Modification history

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

| FBPPHM3002 | Operate a pharmaceutical production process |
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| Application | This unit of competency describes the skills and knowledge required to setup, operate monitor, adjust and shut down a production process in a pharmaceutical manufacturing facility.  The unit applies to individuals who apply operating principles to the production 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 |
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| Elements describe the essential outcomes. | Performance criteria describe the performance needed to demonstrate achievement of the element. |
| 1. Receipt materials and components | 1.1 Confirm incoming goods correspond to workplace documentation  1.2 Clean and label containers with prescribed data, according to workplace procedures  1.3 Quarantine incoming goods including release and reject status according to Good Manufacturing Practice (GMP) requirements and workplace procedures  1.4 Identify and report deviations, unusual events and non-conformances according to GMP and workplace procedures. |
| 2. Set up the production process for operation | 2.1 Confirm equipment and materials meet production requirements  2.2 Confirm cleaning requirements and equipment status  2.3 Select and fit personal protective clothing and equipment according to workplace procedures  2.4 Enter processing and operating parameters according to safety and production requirements  2.5 Check and adjust equipment performance  2.6 Conduct pre-start checks according to workplace procedures. |
| 3. Dispense materials | 3.1 Deliver materials in required quantities and sequence according to batch and production requirements  3.2 Record dispensed material, including weight or volume according to batch and production requirements  3.3 label dispensed materials for each batch and stage according to production requirements. |
| 4. Operate and monitor the production process | 4.1 Start up and monitor production process to confirm products are within required limits  4.2 Rectify, identify and report out-of-specification products or process outcomes to maintain process within specifications  4.3 Maintain work area according to workplace cleaning standards  4.4 Conduct production process according to safety and environmental requirements  4.5 Complete documentation according to workplace requirements. |
| 5. Hand over the production process | 5.1 Perform handover according to workplace procedures  5.2 Inform handover production team of process and related equipment status at completion of handover. |
| 6. Shut down the process | 6.1 Confirm the workplace procedures for shutting down the process  6.2 Complete end-of-batch procedures according to batch instructions and workplace procedures  6.3 Safely shut down the process  6.4 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. | |
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| Skill | Description |
| Reading | * Identify relevant information from workplace documentation and interpret requirements for the pharmaceutical production process |
| Writing | * Complete workplace documentation using appropriate language and in required format |
| Numeracy | * Interpret material and product specifications |
| 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. | |
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| Incoming goods must include at least one of the following: | * active pharmaceutical ingredient (API) * components * excipients * packaging materials * raw materials. |
| Equipment must include at least one of the following: | * bioreactors * compressors * encapsulators * fermenters * filling machines and associated components * filters * isolators * mixing vessels and associated components * sieves * sterilisers * weighing instruments * . |
| Materials must include at least one of the following: | * ampoules * bottles * bulk product * cartons * chemicals * containers and closures * gas * intermediates * labels * liquids * powders * raw materials * vials. |
| Cleaning requirements must include at least one the following: | * area clearance * automated * full clean * line clearance * manual * partial clean * sanitation * semi-automated * sterilisation. |
| Equipment status must include: | * calibrated * clean * clean/dirty hold time * in use * ready to use. |
| Pre-start checks must include at least two of the following: | * area or line clearances * area or room differential pressure checks * area or room status checks * confirming that equipment is clean and correctly configured for processing requirements * confirm product details and ingredients, including: * name * quantity * strength * ensuring scheduled maintenance has been carried out * environmental sampling * inspecting equipment condition to identify any signs of wear * sanitation * selecting appropriate settings and/or related parameters. |
| Monitor must include at least one of the following: | * environmental monitoring * appearance * chemical * microbial * pH * volume * weights * product bioburden * the use of Supervisory Control and Data Acquisition (SCADA) and process control systems * verification of checks performed by other operators. |

