Modification history

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

| FBPPHM4002 | 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, review and communicate workplace operations documentation to support Good Manufacturing Practice (GMP) in a pharmaceutical manufacturing facility.The unit applies to individuals with specialised skills and knowledge of GMP requirements who manage and maintain documentation relevant to pharmaceutical manufacturing operations and have responsibility for the output of others. This includes applying and communicating non-routine technical solutions to predictable and unpredictable problems.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. Review and draft workplace documentation to meet GMP requirements | 1.1 Identify workplace documentation requiring development or review according to workplace document change control process and GMP requirements1.2 Review workplace documentation in consultation with relevant stakeholders to support GMP1.3 Draft workplace documentation in consultation with relevant stakeholders to support GMP1.4 Produce process mapping documents  |
| 2. Finalise workplace documentation to meet GMP requirements | 2.1 Follow workplace document change control process to alter workplace documents2.2 Ensure workplace documentation explains complex information in a simple and clear manner2.3 Complete and release workplace documentation2.4 Report improvements to workplace documentation |
| 3. Communicate changes to workplace documentation | 3.1 Ensure workplace documentation is available3.2 Explain documentation to relevant stakeholders3.3 Identify and address training needs according to team members level of responsibility and 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 | * Interpret key information in GMP requirements and workplace procedures
* Review completed workplace documentation to ensure that GMP requirements are met
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| Writing | * Prepare training documentation using structure, technical language and format appropriate for purpose and audience
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| Oral Communication | * Demonstrate two-way communication including active listening and confirming instructions when explaining workplace documentation to team members
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| Numeracy | * Apply version control procedures to workplace document management systems
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| Navigate the world of work | * Access and use electronic document management systems
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| Interact with others | * Use appropriate vocabulary, including technical language directly relevant to role
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| Unit Mapping Information |
| Code and title current version | Code and title previous version | Comments | Equivalence status |
| FBPPHM4002 Prepare and review workplace documentation to support good manufacturing practice requirements | FDFPH4001A Prepare and review workplace documentation to support Good Manufacturing Practice | Updated to meet Standards for Training Packages. | 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 FBPPHM4002 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 reviewed and developed workplace documentation to support Good Manufacturing Practice (GMP) requirements, including:* identified workplace documentation requiring development or review using workplace document change control process
* reviewed and developed workplace documentation, suitable for purpose and audience, in plain English, including:
* ensuring compliance with workplace procedures and GMP requirements
* reporting improvements
* reviewing and updating existing documentation
* developing new documentation
* applying documentation control procedures when submitting or amending documents
* accessed and used document management systems
* consulted with relevant stakeholders in the preparation and review process and ensured changes are effectively communicated
* communicated information on documentation requirements to others in the work area, including demonstrating:
* two-way communication
* active listening
* constructive responses to feedback
* provided training and support to others in the work area to implement responsibilities according to GMP requirements and 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:* workplace procedures and GMP requirements
* procedures and responsibilities for developing and altering documents, including:
* document types
* version control
* an understanding of system security and access levels
* controls systems, including individual roles and responsibilities
* document authorisation requirements and responsibilities of signatories
* systems 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
* workplace training and development system and responsibilities
* requirements for completion of workplace documentation.
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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:
* document management system
* specifications:
* GMP requirements
* workplace procedures related to GMP
* relationships:
* team members and 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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