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. |

| FDFPHM4004 | 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 to meet Good Manufacturing Practice (GMP) requirements.  This unit applies to individuals who contribute to the development of defined change management and validation programs and procedures that form part of Good Manufacturing Practice (GMP) and ensure that they are supported in the work area. It applies to individuals working in a team leader or supervisory production or packaging roles 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. Participate in planning change | 1.1 Identify regulations, codes and guides relevant to the work area  1.2 Identify procedures, roles and responsibilities for managing change  1.3 Conduct risk assessment for change implementation in the workplace  1.4 Undertake planning of change management according to individual level of responsibility  1.5 Identify workplace procedures affected by change management plan and allocate responsibilities for review according to individual levels of responsibility  1.6 Identify any training needs arising from change and determine delivery methods and responsibilities  1.7 Identify and follow validation or other relevant authorisation requirements and procedures |
| 2. Participate in implementing change | 2.1 Implement change according to the change management plan and work health and safety procedures  2.2 Communicate advice on change to all affected personnel  2.3 Source relevant training for affected personnel according to workplace procedures  2.4 Revise workplace procedures to reflect change requirements  2.5 Monitor change and evaluate against established evaluation criteria  2.6 Identify and implement any further adjustments or modifications according to change control procedures  2.7 Document and report outcomes to meet change control requirements |

| 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, interpret and extract key information from regulations, codes, guides and internal workplace procedures relevant to GMP requirements and products or processes used in the work area |
| Writing | * Document evidence required to support a change management plan |
| Oral Communication | * Initiate discussions about change management implications and encourage contributions from workplace personnel |
| Numeracy | * Monitor data to support change management |
| 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 | * Negotiate issues raised when consulting with workplace personnel affected by change * Use appropriate language and communication skills to engage and consult with workplace personnel affected by change * Appoint internal trainers and external training providers where training needs arise for relevant personnel |
| Get the work done | * Provide a role model to others to support implementation of change in the workplace |

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| Unit Mapping Information | | | |
| Code and title current version | Code and title previous version | Comments | Equivalence status |
| FDFPHM4004 Participate in change control procedures | FDFPH4004A Participate in change control 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 FDFPHM4004 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, including:   * identified situations requiring change control for a given set of change scenarios * participated in developing a change management plan * developed and documented implementation plan to introduce change into a work area * led the implementation of change in a work area * located regulations, codes, guides and internal company documentation relevant to GMP requirements and the products or processes used in the work area * applied communication and consultation skills to engage and consult with workplace personnel affected by change * identified training needs and ensured that related skills and knowledge requirements are addressed by the training system * negotiated and resolved issues for personnel affected by change in the workplace * applied safe work practices and identified work health and safety hazards and controls * documented and reported change control outcomes * prepared workplace documentation. | |

| 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:   * the types of change that come within the scope of change control procedures * change classification procedures and responsibilities * principles of risk management and related procedures * documentary evidence required to support change requests * change control procedures, roles and responsibilities * workplace procedures, including procedures for review, authorisation and document control * training systems, including assessment methods and documentation * validation systems, procedures 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: * change request * specifications: * workplace procedures including procedures relating to change control * 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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