Modification history

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

| FBPPHM3009 | Operate an aseptic form, 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 form, fill and seal process within a graded clean room environment in a pharmaceutical manufacturing facility.  The unit applies to individuals who apply good manufacturing practice (GMP) requirements and operation principles to the aseptic form, fill and seal 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. Set up form, fill and seal process | 1.1 Identify production requirements from workplace documentation  1.2 Confirm materials, packaging components and consumables are available to meet batch and production requirements  1.3 Confirm required facilities and equipment are available  1.4 Source and fit cleanroom garments and personal protective clothing and equipment according to workplace gowning standard operating procedures (SOP)  1.5 Maintain sterile quality of the gown according to workplace gowning SOP  1.6 Fit and adjust machine components and attachments according to production requirements and equipment operation and maintenance manual  1.7 Enter processing and operating parameters according to safety and production requirements  1.8 Check and adjust equipment performance according to equipment operating procedures  1.9 Conduct pre-start checks according to workplace procedures |
| 2. Operate and monitor a form, fill and seal process | 2.1 Start up and monitor aseptic form, fill and seal process to confirm products are within required limits  2.2 Monitor packaging quality and seal integrity to confirm that specifications are met  2.3 Rectify, identify and report out-of-specification products or process outcomes to maintain process within specifications  2.4 Maintain work area according to workplace cleaning standards  2.5 Maintain consistent aseptic techniques  2.6 Conduct process and sampling according to safety requirements and environmental monitoring procedures  2.7 Contain, remove and report spillages according to SOP  2.8 Complete documentation according to workplace requirements |
| 3. Shut down a form, fill and seal process | 3.1 Confirm the workplace procedures for shutting down the process  3.2 Complete end-of-batch procedures according to batch instructions  3.3 Safely shut down the process  3.4 Clean sealing equipment according to workplace procedures  3.5 De-gown according to workplace gowning SOP  3.6 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, standard operating procedures and batch instructions and interpret requirements for the aseptic form, fill and seal process |
| Writing | * Complete workplace documentation using appropriate language and in required format |
| Numeracy | * Confirm process specifications for flow rates, temperature, fill levels, weights, volumes, pressure and wall thickness |
| Navigate the world of work | * Identify workplace requirements, including safety requirements and good manufacturing practice requirements, associated with own role |
| Interact with others | * Report operational and safety information to relevant personnel using required communication method |
| Get the work done | * 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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| Cleanroom garments and personal protective clothing and equipment must include: | * sterile gown * a variety of types and styles of controlled classified cleanroom garments, including disposable and reusable: * surgical or elastic gloves * face masks * hair nets or sterile hoods * beard/moustache covers as required * protective goggles or glasses * sterile disposable overshoes or clean room boots and shoe covers. |
| Pre-start checks must include at least seven of the following: | * inspecting equipment to condition identify signs of wear * disinfecting and sterilising equipment and surfaces * selecting appropriate settings and/or related parameters * checking for loss of sterility * filler testing * cancelling isolation or lock outs as required * identifying location of main steam valve isolation * checking code bar: * box details * expiry over printing or embossing * confirming that room and equipment is clean and correctly configured for processing requirements * components or consumables are loaded * positioning sensor and controls correctly * ensuring scheduled maintenance has been carried out * 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 |
| FBPPHM3009 Operate an aseptic form, fill and seal process | FDFPH2006A Operate an aseptic form, 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 Operate an aseptic form, 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 the individual has operated at least one aseptic form, fill and seal process, including:   * accessed workplace information to confirm production requirements for the aseptic form, fill and seal process * confirmed supply of necessary materials, packaging components and consumables for the aseptic form, fill and seal process * selected, fitted and used cleanroom garments and personal protective clothing and equipment including gowning and de-gowning * maintained the sterile quality of the gown after performance of gowning procedures and aseptic process by microbiological surface sampling of several locations on gown * followed required work area entry and exit procedures and moved around the work area in a manner that does not generate additional contaminants * conducted pre-start checks required for the safe operation of the aseptic form, fill and seal process, including seven of the following: * inspecting equipment to condition identify signs of wear * disinfecting and sterilising equipment and surfaces * selecting appropriate settings and/or related parameters * checking for loss of sterility * filler testing * cancelling isolation or lock outs as required * identifying location of main steam valve isolation * checking code bar; box details and expiry (over print or embossing) * confirming that room and equipment is clean and correctly configured for processing requirements * components or consumables are loaded * positioning sensor and controls correctly * ensuring scheduled maintenance has been carried out * started, operated, monitored and adjusted aseptic form, fill and seal process equipment to achieve required outcomes, including: * container formation and appearance * supply and