Modification history

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| Release | Comments |
| Release 1 | This version released with FBP Food, Beverage and Pharmaceuticals Training Package Version 2.00.. |

| FDFPHM3XXX | Operate an encapsulation process |
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| Application | This unit of competency describes the skills and knowledge required to set up, operate, adjust and shut down an encapsulation process.  The unit is applicable to individuals who are responsible for operating and monitoring an encapsulation process in a pharmaceutical manufacturing environment. They 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 |
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| Elements describe the essential outcomes. | Performance criteria describe the performance needed to demonstrate achievement of the element. |
| 1. Prepare encapsulation process for operation | 1.1 Confirm materials are available 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 workplace requirements |
| 2. Operate and monitor encapsulation process | 2.1 Start up and operate the encapsulation process according to workplace procedures  2.2 Monitor equipment to identify variations in operating conditions  2.3 Monitor process to confirm capsules meet specifications  2.4 Identify, rectify and report out-of-specification products or process outcomes to ensure process remains within specifications  2.5 Maintain work area according to workplace housekeeping standards  2.6 Conduct work according to environmental standards  2.7 Contain, remove and report spillages according to workplace procedures  2.8 Maintain workplace records in required format |
| 3. Shut down encapsulation process | 3.1 Complete end-of-batch procedures according to batch instructions and standard operating procedures (SOP)  3.2 Shut down encapsulation 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. | |
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| Skill | Description |
| Reading | * Read and interpret standard operating procedures for the encapsulation process |
| Writing | * Complete records according to workplace guidelines using paper based and/or electronic media |
| Numeracy | * Verify raw materials with batch instructions * Monitor flow rates and product quantity |
| 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. | |
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| 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 lock outs * confirming line clearance and cleaning status * confirming equipment is correctly configured for processing requirements * positioning sensors and controls correctly * ensuring scheduled maintenance has been carried out * confirming that all safety guards are n place and operational. |

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| Unit Mapping Information | | | |
| Code and title current version | Code and title previous version | Comments | Equivalence status |
| FDFPHM3XXX Operate an encapsulation process | FDFPH2010A Operate an encapsulation process | Updated to meet Standards for Training Packages. Code changed to reflect AQF alignment. | 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 Operate an encapsulation process |
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| 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 an encapsulation process, including:   * accessed workplace information to identify production requirements for the encapsulation process * selected, fitted and used personal protective clothing and equipment * confirmed supply of necessary materials and services to the encapsulation process * conducted all pre-start checks required to ensure safe start-up of the encapsulation process * verified raw materials with batch instructions * started, operated, monitored and adjusted encapsulation process equipment, including monitoring control points and conducting inspections to confirm process remains within specification including: * flow rates and quantity * product quality * taken corrective action in response to out-of-specification results * monitored supply and flow of materials to and from the encapsulation process * responded to or reported equipment failure according to workplace guidelines * located emergency stop functions on equipment * followed isolation and lock out and tag out procedures to take encapsulation 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 * collected samples and conducted tests as required in accordance with workplace procedures * conducted routine maintenance in accordance with workplace procedures * followed work health and safety 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:   * the purpose and basic principles of the encapsulation process * basic operating principles of equipment, including main equipment components, status and purpose of guards, equipment operating capacities and applications, and the purpose and location of sensors and related feedback instrumentation * services required and actions to take if they are unavailable * types of raw materials used in the encapsulation process and related handling and segregation requirements, including handling hazardous goods * stages and changes which occur during encapsulation * quality characteristics to be met by the encapsulation process * flow of the encapsulation process and the effect of outputs on downstream pharmaceutical processes * operating requirements, parameters and corrective actions required where operation is outside specified operating 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 the encapsulation process, including inspecting, measuring and testing * inspection or test points (control points) in the encapsulation process and related procedures and recording requirements * GMP requirements associated with the encapsulation 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 protective clothing and equipment relevant to the work process * end-of-batch procedures, including procedures for calculating yield and materials reconciliation * actions required if yield is not within 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 encapsulation process, including relevant waste collection and handling procedures * basic operating principles of process control, including the relationship between control panels and systems and physical equipment. |

| Assessment Conditions |
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| 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 * encapsulation process and related equipment and services * materials required for the encapsulation process * test equipment * cleaning materials and equipment associated with encapsulation 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 encapsulation 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. |

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