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. |

| FDFPHM4005 | Participate in validation processes |
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| Application | This unit of competency describes the skills and knowledge required to use validation processes to support Good Manufacturing Practice (GMP) requirements in the pharmaceutical sector.  This unit applies to individuals who work in a team leader, supervisory or line management role. Their involvement in validation would typically be as part of a multi-disciplinary team.  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 qualification processes for new or modified facilities, systems or equipment | 1.1 Identify responsibilities and procedures for developing and implementing design qualification, installation qualification, operational qualification and performance qualification  1.2 Develop or review qualification processes and documentation according to workplace procedures and to own level of responsibility  1.3 Document workplace procedures to support operational requirements |
| 2. Participate in validation processes for new or modified facilities, systems or equipment | 2.1 Identify validation requirements in the work area  2.2 Follow validation protocol to support validation activities in the work area  2.3 Collect, analyse and report data to meet GMP 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 | * Access, interpret and extract key information from documentation relating to qualification and validation requirements for a work area |
| Writing | * Develop workplace procedures to support qualification and validation according to required formats |
| Oral Communication | * Use correct technical language and appropriate oral communication skills for the audience to disseminate information about validation processes within work teams |
| Numeracy | * Monitor data to inform and support validation |
| Navigate the world of work | * Identify and describe own skills, knowledge and experience within context of job role * Monitor adherence to regulatory standards and responsibilities for self and others |
| Interact with others | * Liaise with other work areas and functions to coordinate and schedule validation processes |
| Get the work done | * Organise information and manage the impact of qualification and validation procedures on related processes and personnel |

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| Unit Mapping Information | | | |
| Code and title current version | Code and title previous version | Comments | Equivalence status |
| FDFPHM4005 Participate in validation processes | FDFPH4005A Participate in validation processes | 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 Participate in validation processes |
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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 validation processes, including:   * applied principles of risk management to identify critical facilities, systems and equipment * identified and interpreted validation documentation relating to qualification and validation requirements for a work area * participated in qualification and validation procedures according to own level of responsibility * identified and managed the impact of qualification and validation procedures on related processes, or work areas and personnel, according to own level of responsibility * developed workplace procedures to support qualification and validation according to required formats and own level of responsibility * ensured that operators in the work area have the required competence relevant to work role * prepared workplace documentation * communicated 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:   * the principles and purposes of: * qualification and related procedures and responsibilities * validation and related procedures and responsibilities * the purpose and application of prospective, concurrent and retrospective validation * data collection, analysis and reporting requirements * the scope, application and timing of validation, including relevant circumstances that could trigger the need to validate, re-validate or justify not undertaking a validation process prior to commencing production * the relationship between validation and change control * equipment design drawings and process flow-charting * relevant investigation methods, including process capability and root cause analysis * workplace recording and reporting requirements * training and assessment arrangements and responsibilities * workplace procedures and authorisation procedures. |

| 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: * copies of the relevant Act, regulations, codes and guides * specifications: * workplace procedures relating to qualification and validation * 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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