Modification history

|  |  |
| --- | --- |
| 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. |

| FDFPH3MXXX | Implement good manufacturing practice requirements |
| --- | --- |
| Application | This unit of competency describes the skills and knowledge required to comply with relevant Good Manufacturing Practice (GMP) codes through implementation of GMP requirements, workplace and quality procedures.The unit applies to individuals who implement GMP requirements when working in the pharmaceutical sector. It involves the application of policies and procedures to maintain GMP awareness, compliance and continual improvement across a variety of pharmaceutical manufacture operational roles, including quality, manufacturing and warehousing.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 |
| --- | --- |
| Elements describe the essential outcomes. | Performance criteria describe the performance needed to demonstrate achievement of the element. |
| 1. Maintain awareness of GMP as a regulatory concept | 1.1 Identify and access information relevant to work role relating to current Australian and other applicable regulatory frameworks for manufacturing pharmaceuticals1.2 Identify information appropriate to work role relating to regulatory and industry initiatives for global harmonisation of GMP compliance and product registrations |
| 2. Identify requirements of GMP related to own work | 2.1 Locate sources of information on GMP requirements2.2 Identify GMP requirements and responsibilities related to own work2.3 Interpret instructions and labels related to work role2.4 Recognise indications of GMP non-compliant situations and risks to product quality2.5 Alert relevant personnel and take appropriate action according to workplace procedures and applicable GMP requirements |
| 3. Complete workplace documentation to support GMP | 3.1 Identify GMP documentation and recording requirements related to work role3.2 Record information, including calculations and test results according to workplace reporting procedures to meet GMP requirements3.3 Certify records, including electronic records according to GMP requirements |
| 4. Identify and follow biosecurity requirements | 4.1 Identify and access information appropriate to work role relating to biosecurity requirements4.2 Follow biosecurity requirements and responsibilities related to work role |
| 5. Implement GMP requirements when carrying out work activities | 5.1 Identify common forms of contamination5.2 Follow workplace procedures to meet GMP and environmental requirements5.3 Maintain workplace in a clean and tidy manner to meet GMP housekeeping standards5.4 identify and report signs of unacceptable plant or equipment condition, including calibration status5.5 Identify GMP requirements for routinely monitoring work area, materials, equipment and product5.6 Complete records according to GMP and workplace requirements |
| 6. Ensure personal hygiene and conduct meet GMP requirements | 6.1 Maintain personal hygiene to GMP standards6.2 Carry out hand washing according to best practice hygiene standards6.3 Don, wear and maintain personal protective clothing according to GMP requirements and workplace procedures6.3 Comply with entry and exit procedures when transiting the workplace |
| 7. Participate in improving GMP | 7.1 Identify and report processes, practices or conditions which could result in non-compliance with GMP according to workplace reporting requirements 7.2 Identify elements of GMP that help improve products and processes7.3 Implement corrective action within level of responsibility |

| 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. |
| --- |
| Skill | Description |
| Reading | * Read and interpret instructions to comply with GMP requirements and workplace procedures
 |
| Writing | * Complete records according to GMP requirements and workplace procedures 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
* Maintain a clean and hazard free work area
 |
| Interact with others | * Report operational and safety information to relevant personnel using required communication method
 |
| Get the work done | * Solve routine problems within level of responsibility according to GMP requirements and workplace procedures
 |

| 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. |
| --- |
| Work role must include one of the following: | * manufacturing prescription or over the counter pharmaceuticals
* manufacturing biological or biotechnology pharmaceuticals
* manufacturing complementary medicines
* preparing solid or liquid dose
* sterile or non-sterile operations
* API manufacture
* finished dose manufacture
* quality control
* warehousing
* repacking.
 |
| Australian and other applicable regulatory frameworks must include at least one of the following: | * National Medicines Policy
* Therapeutic Goods Act
* Therapeutic Goods Regulations
* Manufacturing Principles
* Therapeutic Goods Orders
* Pharmacopeias
* Code of GMP
* other TGA guidelines relevant to product and market
* legislation relating to environmental manufacturing, Occupational Health & Safety
* US Food, Drug & Cosmetic Act and associated Codes of Federal Regulations and guidance
* European Directives and legislation of EU member states applicable to pharmaceutical manufacturing.
 |
| Global harmonization must include: | * PIC/S background and guidance
* ICH background and guidance.
 |
| GMP compliance must include: | * conformance to site-wide manufacturing quality systems for ensuring that products are consistently produced and controlled according to quality standards.
 |
| GMP requirements must include at least one of the following: | * Quality procedures
* Quality Assurance
* Quality Control
* Risk Management procedures.
 |
| indications of GMP non-compliant situations must include at least one of the following: | * damage to plant or equipment
* equipment or facility breakdown, malfunction or failure
* breaches of regulations and procedures
* poor housekeeping in the workplace
* signs of poor cleaning or pest infestation
* equipment exceeding nominated operating parameters and tolerances
* not following procedures
* operating processes without adequate training
* documentation or data discrepancies
* incorrect storage or labelling of materials, components or products.
 |
| relevant personnel must include at least one of the following: | * line or area supervisor
* leading hand
* unit or departmental manager
* quality manager
* production manager.
 |
| GMP documentation and recording requirements must include at least one of the following: | * production data
* in process or quality control test results
* records of manufacturing and quality control
* test reports
* checklists
* line clearances
* validation reports
* calculations
* incident reports.
 |
| biosecurity requirements must include at least one of the following: | * The Gene Technology Act 2000
* Biosecurity Act 2015
* Export Control Act 1982
* Imported Food Control Act 1992
* Regulatory requirements which apply to the supply of materials which are Genetically Modified Organisms (GMOs)
* Regulatory requirements relating to quarantining and use of materials and products.
 |
| common forms of contamination must include at least one of the following: | * physical from:
* equipment
* environment
* personnel
* chemical from other products or materials, including cleaning agents
* microbial from:
* materials
* equipment
* environment
* personnel.
 |
| Personal protective clothing must include: | * protective gown or scrubs
* surgical masks
* surgical gloves
* disposable overshoes
* hair net.
 |
| elements of GMP that help improve products and processes must include at least one of the following: | * customer complaints
* internal, external, customer and regulatory audits
* deviation reports
* out of specification reports
* non-conforming products
* product quality reviews
* corrective or preventive action requests.
 |

