environment in a pharmaceutical manufacturing facility. The unit applies to individuals who use Good Manufacturing Practice (GMP) requirements and operation principles in the aseptic form, fill and seal process. 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.**Error! Use the Home tab to apply AFSA AR Code to the text that you want to appear here.**
Prerequisite Unit	Nil
Unit Sector	Pharmaceutical (PHM)

Elements	Performance Criteria
Elements describe the essential outcomes.	*Performance criteria describe the performance needed to demonstrate achievement of the element.*
1. Set up form, fill and seal 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 contamination free gloves and 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 form, fill and seal process	2.1 Start up and monitor aseptic form, 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 SOP 2.8 Complete documentation according to workplace requirements

Elements	Performance Criteria
Elements describe the essential outcomes.	*Performance criteria describe the performance needed to demonstrate achievement of the element.*
3. Shut down a form, fill and seal 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

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	• Identify relevant information from workplace documentation, standard operating procedures and batch instructions and interpret requirements for the aseptic form, fill and seal process
Writing	• Complete workplace documentation using appropriate language and in required format
Numeracy	• Confirm process specifications for flow rates, temperature, fill levels, weights, volumes, pressure and wall thickness

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.

Cleanroom garments and personal protective equipment must include:	• coverall
	• disposable and/or reusable:
	  • surgical or elastic gloves
	  • face masks
	  • hair nets and hoods
	  • beard/moustache covers
	  • goggles or glasses
	  • overshoes or cleanroom boots and/or shoe covers.

Pre-start checks must include:	• 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

Unit Mapping Information

Code and title current version	Code and title previous version	Comments	Equivalence status
FBPPHM3009 Operate an aseptic form, fill and seal process Release 2	FBPPHM3009 Operate an aseptic form, fill and seal process Release 1	Foundation skills amended Assessment Conditions clarified	Equivalent unit

Links	Companion Volumes, including Implementation Guides, are available at VETNet https://vetnet.gov.au/Pages/TrainingDocs.aspx?q=78b15323-cd38-483e-aad7-1159b570a5c4

TITLE	**Assessment requirements for** Error! Use the Home tab to apply AFSA Unit Code to the text that you want to appear here. **Operate an aseptic form, fill and seal process**

Performance Evidence

An individual demonstrating competency in this unit must satisfy all the elements and performance criteria of this unit.

There must be evidence that the individual has operated at least one aseptic form, fill and seal process, including:

- accessed workplace information to confirm production requirements for the aseptic form, fill and seal process
- confirmed supply of necessary materials, packaging components and consumables for the aseptic form, fill and seal process
- selected, fitted and used cleanroom garments and personal protective equipment including gowning and de-gowning
- maintained the sterile quality of the gown after performance of gowning procedures and aseptic process by microbiological surface sampling of several locations on gown
- followed required work area entry and exit procedures and moved around the work area in a manner that does not generate additional contaminants
- conducted pre-start checks required for the safe operation of the aseptic form, fill and seal process, 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
- started, operated, monitored and adjusted aseptic form, fill and seal process equipment to achieve required outcomes, including:
  - container formation and appearance
  - supply and flow of materials to and from process and pressure
  - flow rates
  - weights and volumes
  - fill levels
  - temperature, including materials and sealing temperatures
  - supply of packaging components and consumables
  - container closure integrity
- conducted in-process control checks to confirm the process remains within limits
- inspected units for defects
- taken corrective action in response to a non conformance
- maintained consistent aseptic techniques
- followed end-of-batch procedures, including:
  - line clearance and cleaning
  - loss of sterility
  - filler integrity testing
  - yield calculation
  - materials reconciliation
  - environmental monitoring
  - product labelling
  - actions required if yield or reconciliation is not within prescribed limits
- safely shut down the process according to workplace procedures
- cleaned and maintained work area to meet workplace cleaning standards and environmental requirements
- completed records according to 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:

Knowledge Evidence

- stages of the aseptic form, fill and seal process, including:
  - the purpose, methods and outcomes of each stage
  - control points
  - principles of filling and sealing, including properties of packaging materials used
  - the form process
  - principles of heat sterilisation
  - the effect of heat sterilisation on microbiological characteristics of product and packaging materials, and a filling process
  - flow of an aseptic form, fill and seal process and the effect of outputs on downstream processes
- quality characteristics to be achieved by the aseptic form, fill and seal process, including:
  - quality requirements of packaging components and consumables
  - sterilisation requirements and procedures
  - fill volume by levels and weights
  - internal and external leakers
  - appearance, including; legibility of embossing, burnt polymer and streaking
  - requirements of seal formation and integrity
  - importance of maintaining sterile product
  - integrity testing procedures
- aseptic container preparation and forming, filling and sealing requirements
- basic operating principles, requirements and parameters of aseptic form, filling and sealing equipment, including:
  - main components, operating capacities and applications
  - typical equipment 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
- 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 form, filling and sealing performance
- functions and limitations of cleanroom garments and personal protective clothing and equipment, including:
  - sterile gowns
  - surgical or elastic gloves
  - face masks
  - hair nets or sterile hoods
  - beard/moustache covers
  - protective goggles or glasses
  - sterile disposable overshoes, cleanroom boots and shoe covers
- gowning and de-gowning techniques
- cleanroom behaviour and hygiene
- aseptic technique
- microbiology applicable to aseptic form, fill and seal process
- pre-start checks requirements, including:
  - carrying out required area or line clearances
  - inspecting equipment condition to identify signs of wear
  - confirming all safety equipment are 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 form, fill and seal process, including:
  - inspecting
  - measuring
  - testing
- product, packaging and process changeover procedures and responsibilities
- end-of-batch procedures, including:
  - line clearance and cleaning

Knowledge Evidence

- loss of sterility
- filler integrity testing
- calculating yield
- materials reconciliation
- environmental monitoring
- 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
- isolation, lock out and tag out procedures and responsibilities
- operating principles of process control, including the relationship between control panels, systems and physical equipment
- Good Manufacturing Practice (GMP) requirements associated with aseptic form, fill and seal process and related control measures
- environmental issues and controls relevant to the aseptic form, fill and seal process, including;
  - particle count specification
  - waste collection and handling procedures
- requirements for completion of workplace documentation.

Assessment Conditions

Assessment of skills must take place under the following conditions:

- physical conditions:
  - a pharmaceutical workplace or an environment that accurately represents workplace conditions
- resources, equipment and materials:
  - cleanroom garments and personal protective equipment
  - aseptic form, fill and seal process equipment
  - materials, packaging components and consumables for an aseptic form, fill and seal process
  - microbiological surface sampling tools (touch plates)
  - microbiological growth medium for process simulation (media fill)
  - environmental monitoring equipment
  - cleaning materials and equipment associated with aseptic form, fill and seal process
  - record keeping system
- specifications:
  - batch instructions including specifications, control points and processing parameters
  - recording requirements and procedures according to Good Documentation Practice (GDP)
  - workplace documentation relating to aseptic fill and seal process and procedures that comply with GMP requirements information on equipment capacity and operating parameters
  - microbiological surface sampling limits for gown locations
  - cleaning and environmental monitoring procedures associated with aseptic form, fill and seal process.

Assessors of this unit must satisfy the requirements for assessors in applicable vocational education and training legislation, frameworks and/or standards.

Links	Companion Volumes, including Implementation Guides, are available at VETNet https://vetnet.gov.au/Pages/TrainingDocs.aspx?q=78b15323-cd38-483e-aad7-1159b570a5c4