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. |

| FDFPHm1001 | 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) codes and workplace quality standards.  The unit applies to individuals who apply GMP codes and workplace standards when working under supervision in the pharmaceutical sector.  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  1.2 Identify GMP requirements and responsibilities related to own work |
| 2. Observe personal hygiene and conduct to meet GMP requirements | 2.1 Ensure personal hygiene meets GMP requirements  2.2 Prepare, use, store and dispose of clothing according to GMP and workplace procedures  2.3 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 requirements  3.2 Handle raw materials, product and packaging components according to GMP and workplace procedures  3.3 Identify contamination and follow appropriate control measures relating to work responsibilities and GMP requirements  3.4 Identify processes, practices or conditions which are inconsistent with GMP and report according to workplace procedures  3.5 Maintain workplace cleanliness and tidiness to meet GMP housekeeping standards  3.6 Conduct work in accordance with workplace environmental guidelines |
| 4. Complete workplace documentation to support GMP | 4.1 Identify documentation and recording requirements  4.2 Record documentation according to workplace procedures to meet GMP requirements |

| Foundation Skills  This 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 | * Read and interpret instructions to comply with GMP and work health and safety procedures |
| Writing | * Complete records according to workplace guidelines using paper based or electronic media |
| 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, housekeeping standards and environmental care requirements |
| 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 |
| FDFPHM1001 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 FDFPHM1001 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 routinely followed work procedures to maintain Good Manufacturing Practice (GMP), including evidence on at least one occasion for each of the following:   * located and followed workplace information relating to GMP responsibilities * maintained personal hygiene consistent with GMP requirements * followed workplace procedures when moving around the workplace to maintain GMP * used, stored and disposed of appropriate clothing and footwear consistent with GMP requirements * undertaken relevant checks and inspections * identified and responded to performance that fails to meet specifications, including making adjustments or reporting to relevant personnel * followed GMP requirements when carrying out work functions * identified and reported situations that could compromise GMP requirements * handled and disposed of materials that are contaminated or out-of-specification * packaged components and consumables and products, waste and recyclable material according to GMP requirements * maintained work area in a clean and tidy state * followed work health and safety procedures. | |

| 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:   * the role of GMP in preventing contamination, its relationship to legislative responsibilities and potential implications of non-compliance * the relationship between GMP and the quality system, personnel responsible for designing and managing GMP, personal role to maintain GMP, and the role of internal and external auditors * sources of advice on GMP requirements in relation to own work * personal protective equipment requirements * personal clothing use, storage and disposal requirements * 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 an understanding of the purpose of control, the consequences of lack of control and the method of control * monitoring, inspecting and checking procedures relating to process control requirements * performance that is unacceptable or fails to meet specifications * actions required in response to non-compliance * storage and handling requirements for raw materials, packaging components and products relevant to work role * housekeeping requirements and responsibilities relating to own work * waste collection, recycling and handling procedures * responsibilities for reporting and recording quality information. |

| Assessment Conditions |
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| Assessment of skills must take place under the following conditions:   * physical conditions: * a workplace setting 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: * interactions with team members and supervisors or realistic scenarios or roleplays.   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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