Assessment Requirements for FBPPHM2001 Follow work procedures to 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 followed work procedures to maintain Good Manufacturing Practice (GMP) and demonstrated each of the following points at least once:

- located and followed workplace information relating to GMP responsibilities
- maintained good personal hygiene consistent with GMP requirements, including:
  - making team leader or supervisor aware of reportable illness
  - removal of jewellery
  - removal of makeup
- used personal protective equipment and contamination prevention clothing according to workplace procedures
- used and stored personal clothing and footwear consistent with GMP requirements and workplace procedures
- followed workplace procedures when moving around the workplace to maintain GMP
- followed GMP requirements when carrying out work functions
- identified and responded to performance that fails to meet GMP requirements, including:
  - making adjustments
  - reporting to relevant personnel
- handled and disposed of materials that are contaminated or non-conforming
- identified and reported a situation that could compromise GMP requirements
- maintained work area in a clean and tidy state
- followed workplace procedures for documentation and recording.

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:

- sources of advice on GMP requirements in relation to own work
- the role of GMP in preventing contamination and potential implications of non-compliance
- 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
- personal protective equipment and contamination prevention clothing requirements
- personal clothing and footwear use, storage and disposal requirements
- storage and handling requirements for raw materials, product and packaging components relevant to work role
- common types and sources of contamination in the work area including pest infestation
- control methods and procedures used in the work area to maintain GMP, including:
    - the purpose of control
    - the consequences of lack of control
    - control monitoring
- performance that is unacceptable or fails to meet specifications
- actions required in response to non-conformance
- workplace environmental procedures
- workplace procedures for reporting and recording information.

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
    - commercial pharmaceutical production and packaging equipment
- specifications:
    - GMP information relating to the workplace
    - reporting and monitoring systems
    - workplace instructions and procedures
- relationships:
    - supervisor.

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