Modification history

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

| FDFPHM3XXX | 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.  The unit applies to individuals who are responsible for operating and monitoring a liquid manufacturing process in the pharmaceutical sector. These individuals typically work within defined Good Manufacturing Practice (GMP) programs and procedures.  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 availability of materials to meet operating requirements  1.2 Identify and confirm cleaning and maintenance requirements and status  1.3 Use correctly fitted and appropriate personal protective clothing and equipment  1.4 Fit and adjust machine components and related attachments to meet operating requirements  1.5 Enter processing and operating parameters, to meet safety and production requirements  1.6 Check and adjust equipment performance according to equipment operating procedures  1.7 Conduct pre-start checks according to procedures |
| 2. Operate and monitor the liquid manufacturing process | 2.1 Deliver raw materials to the process in required quantities and sequence to meet recipe specifications  2.2 Start up and operate process according to workplace procedures  2.3 Monitor equipment to identify variation in operating conditions  2.4 Monitor process to ensure fulfilment of specifications  2.5 Identify, rectify and report out-of-specification products and process outcomes to ensure the process remains within specifications  2.6 Transfer liquid mix to required production or storage location  2.7 Contain, remove and report spillages according to workplace procedures  2.8 Maintain work area according to housekeeping and environmental standards  2.9 Maintain records in required format |
| 3. Shut down the liquid manufacturing process | 3.1 Complete end-of-batch procedures according to batch instructions and SOP  3.2 Shut down liquid manufacturing process according to workplace procedures  3.3 Identify and report maintenance requirements according to workplace reporting 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 | * Read and interpret standard operating procedures for the liquid manufacturing process |
| Writing | * Complete records according to workplace guidelines using paper based and/or electronic media |
| Numeracy | * Add and load materials in correct quantities and sequence * Monitor automatic or manual ingredient addition |
| Navigate the world of work | * Apply workplace procedures to own role and responsibilities * Understand main tasks, responsibilities and boundaries of own role, including use of personal protective clothing and equipment, housekeeping standards and environmental care requirements * Maintain a clean and hazard free work area |
| Interact with others | * Report operational and safety information to relevant personnel using required communication method |
| Get the work done | * Solve routine problems according to workplace guidelines and using experience of past solutions |

| 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. | |
| --- | --- |
| Personal protective clothing and equipment must include: | * protective gown or scrubs * surgical masks * surgical gloves * disposable overshoes * hair net. |
| Pre start checks must include: | * inspecting equipment condition to identify signs of wear * selecting appropriate settings and/or related parameters * 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 |
| FDFPHM3XXX 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 FDFPHM3XXX 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, on at least one occasion, the individual has operated a liquid manufacturing process, including:   * accessed workplace information to identify liquid manufacturing process requirements * selected, fitted and used personal protective equipment * confirmed supply of necessary materials and services to the liquid manufacturing process * conducted all pre-start checks required to ensure safe start up of the liquid manufacturing process * added and loaded materials in correct quantities and sequences, including monitoring automatic ingredient addition and manual addition * started, operated, monitored and adjusted liquid manufacturing process equipment to achieve required outcomes, including monitoring control points and conducting inspections to confirm the process remains within specifications * taken corrective action in response to out-of-specification results * monitored supply and flow of materials to and from the liquid manufacturing process * paced the liquid manufacturing process to meet production requirements * responded to or reported equipment failure in accordance with level of responsibility * located emergency stop functions on equipment * followed isolation, lock out and tag out procedures, to take the 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 and product labelling * completed workplace records in required format * maintained work area to meet workplace housekeeping standards * used process control systems in accordance with workplace procedures * followed work health and safety 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 purpose and basic principles of a liquid manufacturing process, including the characteristics and basic functions of raw materials used, the method and sequence of addition required to achieve required mix characteristics and, where required, the characteristics of solutions, suspensions and emulsions * specific gravity and bulk density properties of the ingredients used * basic operating principles of liquid manufacturing equipment, including main equipment components, status and purpose of guards, equipment operating capacities and applications, purpose and location of sensors and related feedback instrumentation, and awareness of calibration schedules for scales and related weighing and measuring equipment * services required and actions to take if services are unavailable * stages and changes which occur during liquid manufacturing * quality characteristics to be met by the liquid manufacturing process * flow of the liquid manufacturing process and the effect of outputs on downstream pharmaceutical processes * operating requirements, parameters and corrective actions required where operation falls outside specified parameters * typical equipment faults and related causes, including signs and symptoms of faulty equipment and early warning signs of potential problems * methods used to monitor a liquid manufacturing process, including inspecting, measuring and testing * inspection or test points (control points) in the liquid manufacturing process and related procedures and recording requirements, including the monitoring of: * flow rates * materials addition sequence * times, temperatures and agitator speeds * required characteristics of manufactured liquid * GMP requirements associated with a liquid manufacturing process and related control measures * common causes of variation and corrective action required * product and process changeover procedures and responsibilities * work health and safety hazards and controls, including the limitations of personal protective clothing and equipment * end-of-batch procedures, including procedures for calculating yield and material reconciliation * actions required if yield or reconciliation is outside of prescribed limits * product labelling responsibilities and procedures * requirements of different shutdowns including emergency and routine shutdowns and procedures to follow in the event of a power outage * line clearance, cleaning and sanitation procedures * isolation, lock out and tag out procedures and responsibilities * procedures and responsibilities for reporting production and performance information * environmental issues and controls relevant to the liquid manufacturing process, including waste collection and handling procedures * basic operating principles of process control, including the relationship between control panels and systems and physical equipment. |

| Assessment Conditions |
| --- |
| 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: * personal protective clothing and equipment * liquid manufacturing process and related equipment and services * materials required for the liquid manufacturing process * test equipment * cleaning materials and equipment associated with liquid manufacturing process * specifications: * work procedures, including advice on safe work practices, GMP, quality and environmental requirements * information on equipment capacity and operating parameters * production schedule or batch instructions * specifications, control points and processing parameters * sampling schedules and test procedures * documentation and recording requirements and procedures * cleaning procedures associated with liquid manufacturing process * 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. |

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