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| Unit Mapping Information | | | |
| Code and title current version | Code and title previous version | Comments | Equivalence status |
| FBPPHM3002 Operate a pharmaceutical production process | Not applicable | New unit | No 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 FBPPHM3002 Operate a pharmaceutical production process |
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| Performance Evidence | |
| An individual demonstrating competency must satisfy all of the elements and performance criteria in this unit.  There must be evidence that the individual has safely participated in at least one pharmaceutical production process, including:   * accessed workplace information to confirm production requirements * confirmed supply of necessary equipment and materials * handled and stored materials and products in a manner that prevents contamination and mix-ups * selected, fitted and used personal protective clothing and equipment * conducted pre-start checks, including two of: * area or line clearances * area or room differential pressure checks * area or room status checks * confirming that equipment is clean and correctly configured for processing requirements * confirm product details and ingredients, including; name, quantity and strength * ensuring scheduled maintenance has been carried out * environmental sampling * inspecting equipment condition to identify any signs of wear * sanitation * selecting appropriate settings and/or related parameters * started, operated, monitored and adjusted process equipment to achieve required outcomes, including: * adding and loading materials in correct quantities and sequences * supply and flow of materials to and from the process * pacing process to meet production requirements * checked control points and conducted inspections to confirm process remains within specification, including: * process control testing * product sampling * taken corrective action in response to out-of-specification results * followed end-of-batch procedures, including: * bioburden sampling * environmental sampling * line clearances and cleaning (full or partial) * yield calculation * materials reconciliation * product labelling * change equipment status (sterile/clean to dirty/clean) * used process control systems according to workplace procedures * cleaned and maintained work area to meet workplace cleaning standards and environmental requirements. | |

| 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:   * stages of the pharmaceutical manufacturing process, including: * the purpose, methods and outcomes of each stage * control points * flow of materials, people and waste * flow of the manufacturing process and the effect of outputs on downstream processes * basic operating principles of equipment, requirements and parameters of pharmaceutical 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 * corrective actions required where operation falls outside specified operating parameters and impact on validation status * processing equipment and utility systems, and how product quality and GMP compliance can be impacted by: * performance * functionality * construction * instrumentation * common GMP non-conformances and unusual events found in a pharmaceutical production environment, including: * missing, illegible or inaccurate records * failure to follow workplace procedures * failure of cleaning regime * damaged goods, including; starting materials, components, intermediates and finished products * product diverted from normal course of process * loss of sterility or pressure * spills * out of limit situations inlcuding; yields, reconciliations, in process controls and in process checks * damage or poor maintenance of plant or equipment * signs of inadequate cleaning or pest infestation * terminology associated with control and validation of GMP processes, including: * lifecycle * Installation Qualification of equipment (IQ) * Operational Qualification of equipment (OQ) * Performance Qualification (PQ) * Process Variation (PV) * Critical Quality Attribute (CQA) * Critical Quality Process (CQP) * Critical Process Parameters (CPP) * functions and limitations of protective clothing and equipment relevant to the work process * pre-start checks requirements, including: * area or line clearances * area or room differential pressure checks * area or room status checks * confirming that equipment is clean and correctly configured for processing requirements * confirm product details and ingredients, including; name, quantity and strength * ensuring scheduled maintenance has been carried out * environmental sampling * inspecting equipment condition to identify any signs of wear * sanitation * selecting appropriate settings and/or related parameters * methods used to monitor the production process, including: * inspecting * measuring * testing * product and process changeover procedures and responsibilities * end-of-batch procedures, including: * bioburden sampling * environmental sampling * line clearances and cleaning (full or partial) * yield calculation * materials reconciliation * product labelling * change equipment status (sterile/clean to dirty/clean) * requirements of different shutdowns, including: * emergency and routine shutdowns * procedures to follow in the event of a power outage * isolation, lock out and tag out procedures and responsibilities * operating principles of process control, including the relationship between control panels and systems and the physical equipment * GMP requirements for production and process controls, including: * identification and traceability * yields and reconciliation * segregation and storage * status labels (physical and electronic) * environmental issues and controls relevant to the production environment, including waste collection and handling procedures * requirements for completion of workplace documentation. |

| Assessment Conditions |
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| Assessment of skills must take place under the following conditions:   * physical conditions: * al pharmaceutical manufacturing workplace or an environment that accurately represents workplace conditions * resources, equipment and materials: * personal protective clothing and equipment * manufacturing process equipment * materials required for the manufacturing process * cleaning materials and equipment associated with the manufacturing process * specifications: * specifications, control points and processing parameters * recording requirements and procedures * workplace documentation relating to manufacturing process and procedures * GMP requirements relating to manufacturing process * information and documentation relating to handover * cleaning procedures associated with manufacturing process.   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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