Modification history

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

| FDFPHM3XXX | Operate an aseptic fill and seal 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 aseptic fill and seal process. It involves an aseptic packaging process that takes place within a graded clean room environment.  The unit applies to individuals working in the pharmaceutical sector who apply basic operating principles to the operation and monitoring of an aseptic fill and seal process.  No occupational licensing, legislative or certification requirements apply to this unit at the time of publication. |
| Prerequisite Unit | FDFOP2032 Work in a clean room environment  FDFFS2001 Implement the food safety program and procedures  FBPPHM Implement good manufacturing practice requirements |
| 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 filling and sealing equipment and process for operation | 1.1 Confirm availability of materials, packaging components and consumables 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 operating parameters to meet safety and production requirements  1.6 Check and adjust equipment performance according to operating guidelines  1.7 Carry out pre-start checks according to workplace procedures |
| 2. Operate and monitor the filling and sealing process | 2.1 Start up and operate process according to workplace procedures  2.2 Monitor equipment to identify variation in operating conditions  2.4 Monitor packaging quality and seal integrity to confirm that specifications are met  2.5 Identify, rectify and report out-of-specification outcomes  2.6 Maintain work area according to housekeeping procedures  2.7 Contain, remove and report spillages according to standard operating procedures (SOP)  2.8 Conduct work according to workplace environmental guidelines  2.9 Maintain workplace records according to workplace reporting requirements |
| 3. Shut down filling and sealing process | 3.1 Complete end-of-batch procedures according to batch instructions and standard operating procedures (SOP)  3.2 Shut down process according to workplace procedures  3.3 Identify and report maintenance 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 aseptic fill and seal process |
| Writing | * Complete records and reports according to workplace reporting requirements using paper based and/or electronic media |
| Numeracy | * Confirm process remains within specifications for flow rates, temperature, fill levels, weights and volumes |
| 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 |
| 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 requirements 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 mask * surgical gloves * disposable overshoes * hair net. |
| pre-start checks must include: | * inspecting equipment to identify signs of wear * disinfecting and sterilising equipment and surfaces * selecting appropriate settings and/or related parameters * cancelling isolation or lock outs * confirming that equipment is clean and correctly configured * components or consumables are loaded * sensor and controls are positioned correctly * confirming scheduled maintenance has been performed * confirming all safety guards are in 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 aseptic fill and seal process | FDFPH2005A Operate an aseptic fill and seal 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 FDFPHM3XXX Operate an aseptic fill and seal 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 aseptic fill and seal process, including:   * accessed workplace information to identify aseptic fill and seal processing requirements * selected, fitted and used personal protective clothing and equipment, including gowning up * followed required work area entry and exit procedures and moved around the work area to minimise risk of contamination * confirmed supply of necessary packaging components and consumables and products * conducted pre-start checks to ensure safe operation of the aseptic fill and seal process * started, operated, monitored and adjusting filling and sealing process equipment to achieve required outcomes, including: * flow rates * weights and volumes * fill levels * temperature, including materials and sealing temperatures * supply of packaging components/consumables * packaging quality and seal integrity, and where required, testing packaging integrity * taken corrective action in response to out-of-specification results * monitored supply and flow of materials to and from process * responded to and reported equipment failure * located emergency stop functions on equipment * followed isolation and lock out procedures to take filling and sealing process and related equipment off-line in preparation for cleaning or maintenance, in accordance with level of responsibility * 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 housekeeping standards * used process control systems in accordance with workplace procedures * collected samples and conducted tests 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:   * purpose and basic principles of filling and sealing, including properties of packaging materials used, principles of heat sterilisation and its effect on microbiological characteristics of product and packaging materials, and filling process * aseptic container preparation, handling and loading * basic operating principles of aseptic filling and sealing 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 services required for operation of filling equipment used in the workplace * quality characteristics to be achieved by the filling and sealing process, including: * quality requirements of packaging components/consumables * sterilisation requirements and procedures * filling (fill levels and weights) * requirements of seal formation and integrity * where relevant, integrity testing procedures * flow of processes supplying the filling and sealing process and the effect of outputs on downstream processes * operating requirements and parameters and corrective actions taken 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 process, including inspecting, measuring and testing as required by the process * inspection or test points (control points) in the process and the related procedures and recording requirements * Good Manufacturing Practice (GMP) requirements associated with the liquid manufacturing process and related control measures * common causes of variations and corrective actions required, including the effect of variations in both product and packaging components or consumables on filling and sealing performance * product and packaging changeover procedures * work health and safety hazards and controls, including the limitations of protective clothing and equipment * end-of-batch procedures, including procedures for calculating yield, materials and reconciliation * actions required if yield or reconciliation is not within prescribed limits * product labelling responsibilities and procedures * requirements of different shutdowns, as appropriate to process and workplace production requirements, 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 responsibility for reporting production and performance information * environmental issues and controls relevant to the filling and sealing process, including waste or rework collection and handling procedures * basic operating principles of process control, including the relationship between control panels, 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 * aseptic filling and sealing process and related equipment and services * materials and packaging components and consumables * cleaning materials and equipment associated with aseptic fill and seal process * product * specifications: * work procedures, including advice on safe work practices, GMP requirements associated with liquid manufacturing process and related control measures, quality and environmental requirements, stock flow systems and production or packaging schedules * information on equipment capacity and operating parameters * production schedule/batch instructions * specifications, control points and processing parameters * documentation and recording requirements and procedures * cleaning procedures associated with aseptic fill and seal 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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