Modification history

Release	Comments
Release 2	This version released with FBP Food, Beverage and Pharmaceutical Training Package Version 4.1.
Release 1	This version released with FBP Food, Beverage and Pharmaceutical Training Package Version 2.0.

FBPPHM3002	Operate a pharmaceutical production process
Application	This unit of competency describes the skills and knowledge required to setup, operate monitor, adjust and shut down a production process in a pharmaceutical manufacturing facility. The unit applies to individuals who apply operating principles to the production 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.
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. Receipt materials and components	1.1 Confirm incoming goods correspond to workplace documentation 1.2 Clean and label containers with prescribed data, according to workplace procedures 1.3 Quarantine incoming goods including release and reject status according to Good Manufacturing Practice (GMP) requirements and workplace procedures 1.4 Identify and report deviations, unusual events and non-conformances according to GMP and workplace procedures
2. Set up the production process for operation	2.1 Confirm equipment and materials meet production requirements 2.2 Confirm cleaning requirements and equipment status 2.3 Select and fit personal protective equipment and contamination prevention clothing according to workplace procedures 2.4 Enter processing and operating parameters according to safety and production requirements 2.5 Check and adjust equipment performance 2.6 Conduct pre-start checks according to workplace procedures
3. Dispense materials	3.1 Deliver materials in required quantities and sequence according to batch and production requirements 3.2 Record dispensed material, including weight or volume according to batch and production requirements 3.3 Label dispensed materials for each batch and stage according to production requirements
4. Operate and monitor the production process	4.1 Start up, monitor and control production process to maintain process within required limits 4.2 Identify and report out of limit products or processes according to workplace procedures 4.3 Maintain work area according to workplace cleaning standards 4.4 Conduct production process according to safety and environmental requirements 4.5 Complete documentation according to workplace procedures
5. Hand over the production process	5.1 Perform handover according to workplace procedures 5.2 Inform handover production team of process and related equipment status at completion of handover

Elements	Performance Criteria
Elements describe the essential outcomes.	*Performance criteria describe the performance needed to demonstrate achievement of the element.*
6. Shut down the process	6.1 Confirm the workplace procedures for shutting down the process 6.2 Complete end-of-batch procedures according to batch instructions and workplace procedures 6.3 Safely shut down the process 6.4 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 and interpret requirements for the pharmaceutical production process
Writing	• Complete workplace documentation using appropriate language and in required format
Numeracy	• Interpret material and product specifications

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.

Cleaning requirements must include:	• area or line clearance • full or partial clean • automated or semi-automated or manual cleaning of equipment • sanitation or sterilisation.
Equipment status must include:	• calibrated • clean • clean/dirty hold time • in use • ready to use.
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
Items to monitor must include:	• environment • product appearance • volume or weight.

Unit Mapping Information

Code and title current version	Code and title previous version	Comments	Equivalence status
FBPPHM3002 Operate a pharmaceutical production process Release 2	FBPPHM3002 Operate a pharmaceutical production process Release 1	Minor updates to Range of Conditions for clarity Foundation skills refined	Equivalent unit

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

TITLE	Assessment requirements for FBPPHM3002 Operate a pharmaceutical production process

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 safely operated at least one pharmaceutical production process, including:

- accessed workplace information to confirm production requirements
- confirmed supply of necessary equipment and materials
- handled and stored materials and products in a manner that prevents contamination and mix-ups
- selected, fitted and used personal protective equipment and contamination prevention clothing
- conducted pre-start checks, 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 equipment to achieve required outcomes, including:
  - adding and loading materials in correct quantities and sequences
  - supply and flow of materials to and from the process
- checked process control points and conducted inspections to confirm process remains within limits, including:
  - product sampling
  - process control testing
  - adjusting process according to workplace procedures
- followed end-of-batch procedures, including three of the following:
  - product sampling
  - environmental sampling
  - line clearances and cleaning (full or partial)
  - yield calculation
  - materials reconciliation
  - change equipment status (sterile/clean to dirty/clean)
- 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:

- stages of the pharmaceutical manufacturing process, including:
  - the purpose, methods and outcomes of each stage
  - control points
  - checking materials are suitable for use including release status
  - flow of materials, people and waste
  - flow of the manufacturing process and the effect of outputs on downstream processes
- basic operating principles of equipment, requirements and parameters of pharmaceutical manufacturing equipment, including:
  - main equipment 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
- processing equipment and utility systems and how product quality and Good Manufacturing Practice (GMP) compliance can be impacted by:
  - performance

Knowledge Evidence

- functionality
- construction
- instrumentation

- common GMP non-conformances and unusual events found in a pharmaceutical production environment, including:
  - missing, illegible or inaccurate records
  - failure to follow workplace procedures
  - failure of cleaning regime
  - damaged goods, including; starting materials, components, intermediates and finished products
  - product diverted from normal course of process
  - loss of sterility or pressure
  - spills
  - out of limit situations including; yields, reconciliations, in process controls and in process checks
  - damage or poor maintenance of plant or equipment
  - signs of inadequate cleaning or pest infestation
- terminology associated with control of GMP processes, including:
  - process variation
  - critical quality attribute
  - critical process parameter
- functions and limitations of personal protective equipment and contamination prevention clothing relevant to the work process
- pre-start checks requirements, including:
  - carrying out required area or line clearances
  - carrying out differential pressure checks or room status checks
  - inspecting equipment condition to identify any signs of wear
  - confirming that equipment is clean or sanitised
  - confirming appropriate settings and/or related parameters
  - confirming product details and ingredients
- methods used to monitor the production process, including:
  - inspecting
  - measuring
  - testing
- items to monitor during the production process, including:
  - environment
  - product appearance
  - pH
  - volume or weight
  - temperature
- product and process changeover procedures and responsibilities
- end-of-batch procedures, including:
  - product sampling
  - environmental sampling
  - line clearances and cleaning (full or partial)
  - yield calculation
  - materials reconciliation
  - change equipment status (sterile/clean to dirty/clean)
- requirements of different shutdowns, including:
  - emergency and routine shutdowns
  - procedures to follow in the event of a power outage
- isolation, lock out and tag out procedures and responsibilities
- operating principles of process control, including the relationship between control panels and systems and the physical equipment
- GMP requirements for production and process controls, including:
  - identification and traceability
  - yields and reconciliation
  - segregation and storage

Knowledge Evidence

- status labels (physical and electronic)
- environmental issues and controls relevant to the production environment, including 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 manufacturing workplace or an environment that accurately represents workplace conditions
- resources, equipment and materials:
  - personal protective equipment and contamination prevention clothing
  - manufacturing process equipment
  - materials required for the manufacturing process
  - cleaning materials and equipment associated with the manufacturing process
  - record keeping system
- specifications:
  - batch instructions including product specifications, control points and processing parameters
  - recording requirements and procedures
  - workplace documentation relating to manufacturing process and procedures that comply with GMP requirements
  - information and documentation relating to handover
  - cleaning procedures associated with manufacturing 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.education.gov.au/Pages/TrainingDocs.aspx?q=78b15323-cd38-483e-aad7-1159b570a5c4