Australian Government

Assessment Requirements for FBPPHM3003 Work in a controlled environment

Release: 1

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Modification History

Release	Comments
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 worked in at least one controlled environment, and demonstrated that they have:

- accessed workplace information to identify controlled environment work requirements
- read and interpreted workplace procedures, including pictorial and written signs/instructions applicable to working in a controlled environment
- checked operating conditions of the controlled environment according to workplace and Good Manufacturing Practice (GMP) requirements
- maintained good personal hygiene and cleanliness appropriate to working in a controlled environment, consistent with GMP requirements, including:
  - making team leader or supervisor aware of reportable illness
  - removal of jewellery
  - removal of makeup
  - following changing procedures
- cleaned and sanitised hands using recognised procedures for:
  - washing with soap and water
  - rubbing with an alcohol-based formulation
- used facility suits and personal protective equipment appropriate for the grade of controlled environment or cleanroom in a manner that does not generate additional contaminants
- entered and exited a controlled environment in a manner to minimise contamination
- identified and reported any condition that may cause shedding of abnormal numbers or types of contaminants
- identified contamination hazards typically encountered in pharmaceutical manufacturing environments and took steps to prevent identified hazards
- cleaned and maintained work area to meet workplace cleaning standards and environmental requirements.

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:

- international nomenclature and classification of controlled environments and cleanrooms
- GMP grades of cleanrooms and their relationship to the International Organization for Standardization (ISO) classification system
- GMP requirements for the qualification of cleanrooms
- key design requirements for controlled environments and cleanroom for product protection:
  - layout and architecture
  - product and process requirements for clean air
  - filtration, including High Efficiency Particulate Air (HEPA) filters and the theory of particle filtration
  - airlocks for materials, equipment and people
  - turbulent and laminar air flows
  - pressure differentials
  - box-within-a-box principle
  - cleanability and maintainability
- how controlled environments operate to control contamination, including:
  - clean rooms, including how they are certified
  - controlled, non-classified environments
  - clean zones
  - monitor and test systems
  - isolator technology
  - at rest and in operation
  - gowning and cleaning
- GMP requirements and workplace procedures for working in controlled environments and cleanrooms, including:
  - requirements for approving and taking commodity items into the cleanroom
  - restrictions on movement of personnel to minimise cross-contamination
  - cleanroom garments, including types, materials, processing and reprocessing
  - personal hygiene requirements
  - clothing and footwear requirements for working in and moving between work areas
  - personal clothing use, storage and disposal requirements
  - workplace cleaning standards and environmental requirements relating to own work
  - responsibilities of general cleaning staff and how to work with a cleaning team
- the role of cleaning and sanitising in preventing contamination of materials and products and protection of personnel, including:
  - how improper cleaning of a controlled environment or cleanroom can lead to product contamination

    - the need for proper selection of equipment and materials for proper cleaning
- controlled environment operating conditions, including:
    - differentials pressures
    - particle counts
    - microbial sampling
    - laminar air flow
    - humidity
    - temperature
    - room status
    - cleanliness status
- hygiene and basic elements of microbiology
- sources of contamination, including:
    - product
    - people
    - tools
    - facilities
    - equipment
- risks associated with controlled environment and cleanroom operators:
    - physical behaviour, including how to walk and stand in a cleanroom
    - personal hygiene
    - psychological
    - workplace attitudes and habits
    - communications between workers
    - electrostatic discharge
- contamination risks associated with controlled environment and clean room operations, including:
    - number of personnel in the controlled environment
    - activities being undertaken
    - leaks
    - malfunctioning equipment
    - low differential pressures
    - high particle counts
    - incorrect air flow and velocity
    - humidity
    - temperature
    - room status inactive or in alarm
    - lack of cleanliness
- common practices inconsistent with GMP found in controlled environment and clean room operations, including:
    - damage to plant or equipment

- failure of cleaning regime
- signs of pest infestation
- missing or inaccurate records
- failure to follow workplace procedures.

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
  - cleaning materials and equipment associated with working in a controlled environment
- specifications:
  - workplace procedures related to working in a controlled environment including gowning/de-gowning procedures that comply with GMP requirements
  - workplace cleaning standards and environmental requirements related to working in a controlled environment.

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