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. |

| FDFPHM4XXX | Monitor and maintain good manufacturing practice requirements |
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| Application | This unit of competency describes the skills and knowledge required to provide a leadership role in the day-to-day implementation of Good Manufacturing Practices (GMP) in the workplace. The unit applies to individuals who model workplace policies and procedures and have formal responsibility for others, without holding a formal management role in a pharmaceutical manufacturing environment.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. Ensure ability of others in work area to meet GMP requirements | 1.1 Make available functional and correctly fitted personal protective clothing and equipment1.2 Clearly explain and make accessible advice on GMP requirements and workplace procedures1.3 Ensure GMP control measures used in the work area are identifiable by workers1.4 Provide mentoring and coaching to support individuals and groups to implement GMP requirements and related workplace procedures1.5 Identify and address training needs according to level of responsibility |
| 2. Monitor personal hygiene and conduct of team members in the work area | 2.1 Ensure personal hygiene of work team meets GMP requirements2.2 Prepare, use, store and dispose of personal protective clothing according to GMP requirements and workplace procedures2.3 Ensure personal movements within workplace comply with area entry and exit procedures |
| 3. Monitor implementation of GMP requirements in the work area | 3.1 Clearly define, document and follow GMP requirements in work area 3.2 Report non-compliance from procedures and address according to individual level of responsibility3.3 Identify and report signs of unacceptable plant or equipment condition3.4 Model personal behaviour to others to support implementation of GMP requirements and workplace procedures3.5 Follow workplace procedures to control resource allocation and meet GMP requirements3.6 Identify and report GMP non-conformance3.7 Record information according to workplace reporting procedures to meet GMP requirements3.8 Maintain workplace to meet GMP housekeeping standards |
| 4. Participate in validation processes | 4.1 Follow validation procedures for GMP requirements4.2 Raise issues arising from validation with designated personnel4.3 Document validation procedures according to GMP requirements |
| 5. Take corrective action in response to GMP non-compliance | 5.1 Identify and report processes, practices or conditions which could result in non-compliance with GMP according to workplace reporting procedures5.2 Take corrective action according to individual level of responsibility5.3 Raise GMP issues with designated personnel |
| 6. Maintain and improve GMP in the work area | 6.1 Identify, report and correct processes or conditions which could result in GMP non-conformance according to individual level of responsibility6.2 Promptly resolve matters relating to GMP or refer them to appropriate personnel6.3 Monitor effectiveness of control measures according to level of responsibility6.4 Advise others in the work area of GMP matters relevant to work role6.5 Maintain workplace records and documents according to workplace procedures and GMP requirements |

| 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 | * Locate and interpret key information in GMP requirements and workplace procedures
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| Writing | * Access and use document management systems
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| Numeracy | * Monitor data for workplace reporting procedures and GMP recording requirements
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| Oral Communication | * Demonstrate two-way communication including active listening and confirming instructions when discussing and disseminating GMP information
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| Navigate the world of work | * Apply workplace procedures to own role and responsibilities and seek clarification or other assistance when required
* Identify and describe own skills, knowledge and experience within context of job role
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| Interact with others | * Use appropriate vocabulary, including technical language directly relevant to role
* Report GMP performance to relevant personnel using required communication method
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| Get the work done | * Provide a role model to others in the workplace to support implementation of GMP
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| Range Of ConditionsThis section specifies different work environments and conditions that may affect performance. Essential operating conditions that may be present (depending on the work situation, needs of the candidate, accessibility of the item, and local industry and regional contexts) are included. |
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| Personal protective clothing and equipment must include: | * protective gown or scrubs
* surgical masks
* surgical gloves
* disposable overshoes
* hair net.
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| Unit Mapping Information |
| Code and title current version | Code and title previous version | Comments | Equivalence status |
| FDFPHM4XXX Monitor and maintain good manufacturing practice requirements | FDFPH3001A Monitor and maintain Good Manufacturing Practice procedures | 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 FDFPHM4XXX Monitor and 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, on at least one occasion, the individual has routinely monitored and maintained Good Manufacturing Practice (GMP) procedures, including evidence on at least one occasion, for each of the following:* communicated information on GMP requirements to others in the work area, including demonstrating:
* two-way communication
* active listening
* providing constructive responses to feedback
* accessed and used document management systems
* modelled personal conduct and work activities in accordance with GMP requirements
* monitored recorded data to meet GMP recording requirements according to workplace guidelines
* provided guidance and support to others in the work area to implement GMP responsibilities according to workplace guidelines
* determined actions required to respond to GMP non-compliance according to workplace guidelines
* 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.
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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:* role of GMP in preventing contamination, its relationship to legal requirements of pharmaceutical manufacturers and potential implications of non-compliance
* GMP arrangements in the workplace, including relevant GMP codes of practice, and related workplace policies and procedures for implementing these responsibilities
* role of effective communication and consultation processes
* workplace training and development system and responsibilities
* role of quality assurance, related system components and activities in GMP
* procedures followed to investigate contamination events and performance improvement processes
* personal clothing and footwear requirements for working in and moving between work areas
* personal clothing use, storage and disposal requirements
* current technical and process knowledge required to monitor GMP and participate in investigating GMP non-compliance within level of responsibility; including common microbiological, physical and chemical contaminants; conditions under which types of contamination, including cross-contamination are likely to occur; related control methods and validation procedures and responsibilities
* control methods and procedures used in the work area to maintain GMP, including the purpose of control, the consequences if not controlled and methods of control
* methods used to monitor process control, purpose and requirements of validation procedures and purpose of equipment calibration
* recall and traceability procedures relevant to the work area
* line clearance procedures and responsibilities
* properties, handling and storage requirements of raw materials, packaging components and final products handled and used in the work area
* standards for materials, equipment and utensils used in the work area
* procedures for responding to out-of-specification, or unacceptable, performance and outcomes, including procedures for identifying and isolating, or quarantining, materials or products of unacceptable quality in accordance with individual level of responsibility
* documentation systems and procedures, including record keeping to meet both company and legal requirements, processes for developing or reviewing workplace procedures and document control systems used in the workplace, and responsibilities for reporting and recording information
* housekeeping requirements and responsibilities relating to own work, including waste collection, recycling, handling and disposal for different types of waste, including hazardous waste.
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| 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
* GMP and workplace documentation
* specifications:
* advice on safe work practices, GMP, quality and environmental requirements
* workplace procedures related to GMP
* 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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