Modification history

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

| FDFPHM3XXX | Participate in a pharmaceutical production environment |
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| Application | This unit of competency describes the skills and knowledge required to setup, monitor and adjust a production process or sub-system in a pharmaceutical manufacturing environment.  The unit applies to individuals who work in pharmaceutical manufacturing facilities of different sizes, producing various pharmaceutical products under broad direction and taking 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 are integral and correspond to workplace information  1.2 Clean and label containers with prescribed data, according to workplace information  1.3 Physically or administratively quarantine incoming goods according to Good Manufacturing Practices (GMP) 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, materials and services meet operating requirements  2.2 Identify and confirm cleaning requirements and equipment status  2.3 Select and adjust equipment settings to meet operating requirements  2.4 Enter processing/operating parameters to meet production requirements  2.5 Perform pre-start checks according to GMP and workplace procedures  2.6 Check and adjust equipment performance. |
| 3. Dispense materials | 3.1 Dispense starting materials according to GMP and workplace procedures  3.2 Check and record dispensed material, including weight or volume according to GMP and workplace procedures  3.3 label dispensed materials for each batch and stage according to GMP and workplace procedures. |
| 4. Operate and monitor the production process | 4.1 Start up and operate process according to workplace procedures  4.2 Monitor equipment to identify variation in operating conditions  4.3 Identify variation in equipment operation and report maintenance requirements according to workplace procedures  4.4 Monitor process and confirm that specifications are met  4.5 Identify, rectify and report deviations from standard procedures, out of specification product/process outcomes or any other unusual events according to GMP and workplace procedures, to maintain the process within specification  4.6 Maintain work area according to workplace procedures  4.7 Conduct work according to workplace procedures  4.8 Maintain workplace records according to GMP and workplace procedures. |
| 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 Identify appropriate shutdown procedure  6.2 Shut down process according to workplace procedures  6.3 Identify and report maintenance requirements according to workplace reporting procedures  6.4 Perform yield checks and reconciliation of quantities according to workplace procedures  6.5 Identify, rectify and report discrepancies outside acceptable limits  6.6 Maintain workplace records according to GMP and 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 and follow signs, symbols, checklists, production schedules, cleaning schedules and other technical information relevant to pharmaceutical production * Identify and follow workplace information and procedures * Identify and interpret Good Manufacturing Practice codes relevant to pharmaceutical production |
| Writing | * Complete labels, checklists, standard forms and reports relevant to pharmaceutical production * Maintain workplace reports and records relevant to pharmaceutical production and reporting of deviations, unusual events, non-conformances and discrepancies outside of acceptable limits |
| Oral communication | * Use clear language to report deviations, unusual events, non-conformances and discrepancies outside of acceptable limits * Participate in verbal exchanges to respond to questions and clarify information |
| Numeracy | * Interpret room data sheets, purchase orders, picking lists, bills of materials, material and product specifications |
| Navigate the world of work | * Recognise and follow workplace requirements, including safety requirements and Good Manufacturing Practice, associated with own role and area of responsibility |

| 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: | * Raw materials * Packaging materials * Components. |
| Workplace information must include at least one of the following: | * relevant clauses of the GMP codes * signs and symbols * workplace instructions * production schedules, including cleaning schedules * approved workplace checklists * room data sheets (specifications) * purchase orders * picking lists and bills of materials * change notes * deviation reports * material and product specifications * standard forms and reports. |
| Prescribed data must include at least one of the following: | * status labels * identification labels. |
| Good Manufacturing Practice (GMP) must include: | * conformance to site-wide manufacturing quality systems for ensuring that products are consistently produced and controlled according to quality standards. |
| Workplace procedures must include at least one of the following: | * company quality policies, procedures, protocols and instructions * Master Processing Instructions * Master Packaging Instructions * reporting, housekeeping and environmental guidelines * safety and security policies, procedures and guidelines. |
| Equipment must include at least one of the following: | * weighing instruments * mixing vessels and associated components * bioreactors * fermenters * filling machines and associated components * ancillary equipment such as: * sieves * filters. |
| Materials must include at least one of the following: | * chemicals (raw materials) * intermediates * bulk product * packaging components: * vials * ampoules * bottles * printed material: * labels * cartons. |
| Services must include at least one of the following: | * power * water: * potable * purified * steam * compressed air * instrumentation air * vacuum. |
| Cleaning requirements must include at least one the following: | * line clearance * area clearance * partial clean * full clean * sanitation * sterilisation * automated * semi-automated * manual. |
| Equipment status must include at least one of the following: | * clean * ready to use * in use * calibrated. |
| Equipment settings must include at least one of the following: | * machine speed * mixing speed * pressure * chemical additive addition rates * time. |
| Pre-start checks must include at least one of the following: | * area and/or line clearances * area/rooms checks such as: * differential pressures * room status * environmental sampling * cleaning * sanitation. |
| Starting materials must include at least one of the following: | * liquids * powders. |
| Monitor must include at least one of the following: | * the use of Supervisory Control and Data Acquisition (SCADA) and process control systems * in process checks such as: * weights * pH * environmental monitoring * bioburden sampling * verification of checks performed by other operators. |
| Equipment operation must include at least one of the following: | * Operation of any equipment used in the dispensing manufacturing or packaging of pharmaceutical or biopharmaceuticals, including the use of automated equipment and process control systems. |
| Specifications must include: | * monitoring the acceptable range for each production process variable: * lower and upper limit for machine or mixing speed * anything falling outside of the acceptable range which may result in unacceptable product quality. |
| Workplace records must include at least one of the following: | * logs: * cleaning * equipment * event * batch records * cleaning records * event report. |
| Handover must include at least one of the following: | * in person * using recorded information: * records * reports * via notice boards. |
| Shutdown procedure must include at least one of the following: | * line clearances * environmental sampling * cleaning (in some cases cleaning might be carried out by a dedicated cleaning crew). |

