Modification history

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| Release | Comments |
| Release 1 | This version released with FBP Food, Beverage and Pharmaceuticals Training Package Version 2.0 and meets the Standards for Training Packages 2012. |

| FBPPHm2001 | Follow work procedures to maintain good manufacturing requirements |
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| Application | This unit of competency describes the skills and knowledge required to comply with relevant Good Manufacturing Practice (GMP) requirements and workplace quality standards in a pharmaceutical manufacturing facility.The unit applies to individuals who follow good manufacturing practice (GMP) requirements to undertake routine pharmaceutical manufacture work, under supervision.No occupational licensing, legislative or certification requirements apply to this unit at the time of publication. |
| Prerequisite Unit | Nil |
| Unit Sector | Pharmaceutical (PHM) |

| Elements | Performance Criteria |
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| Elements describe the essential outcomes. | Performance criteria describe the performance needed to demonstrate achievement of the element. |
| 1. Identify requirements of GMP related to own work | 1.1 Locate sources of information on GMP requirements in the workplace1.2 Identify GMP requirements for pharmaceutical manufacture tasks1.3 Confirm specific GMP requirements for own work  |
| 2. Prepare for work | 2.1 Ensure personal hygiene meets GMP requirements2.2 Prepare, use, store and dispose of personal protective clothing and equipment according to GMP requirements and workplace procedures2.3 Comply with area entry and exit procedures when moving around the workplace  |
| 3. Follow GMP requirements when carrying out work activities | 3.1 Routinely monitor work area, materials, equipment to ensure compliance with GMP requirements3.2 Handle raw materials, product and packaging components according to GMP requirements and workplace procedures3.3 Identify contamination and follow appropriate control measures relating to work responsibilities and GMP requirements3.4 Identify processes, practices or conditions which are inconsistent with GMP requirements and report according to workplace procedures3.5 Maintain workplace cleanliness and tidiness to meet GMP requirements3.6 Conduct work according to workplace environmental procedures3.7 Complete documentation according to workplace procedures  |

| Foundation SkillsThis section describes those language, literacy, numeracy and employment skills that are essential for performance in this unit of competency but are not explicit in the performance criteria. |
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| Skill | Description |
| Reading | * Identify instructions to comply with GMP requirements and workplace procedures
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| Writing | * Record workplace information using appropriate language and in required format
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| Navigate the world of work | * Apply workplace procedures to own role and responsibilities
* Understand main tasks, responsibilities and boundaries of own role, including use of personal protective clothing and equipment, and workplace environmental procedures
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| Interact with others | * Report operational and safety information to relevant personnel using required communication method
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| Unit Mapping Information |
| Code and title current version | Code and title previous version | Comments | Equivalence status |
| FBPPHM2001 Follow work procedures to maintain good manufacturing practice requirements | FDFPH1001A Follow work procedures to maintain Good Manufacturing Practice | Updated to meet Standards for Training Packages. Code changed to reflect AQF alignment. | Equivalent unit |

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| Links | Companion Volumes, including Implementation Guides, are available at VETNet <https://vetnet.education.gov.au/Pages/TrainingDocs.aspx?q=78b15323-cd38-483e-aad7-1159b570a5c4> |

| TITLE | Assessment requirements for FBPPHM2001 Follow work procedures to maintain good manufacturing practice requirements |
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| 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) on at least one occasion, including: * 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 clothing and equipment according to workplace procedures
* used, stored and appropriately disposed of 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 out-of-specification
* identified and reported situations that could compromise GMP requirements
* maintained work area in a clean and tidy state
* followed documentation and recording requirements according to workplace procedures.
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| Knowledge Evidence |
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| 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 clothing and equipment 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-compliance
* workplace environmental procedures
* workplace procedures for reporting and recording information.
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| Assessment Conditions |
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| 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 clothing and equipment
* commercial pharmaceutical production and packaging equipment
* specifications:
* GMP information relating to the workplace
* reporting and monitoring systems
* workplace instructions and procedures
* relationships:
* supervisors.

Assessors of this unit must satisfy the requirements for assessors in applicable vocational education and training legislation, frameworks and/or standards. |

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