Modification history

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| Release | Comments |
| Release 1 | This version released with FBP Food, Beverage and Pharmaceuticals Training Package Version 2.0 |

| FDFPHM4001 | Prepare and review workplace documentation to support good manufacturing requirements |
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| Application | This unit of competency describes the skills and knowledge required to develop and review workplace documentation to support Good Manufacturing Practice (GMP).  The unit applies to individuals who focus on managing documentation relevant to their work area including document development, review and maintenance. It applies to those who work in a team leader or line management role in production or packaging 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. Develop and review workplace documentation to meet GMP requirements | 1.1 Identify policies and master plans to determine work area requirements  1.2 Identify and review workplace documentation to confirm fulfilment of GMP requirements  1.3 Develop or review procedures and records to confirm fulfilment of GMP requirements  1.4 Identify and report improvements to workplace documentation  1.5 Follow procedures to alter workplace documents |
| 2. Facilitate development and communication of workplace documentation | 2.1 Develop workplace documentation in consultation with relevant stakeholders to support GMP  2.2 Make documentation available and clearly explain it to relevant stakeholders  2.3 Identify and address training requirements, where necessary, for workplace personnel |

| 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 GMP requirements to extract information on key requirements * Review completed GMP related documents and records to ensure that GMP requirements are met |
| Writing | * Access and use document management systems, recording and reporting formats and applicable software |
| Oral Communication | * Initiate discussions about GMP and encourage contributions from stakeholders |
| Numeracy | * Monitor data for GMP requirements * Apply version control procedures to workplace document management systems |
| Navigate the world of work | * Identify and describe own skills, knowledge and experience within context of job role * Monitor adherence to legal and regulatory standards and responsibilities for self and others |
| Interact with others | * Use appropriate vocabulary, including technical language directly relevant to role * Use appropriate language and communication skills to disseminate information about document control procedures within the work team * Report GMP requirements to relevant personnel using required communication methods * Organise internal trainers and external training providers where training needs arise for relevant personnel |
| Get the work done | * Provide a role model to others in the workplace to support implementation of GMP when managing documentation |

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| Unit Mapping Information | | | |
| Code and title current version | Code and title previous version | Comments | Equivalence status |
| FDFPHM4001 Prepare and review workplace documentation to support good manufacturing practice requirements | FDFPH3001A Prepare and review workplace documentation to support 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 FDFPHM4001 Prepare and review workplace documentation to support 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 prepared and reviewed workplace documentation to support Good Manufacturing Process (GMP), including:   * identified workplace policies and plans to establish work requirements * developed and reviewed documentation to ensure compliance with GMP principles * identified and reported improvements including reviewing and updating existing documentation or developing new documentation within required formats * applied documentation control procedures when submitting or amending documents * consulted with relevant stakeholders on GMP in the preparation and review process and ensured changes are effectively communicated * identified and addressed training needs according to workplace practices * prepared workplace documentation, suitable for purpose and audience, in plain English * used communication skills to interpret and complete work information to support operations of work team or area. | |

| 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:   * GMP documentation requirements (as outlined in Australian Code of Good Manufacturing Practice for Medicinal Products) * document authorisation requirements and procedures and legal responsibilities of signatories * document types for supporting workplace systems, related development and controls systems, and roles and responsibilities, including an understanding of system security and access levels * procedures and responsibilities for altering documents and managing version control * systems, methods and procedures for recording and storing data and authorised levels of access to electronic systems * use of documentation, including documents that can be used as evidence during audit processes * recording and reporting requirements to support implementation of GMP in the workplace * training and assessment arrangements and responsibilities. |

| 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: * GMP documentation including Australian Code of Good Manufacturing Practice for Medicinal Products * specifications: * workplace documentation and related document control and management system * Australian Code of Good Manufacturing Practice for Medicinal Products * 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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