Australian Government

Assessment Requirements for FBPPHM3019 Operate a chromatography manufacturing 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 5.0.

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 at least one separation process using chromatography, including:

- accessed workplace information to confirm requirements for the process
- selected, fitted and used personal protective equipment and contamination prevention clothing
- conducted pre-start checks required for the safe operation of a chromatography separation process, including:
  - carried out required area or line clearances
  - inspected equipment condition to identify signs of wear
  - confirmed all safety equipment in place and operational
  - confirmed that equipment is clean or sanitised
  - confirmed that equipment is correctly configured for processing requirements
- performed procedures for packing columns and for loading material into columns
- started, operated, monitored and adjusted a process to achieve required outcomes
- conducted in-process control checks to confirm the process remains within limits
- maintained security, integrity and traceability of:
  - samples
  - sub-samples
  - documentation
- followed isolation and lock out procedures to take process and related equipment off-line in preparation for cleaning and maintenance according to workplace procedures
- performed product and process changeovers, including demonstrating column storage procedures
- taken corrective action in response to out-of-specification results
- safely shut down the process according to workplace procedures

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- cleaned and maintained work area to meet workplace cleaning standards and environmental requirement
- 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 chromatography separation process, including:
  - the purpose, methods and outcomes of each stage
  - quality characteristics achievable by the separation process
  - methods of analysis
- basic operating principles, requirements and parameters of chromatography equipment, including:
  - main equipment components, operating capacities and applications
  - consequences of incorrect equipment preparation, such as incorrectly positioned non-return valve, supply pump failure and air in the column
  - typical equipment faults and related causes, including signs and symptoms of faulty equipment and early warning signs of potential problems
- line clearance cleaning and sanitation procedures
- functions and limitations of personal protective equipment and contamination prevention clothing
- pre-start check 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
  - sample test methods analysis and interpretation of results
  - implications and actions taken if results are out-of-specification
- procedures used for:
  - collecting in process samples as specified in documentation appropriate to columns and process requirements
  - interpreting traces and corrective action where traces are not within specifications
- typical profile for a production cycle and events to be monitored during the cycle
- common causes of out-of-specification product or process and corrective actions required
- procedures and requirements of different shutdowns, including:
  - an understanding of the requirements for column storage
  - emergency and routine shutdowns
  - procedures to follow in the event of power outage
- isolation, lock out and tag out procedures and responsibilities

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- Good Manufacturing Practice (GMP) requirements associated with a separation process and related control measures
- 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
  - chromatography equipment
  - materials dispensed for the process
  - cleaning materials and equipment associated with a separation process using chromatography
  - record keeping system
- specifications:
  - product and intermediate product specifications, control points and processing parameters
  - workplace documentation relating to separation process and procedures that comply with GMP requirements
  - cleaning procedures associated with a separation process using chromatography.

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

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