Australian Government

Assessment Requirements for FBPPHM3008 Operate an aseptic fill and seal process

Release: 2

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Modification History

Release	Comments
Release 2	This version released with FBP Food, Beverage and Pharmaceutical Training Package Version 5.0.
Release 1	This version released with FBP Food, Beverage and Pharmaceutical Training Package Version 2.0.

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 operated at least one aseptic fill and seal process, including:

- accessed workplace information to confirm production requirements for the aseptic fill and seal process
- confirmed supply of necessary materials, packaging components and consumables for the aseptic fill and seal process
- prepared for and completed sterile gowning via operator gowning validation
- 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 fill and seal process, including:
  - carrying out required area or line clearances
  - inspecting equipment condition to identify signs of wear
  - confirming all safety equipment including environmental monitoring equipment is in place and operational
  - confirming that equipment is clean or sanitised and aseptic components installed
  - confirming that equipment is correctly configured for processing requirements
- started, operated, monitored and adjusted aseptic fill and seal process equipment to achieve required outcomes, including:
  - supply and flow of materials to and from process

  - 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
- conducted an environmental operating procedure, including taking samples of air and surfaces using air sampling and settle plates and contact plates
- 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
  - yield calculation
  - materials reconciliation
  - product labelling
- 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 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
- depyrogenation and presterilisation components
- 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
- isolation, lock out and tag out procedures and responsibilities

- Good Manufacturing Practice (GMP) requirements associated with aseptic fill and seal process and related control measures
- environmental issues and controls relevant to the aseptic fill and seal process, 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 workplace or an environment that accurately represents workplace conditions
- resources, equipment and materials:
  - cleanroom garments and personal protective equipment
  - aseptic fill and seal process equipment
  - materials, packaging components and consumables for an aseptic 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 fill and seal process
  - record keeping system
- specifications:
  - product and intermediate product specifications, control points and processing parameters
  - specifications, control points and processing parameters
  - 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 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 Volume Implementation Guides are found in VETNet: - https://vetnet.gov.au/Pages/TrainingDocs.aspx?q=78b15323-cd38-483e-aad7-1159b570a5c4