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. |

| FBPPHM4004 | Participate in change control procedures |
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| Application | This unit of competency describes the skills and knowledge required to participate in planning and implementing change control procedures to meet Good Manufacturing Practice (GMP) requirements in a pharmaceutical manufacturing facility.The unit applies to individuals with specialised skills and knowledge of GMP requirements who contribute to the development of defined change management programs and procedures 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 |
| --- | --- |
| Elements describe the essential outcomes. | Performance criteria describe the performance needed to demonstrate achievement of the element. |
| 1. Participate in planning change | 1.1 Interpret change proposal including impact of change1.2 Interpret procedures for managing change1.3 Conduct risk assessment for change implementation in the workplace1.4 Undertake planning of change management1.5 Identify workplace procedures affected by change management plan and allocate responsibilities for review1.6 Identify and address training needs arising from change and determine delivery methods and responsibilities1.7 Apply authorisation requirements according workplace change control procedures |
| 2. Participate in implementing change | 2.1 Implement change management plan2.2 Communicate change to all affected personnel2.3 Implement training to support individuals and groups to implement change according to workplace procedures2.4 Revise workplace procedures to reflect change requirements2.5 Monitor and evaluate change according to workplace change control procedures2.6 Implement adjustments to change according to workplace change control procedures2.7 Maintain workplace records and documents according to workplace change control 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 | * Interpret key information in change proposal and workplace change control procedures
* Interpret key information in GMP requirements and workplace procedures relevant to change control
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| Writing | * Prepare change management plan
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| Oral Communication | * Demonstrate two way communication including active listening and confirming instructions when explaining change management plan to team members
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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 |
| FBPPHM4004 Participate in change control procedures | FDFPH4004A Participate in change control procedures | 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 FBPPHM4004 Participate in change control procedures |
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| Performance Evidence |
| An individual demonstrating competency in this unit must satisfy all the elements and performance criteria of this unit.There must be evidence that, on at least one occasion, the individual has participated in change control procedures in a pharmaceutical manufacturing facility, including:* identified situations requiring change control according to change proposal
* participated in developing a change management plan
* led the implementation of change in a work area
* communicated information on change requirements to others in the work area, including demonstrating:
* two way communication
* active listening
* responses to feedback
* accessed and used document management systems
* implemented training to support others in the work area to implement responsibilities according to change management plan
* interpreted GMP requirements and workplace procedures related to change control
* documented change according to GMP requirements and workplace change control 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:* principles of risk management and related procedures
* documentary evidence required to support change requests
* workplace change control procedures, including:
* evaluation criteria
* change classification
* authorisation requirements
* document control
* roles and responsibilities
* workplace training systems and responsibilities
* GMP requirements and workplace procedures relevant to change control
* documentation systems and procedures, including:
* record keeping to meet both company and legal requirements
* processes for developing or reviewing workplace procedures
* document control systems used in the workplace
* responsibilities for reporting and recording information.
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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:
* change proposal
* specifications:
* workplace change control procedures
* workplace documentation relating to change control procedures
* GMP requirements related to change control
* relationships:
* team members.

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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