



Australian Government

Assessment Requirements for FBPPHM4001 Monitor and maintain Good Manufacturing Practice requirements

Release: 2

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Modification History

Release	Comments
Release 2	This version released with FBP Food, Beverage and Pharmaceutical Training Package Version 7.0.
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 monitored and maintained Good Manufacturing Practice (GMP) requirements of one or more work teams, including:

- communicated information on GMP requirements to others in the work area, including demonstrating:
 - two-way communication
 - active listening
 - constructive responses to feedback
- accessed and used document management systems
- demonstrated personal hygiene according to GMP requirements and workplace procedures
- monitored recorded data to meet GMP recording requirements according to workplace procedures
- documented GMP requirements for a specific work area
- provided training and support to others in the work area to implement responsibilities according to GMP requirements and to workplace procedures
- determined actions required to respond to GMP non-compliance according to workplace procedures
- participated in improvement processes, including investigating actual and potential GMP non-compliance
- participated in, or reviewed, practices and procedures to prevent or minimise the likelihood of unacceptable performance.

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:

- the role of GMP in preventing contamination, including:
 - its relationship to legal requirements of pharmaceutical manufacturers
 - potential implications of non-compliance
- GMP requirements, including:
 - relevant GMP codes of practice
 - related workplace procedures
 - organisational structures for implementing these requirements
 - quality assurance
- principles and process of effective communication and consultation
- workplace training and coaching system and responsibilities
- personal clothing use, storage and disposal requirements and hygiene requirements, including:
 - making team leader or supervisor aware of reportable illness
 - removal of jewellery
 - removal of makeup
- personal clothing and footwear requirements for working in and moving between work areas
- current technical and process knowledge required to monitor and maintain GMP and participate in investigating GMP non-compliance including:
 - common microbiological, physical and chemical contaminants
 - conditions under which types of contamination, including cross-contamination are likely to occur
 - purpose of equipment calibration
 - control methods and procedures, including the purpose of control and the consequences if not controlled
- recall and traceability procedures relevant to the work area, including:
 - reconciliation
 - line clearance
 - stored versus dedicated
- procedures followed to investigate contamination events and performance improvement processes, including:
 - root cause analysis (RCA)
 - corrective action or preventive action (CAPA)
- documentation systems and procedures, including:
 - record keeping to meet both company and legal requirements
 - responding to out-of-specification, or unacceptable, performance and outcomes
 - procedures for identifying and isolating, or quarantining, materials or products of unacceptable quality

- processes for developing or reviewing workplace procedures
- document control systems used in the workplace
- responsibilities for reporting and recording information
- 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.

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
 - document management system
- specifications:
 - GMP requirements
 - workplace cleaning standards
 - workplace reporting procedures
 - workplace procedures related to GMP
- relationships:
 - team members.

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>