Modification history

|  |  |
| --- | --- |
| 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. |

| FBPPHM4005 | Participate in validation processes |
| --- | --- |
| Application | This unit of competency describes the skills and knowledge required to use qualification and validation processes 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 participate in validation process relevant to pharmaceutical manufacturing operations as part of a multi-disciplinary team 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 qualification processes for facilities, systems or equipment | 1.1 Identify procedures for developing and implementing qualification processes  1.2 Develop and review qualification processes and documentation according to workplace procedures  1.3 Implement qualification process training needs |
| 2. Participate in validation processes for facilities, systems or equipment | 2.1 Identify validation requirements according to workplace procedures and GMP requirements  2.2 Follow validation protocol to support validation activities in the work area  2.3 Evaluate and document deviations and exceptions from protocol  2.4 Maintain workplace records and documents according to workplace procedures and 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. | |
| --- | --- |
| Skill | Description |
| Reading | * Interpret key information in GMP requirements and workplace procedures relevant to qualification and validation processes |
| Writing | * Create qualification procedures and validation reports using relevant technical terminology and format to suit regulatory requirements |
| Oral Communication | * Demonstrate two way communication including active listening and confirming instructions when explaining qualification processes to team members |
| Navigate the world of work | * Access and use electronic document management systems |
| Interact with others | * Use appropriate vocabulary, including technical language directly relevant to role |

|  |  |  |  |
| --- | --- | --- | --- |
| Unit Mapping Information | | | |
| Code and title current version | Code and title previous version | Comments | Equivalence status |
| FBPPHM4005 Participate in validation processes | FDFPH4005A Participate in validation processes | Updated to meet Standards for Training Packages. | Equivalent unit |

|  |  |
| --- | --- |
| 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 |
| --- | --- |
| 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:   * identified procedures for developing and implementing qualification processes, including a: * design qualification * installation qualification * operational qualification * performance qualification * applied principles of risk management to identify critical: * facilities * systems * equipment * communicated information on qualification process requirements to others in the work area, including demonstrating: * two way communication * active listening * constructive responses to feedback * implemented training to support others in the work area to implement responsibilities according to qualification process requirements * interpreted GMP requirements and workplace procedures related to qualification and validation requirements * managed the impact of qualification and validation procedures on: * related processes * work areas * personnel * developed workplace procedures to support qualification and validation according to GMP requirements and workplace procedures * documented qualification and validation processes according to GMP requirements and workplace procedures. | |

| Knowledge Evidence |
| --- |
| 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 procedures for developing and implementing qualification processes * types of qualification processes, including: * design * installation * operational * performance * validation objectives and procedures, including: * prospective validation * concurrent validation * re-validation * circumstances that justify not undertaking a validation process prior to commencing production * procedure updates and sampling requirements * workplace training systems and responsibilities * GMP requirements and workplace procedures relevant to qualification and validation processes * 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. |

| Assessment Conditions |
| --- |
| 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: * qualification and validation process documentation * specifications: * workplace procedures relating to validation * GMP requirements related to validation * relationships: * team members.   Assessors of this unit must satisfy the requirements for assessors in applicable vocational education and training legislation, frameworks and/or standards. |

|  |  |
| --- | --- |
| Links | Companion Volumes, including Implementation Guides, are available at VETNet <https://vetnet.education.gov.au/Pages/TrainingDocs.aspx?q=78b15323-cd38-483e-aad7-1159b570a5c4> |