Modification history

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

| FBPPHM3014 | Operate a liquid manufacturing process |
| --- | --- |
| Application | This unit of competency describes the skills and knowledge required to set up, operate, adjust and shut down a liquid manufacturing process in a pharmaceutical manufacturing facility.  The unit applies to individuals who apply good manufacturing practice (GMP) and operating principles to the liquid manufacturing process under broad direction, and take responsibility for their own work.  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. Prepare the liquid manufacturing process for operation | 1.1 Confirm materials and equipment are available and meet production requirements  1.2 Select and fit personal protective clothing and equipment according to workplace procedures  1.3 Fit and adjust machine components and attachments according to production requirements and equipment operation and maintenance manual  1.4 Enter processing and operating parameters according to safety and production requirements  1.5 Check and adjust equipment performance according to equipment operating procedures  1.6 Conduct pre-start checks according to workplace requirements |
| 2. Operate and monitor the liquid manufacturing process | 2.1 Deliver raw materials in required quantities and sequence according to recipe specifications, batch and production requirements  2.2 Start up and monitor liquid manufacturing process to confirm specifications are within required limits  2.3 Rectify, identify and report out-of-specification liquid products or process outcomes to maintain process within specifications  2.4 Conduct in process testing  2.5 Transfer liquid mix according to production requirements  2.6 Maintain work area according to workplace cleaning standards  2.7 Conduct process according to safety and environmental requirements  2.8 Contain, remove and report spillages according to workplace procedures  2.9 Complete documentation according to workplace requirements |
| 3. Shut down the liquid manufacturing process | 3.1 Confirm the workplace procedures for shutting down the process  3.2 Complete end-of-batch procedures according to batch instructions and workplace procedures  3.3 Safely shut down the process  3.4 Complete records according to workplace procedures |

| 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 | * Identify relevant information from workplace documentation and interpret requirements for the liquid manufacturing process |
| Writing | * Complete workplace documentation using appropriate language and in required format |
| Numeracy | * Interpret recipe specifications for loading materials in correct quantities and sequence * Confirm equipment timers, product weights and mixing times |
| Navigate the world of work | * Identify workplace procedures relevant to own role |
| Interact with others | * Report operational and safety information to relevant personnel using required communication method |
| Get the work done | * Plan, organise and implement tasks required to achieve production outcomes * Use problem-solving skills to analyse product and process faults and decide on appropriate action |

| Range Of Conditions  This section specifies different work environments and conditions that may affect performance. Essential operating conditions that may be present (depending on the work situation, needs of the candidate, accessibility of the item, and local industry and regional contexts) are included. | |
| --- | --- |
| Pre start checks must include at least six of the following: | * inspecting equipment condition to identify signs of wear * selecting appropriate settings and/or related parameters * install format/change parts and load correct program * cancelling isolation or lockouts * confirming line clearance and cleaning status * confirming that equipment is clean and correctly configured for processing requirements * positioning sensors and controls correctly * ensuring scheduled maintenance has been carried out * confirming that all safety guards are in place and operational. |

