



Australian Government

Assessment Requirements for 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.

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 one or more 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
 - 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
 - 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 the skills in this unit of competency 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.gov.au/Pages/TrainingDocs.aspx?q=78b15323-cd38-483e-aad7-1159b570a5c4>