flow of materials to and from process and pressure * flow rates * weights and volumes * fill levels * temperature, including materials and sealing temperatures * supply of packaging components and consumables * packaging quality and seal integrity * testing packaging integrity where required * checked control points and conducted inspections to confirm the process remains with specification, including: * process control testing * fill volume * product sampling * container sampling, including; weight variation, fill weight, leakers, air pressure, closure defects, wall thickness variation * taken corrective action in response to out-of-specification results * maintained consistent aseptic techniques * located emergency stop functions on equipment * followed isolation and lock out procedures to take aseptic form, fill and seal process and related equipment off-line in preparation for cleaning and maintenance * followed end-of-batch procedures, including: * line clearance and cleaning * loss of sterility * filler integrity testing * yield calculation * materials reconciliation * environmental monitoring * product labelling * actions required if yield or reconciliation is not within prescribed limits * 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 aseptic form, fill and seal process, including: * the purpose, methods and outcomes of each stage * control points * principles of filling and sealing, including properties of packaging materials used * the form process * principles of heat sterilisation * the effect of heat sterilisation on microbiological characteristics of product and packaging materials, and a filling process * flow of an aseptic form, fill and seal process and the effect of outputs on downstream processes * quality characteristics to be achieved by the aseptic form, fill and seal process, including: * quality requirements of packaging components and consumables * sterilisation requirements and procedures * fill volume by levels and weights * internal and external leakers * appearance, including; legibility of embossing, burnt polymer and streaking * requirements of seal formation and integrity * importance of maintaining sterile product * integrity testing procedures * aseptic container preparation and forming, filling and sealing requirements * basic operating principles, requirements and parameters of aseptic form, filling and sealing equipment, including: * main 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 taken where operation is outside specified operating parameters * common causes of out-of-specification product or process and corrective actions required, including the effect of variations in both product and packaging components or consumables on form, filling and sealing performance * functions and limitations of cleanroom garments and personal protective clothing and equipment, including: * sterile gowns * surgical or elastic gloves * face masks * hair nets or sterile hoods * beard/moustache covers * protective goggles or glasses * sterile disposable overshoes or clean room boots and shoe covers * gowning and de-gowning techniques * clean room behaviour and hygiene * aseptic technique * microbiology applicable to aseptic form, fill and seal process * pre-start checks requirements, including: * inspecting equipment to condition identify signs of wear * disinfecting and sterilising equipment and surfaces * selecting appropriate settings and/or related parameters * checking for loss of sterility * filler testing * cancelling isolation or lock outs as required * identifying location of main steam valve isolation * checking code bar; box details and expiry (over print or embossing) * confirming that room and equipment is clean and correctly configured for processing requirements * components or consumables are loaded * positioning sensor and controls correctly * ensuring scheduled maintenance has been carried out * confirming all safety guards are in place and operational * methods used to monitor an aseptic form, fill and seal process, including: * inspecting * measuring * testing * product, packaging and process changeover procedures and responsibilities * end-of-batch procedures, including: * line clearance and cleaning * loss of sterility * filler integrity testing * calculating yield * materials reconciliation * environmental monitoring * product labelling * actions required if yield or reconciliation is not within prescribed limits * requirements of different shutdowns, including: * emergency and routine shutdowns * procedures to follow in the event of a power outage * line clearance procedures, including cleaning and sanitation procedures * isolation, lock out and tag out procedures and responsibilities * operating principles of process control, including the relationship between control panels, systems and physical equipment * GMP requirements associated with aseptic form, fill and seal process and related control measures * environmental issues and controls relevant to the aseptic form, fill and seal process, including; * particle count specification * 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: * a pharmaceutical workplace or an environment that accurately represents workplace conditions * resources, equipment and materials: * cleanroom garments and personal protective clothing and equipment * aseptic form, fill and seal process equipment * materials, packaging components and consumables for an aseptic form, fill and seal process * microbiological surface sampling tools (touch plates) * microbiological growth medium for process simulation (media fill) * environmental monitoring equipment * cleaning materials and equipment associated with aseptic form, fill and seal process * specifications: * specifications, control points and processing parameters * recording requirements and procedures * workplace documentation relating to aseptic form, fill and seal process and procedures including gowning/de-gowning procedures * GMP requirements relating to aseptic form, fill and seal process * information on equipment capacity and operating parameters * production schedule/batch instructions * microbiological surface sampling limits for gown locations * cleaning and environmental monitoring procedures associated with aseptic form, fill and seal 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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