|  |
| --- |
| Unit Mapping Information |
| Code and title current version | Code and title previous version | Comments | Equivalence status |
| FDFPHM3XXX Implement good manufacturing practice requirements | FDFPH2001A Apply Good Manufacturing Practice procedures | Updated to meet Standards for Training PackagesAdditional elements and performance criteriaCode changed to reflect AQF alignment | No equivalent unit |

|  |  |
| --- | --- |
| 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 FDFPHM3XXX Implement good manufacturing practice requirements |
| --- | --- |
| 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 applied Good Manufacturing Practice (GMP) requirements, including evidence that, on at least one occasion, the individual has:* maintained good personal hygiene
* maintained workplace to meet GMP housekeeping standards
* cleaned and sanitised hands using recognised procedures for:
* washing with soap and water
* rubbing with an alcohol-based formulation
* read and interpreted relevant instructions and labels applicable to GMP operations, including pictorial and written signs and instructions
* followed workplace information relating to GMP responsibilities
* completed forms and reports according to GMP requirements and workplace procedures
* completed calculations and test results
* identified and given accurate verbal and/or written descriptions of incidents or situations that did or could have compromised GMP compliance or product quality
* identified and given accurate verbal and/or written descriptions of incidents or situations that did or could have provided the potential for product contamination
* identified and responded to out-of-calibration equipment
* participated in procedures to support GMP within level of responsibility
* identified and responded to out-of-specification or unacceptable raw materials, packaging components, final or part processed product within level of responsibility
* participated in failure investigations and in implementing improvement strategies.
 |

| 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:* GMP as a regulatory concept, including regulatory obligations of employees, and the potential implications of non-compliance
* GMP as a way of working to ensure product quality
* the development of GMP and the applicable regulatory frameworks, including enforcement, for manufacturing pharmaceuticals
* drivers of global harmonisation initiatives, including risks in the supply chain when operating in a global environment
* basic principles of quality assurance, GMP and quality control as currently defined for the industry sector
* GMP arrangements in the workplace, including:
* Manufacturing Principles
* relevant GMP codes of practice
* related workplace policies and procedures to implement responsibilities
* 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
* the roles and responsibilities of employees, supervisors and managers in the workplace and the GMP requirements for training
* personal hygiene, and the clothing and footwear requirements for working in and moving between work areas
* housekeeping requirements and responsibilities relating to own work, including the use and storage of housekeeping and cleaning equipment
* awareness of common contaminants relevant to the work process, including:
* micro-biological
* physical
* chemical
* awareness of control methods and procedures used in the work area to maintain GMP, including an understanding of the purpose of control, the consequence if not controlled and the method of control where relevant, as well as an understanding of the methods used to monitor process control
* basic understanding of the standards, properties, handling and storage requirements of raw materials, packaging components and final product
* GMP requirements for maintaining plant and process equipment fit for use
* recording requirements of GMP, including product and materials traceability procedures, and the legal significance of certifying and verifying GMP records
* awareness of the controls and methods for ensure electronic data integrity
* responsibilities for reporting and recording quality information
* the processes needed to investigate undesirable events and improve performance of processes
* procedures for responding to out-of-specification or unacceptable process performance/outcomes
* awareness of controls to protect personnel and the environment from contamination by products and materials
* awareness of how GMP contributes to a safe workplace.
 |

| Assessment Conditions |
| --- |
| 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 relevant to task being performed
* alcohol based hand cleanser
* soap and water
* commercial pharmaceutical production and packaging equipment
* cleaning materials and equipment
* specifications:
* workplace documentation related to GMP
* workplace environmental guidelines
* information on equipment capacity and operating parameters
* cleaning procedures
* relationships:
* interactions with team members and supervisors or realistic scenarios or role plays.

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

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