|  |  |  |  |
| --- | --- | --- | --- |
| Unit Mapping Information | | | |
| Code and title current version | Code and title previous version | Comments | Equivalence status |
| FBPPHM3014 Operate a liquid manufacturing process | FDFPH2012A Operate a liquid manufacturing process | Updated to meet Standards for Training Packages. Code changed to reflect AQF alignment. | 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 FBPPHM3014 Operate a liquid manufacturing process |
| --- | --- |
| 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 the individual has operated at least one liquid manufacturing process, including:   * accessed workplace information to confirm production requirements for the liquid manufacturing process * confirmed supply of necessary materials and services to the liquid manufacturing process * selected, fitted and used one of the following: * protective gown * scrubs * smock * statcoat * disposable coverall * selected, fitted and used personal protective clothing and equipment, including: * surgical mask * surgical gloves * disposable overshoes * hair net * conducted pre-start checks required for the safe operation of the liquid manufacturing process, including six of the following: * inspecting equipment condition to identify signs of wear * selecting appropriate settings and/or related parameters * install format/change parts and load correct program * cancelling isolation or lockouts * confirming line clearance and cleaning status * confirming that equipment is clean and correctly configured for processing requirements * positioning sensors and controls correctly * ensuring scheduled maintenance has been carried out * confirming that all safety guards are in place and operational * started, operated, monitored and adjusted a liquid manufacturing process to achieve required outcomes, including: * adding and loading materials in correct quantities and sequences, including monitoring automatic ingredient addition and manual addition * supply and flow of materials to and from the liquid manufacturing process * pacing the liquid manufacturing process to meet production requirements * checked control points and conducted inspections to confirm the process remains within specification, including: * process control testing * fill volume * product sampling * taken corrective action in response to out-of-specification results * located emergency stop functions on equipment * followed isolation and lock out and tag out procedures to take liquid manufacturing process and related equipment off-line in preparation for cleaning and maintenance * followed end-of-batch procedures, including: * line clearance and cleaning * yield calculation * materials reconciliation * product labelling * change status to dirty/non sterile * used process control systems according to workplace procedures * cleaned and maintained work area to meet workplace cleaning standards and environmental requirements. | |

| 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:   * stages of the liquid manufacturing process, including: * the purpose, methods and outcomes of each stage * control points * quality characteristics to be met by the liquid manufacturing process * stages and changes which occur during liquid manufacturing * types of raw materials used in the liquid manufacturing process * specific gravity and bulk density properties of the ingredients used * method and sequence of addition required to achieve required mix characteristics * required characteristics of manufactured solutions, suspensions and emulsions * flow of the liquid manufacturing process and the effect of outputs on downstream pharmaceutical processes * basic operating principles of equipment, requirements and parameters of liquid manufacturing equipment, including: * main equipment components, operating capacities and applications * typical equipment faults and related causes, including signs and symptoms of faulty equipment and early warning signs of potential problems * status and purpose of guards * the purpose and location of sensors and related feedback instrumentation * awareness of calibration schedules for scales and related weighing and measuring equipment * corrective actions required where operation falls outside specified parameters * functions and limitations of personal protective clothing and equipment, including: * protective gown, scrubs, smocks, statcoats, or disposable coveralls * surgical masks * surgical gloves * disposable overshoes * hair nets * pre-start checks requirements, including: * inspecting equipment condition to identify signs of wear * selecting appropriate settings and/or related parameters * install format/change parts and load correct program * cancelling isolation or lockouts as required * confirming line clearance and cleaning status * confirming that equipment is clean and correctly configured for processing requirements * positioning sensors and controls correctly as required * ensuring scheduled maintenance has been carried out * confirming that all safety guards are in place and operational * methods used to monitor a liquid manufacturing process, including: * inspecting * measuring * testing * flow rates * materials addition sequence * times, temperatures and agitator speeds * spills and leaks during filling * polymer issues, such as parison formation and burning polymer * product and process changeover procedures and responsibilities * end-of-batch procedures, including: * calculating yield * materials reconciliation * product labelling * change status to dirty/non sterile * requirements of different shutdowns, including: * emergency and routine shutdowns * procedures to follow in the event of a power outage * loss of environmental conditions * filter issue trouble shooting * line clearance procedures, including cleaning and sanitation procedures * isolation, lock out and tag out procedures and responsibilities * operating principles of process control, including the relationship between control panels and systems and physical equipment * GMP requirements associated with a liquid manufacturing process and related control measures * environmental issues and controls relevant to the liquid manufacturing process, including waste collection and handling procedures * requirements for completion of workplace documentation. |

| 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: * personal protective clothing and equipment * liquid manufacturing process equipment * materials required for the liquid manufacturing process * test equipment * cleaning materials and equipment associated with liquid manufacturing process * specifications: * specifications, control points and processing parameters * recording requirements and procedures * workplace documentation relating to liquid manufacturing process and procedures, including labels * GMP requirements relating to liquid manufacturing process * information on equipment capacity and operating parameters * production schedule/batch instructions * sampling schedules and test procedures * cleaning procedures associated with liquid manufacturing process   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> |