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| Unit Mapping Information | | | |
| Code and title current version | Code and title previous version | Comments | Equivalence status |
| FDFPHM3XXX Participate in a pharmaceutical production environment | 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 FDFPHM3XXX Participate in a pharmaceutical production environment |
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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, on at least one occasion, the individual has cleaned and sanitised facilities and equipment, including:   * accessed workplace information to identify processing requirements * selected, fitted and used personal protective clothing and equipment * confirmed supply of necessary materials and services * handled and stored materials and products in a manner that prevents contamination and mix-ups * performed area or line clearances * conducted pre-start checks, such as: * inspecting equipment condition to identify any signs of wear * selecting appropriate settings and/or related parameters * confirming that equipment is clean and ready for use * ensuring any scheduled maintenance has been carried out * monitored and adjusted process equipment to achieve required outcomes, including monitoring control points and conducting inspections as required to confirm process remains within specification * monitored supply and flow of materials to and from the process * taken appropriate action in response to deviations, such as: * events out of trend * out of specification results * completed workplace records to maintain data integrity * performed yield and reconciliation calculations * maintained work area to meet housekeeping standards * used process control systems according to workplace procedures * collected samples and conducted tests according to workplace procedures. | |

| 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:   * purpose and basic principles of steps and unit operations in pharmaceutical manufacturing processes * typical processing equipment and utility systems, and how product quality and GMP compliance can be impacted by their attributes: * performance * functionality * construction * instrumentation * common GMP deviations and unusual events observed in pharmaceutical production environment, including: * missing or inaccurate records * failure to follow workplace procedures * product diverted from normal course of process * spills * out of limit situations such as; yields, reconciliations, in process controls and in process checks * damage to plant or equipment * signs of inadequate cleaning or pest infestation * common GMP non-conformances observed in pharmaceutical production environment, including: * failure of cleaning regime * damaged goods, such as; starting materials, components, intermediates and products * basic operating principles of equipment, such as: * main equipment components * status and purpose of guards * equipment operating capacities and applications * purpose and location of sensors and related feedback instrumentation * the flow of processes, including: * inputs and outputs of each step or unit operation * the effect of outputs on downstream processes * critical factors that impact product quality and the need for process control * terminology associated with control and validation of GMP processes, including: * lifecycle * Installation Qualification of equipment (IQ) * Operational Qualification of equipment (OQ) * Performance Qualification (PQ) * Product Vigilance (PV) * Critical Quality Attribute (CQA) * Certificate of a Pharmaceutical Product (CPP) * Quality Care Pharmacy Program (QCPP) * quality characteristics to be achieved by the process * quality requirements of materials and effect of variation on process performance * methods commonly used for establishing causal relationship between: * a process step * process parameters * product quality * GMP requirements for material handling, storage and preservation * GMP requirements for production and process controls, including: * identification and traceability * yields and reconciliation * segregation and storage * status labels (physical and electronic) * what validation is, and why it is legislated in the pharmaceutical industry * what requires validation and the current approaches used to qualify equipment and systems and to validate processes: * V-model * Lifecycle * hybrid approach * relationship between change control and validation and the GMP requirements for maintaining processes in a validated state * types of process automation typically encountered in the pharmaceutical industry and typical controls * intent and basic principles of GMP requirements when processes are automated or semi-automated * critical factors that affect the scale up processes, and their potential impact on product quality and the validated state * operating requirements, parameters and corrective action required where operation is outside specified operating parameters * typical equipment faults and failure modes, and related causes and potential effects on process control and product quality, including recognition of signs and symptoms of faulty equipment and early warning signs of potential problems * methods used to monitor the production process, such as inspecting, measuring and testing as required by the process * GMP requirements for record keeping and data integrity, including electronic data and information management systems * Inspection, test points or control points in the process and the related procedures and recording requirements * contamination and mix-up risks associated with the process and related control measures * common causes of variation * workplace health and safety (WHS) hazards and controls, including limitations of protective clothing and equipment relevant to the work process * requirements of different shutdowns as appropriate to the process and workplace production requirements, including emergency and routine shutdowns and procedures to follow in the event of a power outage * isolation, lock out and tag out procedures and responsibilities * procedures and responsibility for reporting production and performance information * environmental issues and controls relevant to the process, including waste and rework collection and handling procedures related to the process * basic operating principles of process control, where relevant, including the relationship between control panels and systems and the physical equipment * product or process changeover procedures and responsibilities * sampling and testing associated with process monitoring and control * cleaning, sanitation and routine maintenance procedures. |

| Assessment Conditions |
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| Assessment of skills must take place under the following conditions:   * physical conditions: * skills must be demonstrated in a commercial pharmaceutical or complementary medicine manufacturing workplace setting or an environment that accurately represents workplace conditions * resources, equipment and materials: * data collection forms and information recording systems * specifications: * GMP workplace procedures * Material handling and storage procedures * pre-start checks on production system components and related advice on equipment operation, including advice on safe work practices and environmental requirements * information relating to the operation, monitoring and typical adjustments of pharmaceutical and/or biopharmaceutical processes * information and documentation relating to handover * information relating to the regulatory and management of events or issues associated with production processes, relevant to work responsibilities * data collection and information recording system requirements and procedures * relationships: * team member(s)/supervisors or realistic scenarios or role plays * timeframes: * according to the job requirements.   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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