Australian Government

FBPPHM3021 Operate a pharmaceutical production process

Release: 1

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Modification History

Release	Comments
Release 1	This version released with FBP Food, Beverage and Pharmaceutical Training Package Version 7.0.

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 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
Elements describe the essential outcomes.	*Performance criteria describe the performance needed to demonstrate achievement of the element.*
1. Move goods and components	1.1 Confirm transfer of goods and components correspond to workplace documentation 1.2 Clean and label containers with prescribed data, according to workplace procedures 1.3 Quarantine goods and components according to release and reject status, Good Manufacturing Practice (GMP) requirements and workplace procedures' 1.4 Identify and report deviations, unusual events and

Elements	**Performance Criteria**
Elements describe the essential outcomes.	*Performance criteria describe the performance needed to demonstrate achievement of the element.*
	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 and deliver materials in required quantities and sequence according to batch and 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. Operate and monitor the production process	3.1 Start up, monitor and control production process to maintain process within required limits 3.2 Identify and report out of limit products or processes according to workplace procedures 3.3 Maintain work area according to workplace cleaning standards 3.4 Conduct production process according to safety and environmental requirements 3.5 Complete documentation according to workplace procedures
4. Hand over the production process	4.1 Perform handover according to workplace procedures 4.2 Inform handover production team of process and related equipment status at completion of handover
5. Shut down the process	5.1 Confirm the workplace procedures for shutting down the process 5.2 Complete end-of-batch procedures according to batch instructions and workplace procedures 5.3 Shut down the process according to workplace procedures and safety requirements 5.4 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
FBPPHM3021 Operate a pharmaceutical production process	FBPPHM3002 Operate a pharmaceutical production process	Deletion of Element that relates to dispensing of pharmaceutical material Changes to Element, Performance Criteria and Performance Evidence	Not equivalent

Links

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