Australian Government

Assessment Requirements for FBPPHM3020 Apply Good Manufacturing Practice requirements

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 applied Good Manufacturing Practice (GMP) requirements, and demonstrated each of the following points **on one or more occasions**:

- read and interpreted relevant instructions and labels applicable to GMP operations, including pictorial and written signs and instructions
- followed workplace information relating to GMP responsibilities
- completed forms and reports according to GMP requirements and workplace procedures
- recorded calculations and test results
- identified and responded to:
  - out-of-calibration equipment
  - out-of-specification or unacceptable raw materials, packaging components, final or part processed product
- maintained workplace cleanliness and tidiness to meet GMP requirements
- maintained personal hygiene consistent with GMP requirements, including:
  - making team leader or supervisor aware of reportable illness
  - removal of jewellery
  - removal of makeup
- cleaned and sanitised hands using recognised procedures for:
  - washing with soap and water
  - rubbing with an alcohol-based formulation
- used personal protective clothing and equipment and contamination prevention clothing according to GMP requirements
- provided accurate verbal and written descriptions of incidents or situations that did or could have:
  - compromised GMP compliance or product quality
  - provided the potential for product contamination.

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:

- GMP as a regulatory concept, including regulatory obligations of employees, and the potential implications of non-compliance
- applicable sections of Australian and other applicable regulatory frameworks relevant to pharmaceutical manufacturing:
  - Therapeutic Goods Act (TGA)
  - Manufacturing Principles
  - Guide to GMP
- the relationship between GMP and the quality system, including:
  - personnel responsible for designing and managing GMP
  - personal role to maintain GMP
  - the role of internal and external auditors
  - quality procedures
  - quality assurance
  - quality control
  - risk management procedures
- personal clothing use, storage and disposal requirements and hygiene requirements, including:
  - informing team leader or supervisor of reportable illness
  - removal of jewellery
  - removal of makeup
- personal clothing and footwear requirements for working in and moving between work areas
- workplace cleaning standards and responsibilities relating to own work, including:
  - waste collection
  - recycling, safe handling and disposal for different types of waste
  - safe handling and disposal of hazardous waste
- awareness of common contaminants relevant to the work process, including:
  - microbiological, from materials, equipment, environment and personnel
  - physical, from equipment, environment and personnel
  - chemical, from other products or materials, including cleaning agents
- quality control methods and procedures, including the purpose of control and the consequence if not controlled
- properties, handling and storage requirements of raw materials, packaging components and final product
- GMP requirements for maintaining plant and process equipment
- GMP requirements for transferring of equipment and material between areas
- GMP requirements for equipment status labelling
- documentation systems and procedures, including:

    - recordkeeping to meet both workplace and legal requirements
    - responsibilities for reporting and recording information
    - batch documentation
    - cleaning records
    - training records
    - product and materials traceability procedures
    - controls and methods for ensuring electronic data integrity and paper data integrity
    - significance of certifying and verifying GMP records
- procedures for responding to out-of-specification or unacceptable process performance or outcomes
- awareness of controls to protect personnel and the environment from contamination by products and materials.

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
    - alcohol based hand cleanser
    - soap and water
    - pharmaceutical production and packaging equipment
- specifications:
    - GMP requirements
    - workplace reporting procedures
    - workplace procedures related to GMP
    - workplace biosecurity requirements
    - workplace environmental procedures.

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