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 a terminal sterilisation process |
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| Application | This unit of competency describes the skills and knowledge required to set up, operate, adjust and shut down a terminal sterilisation process using an autoclave.  The unit applies to individuals who are responsible for applying basic operating principles to the operation and monitoring of an autoclave in a pharmaceutical manufacturing environment.  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 equipment and process for operation | 1.1 Confirm and prepare items for sterilisation  1.2 Prepare autoclave for operation  1.3 Use correctly fitted and appropriate personal protective clothing and equipment  1.4 Select operating parameters, to meet safety and terminal sterilisation requirements  1.5 Conduct pre-start checks according to workplace requirements  1.6 Load items according to with load pattern |
| 2. Operate autoclave to terminally sterilise items | 2.1 Start up and operate autoclave according to workplace procedures  2.2 Monitor time and temperature parameters to confirm fulfilment of specification requirements  2.3 Identify variations in equipment operation  2.4 Maintain workplace records according to workplace recording requirements  2.5 Conduct work according to workplace environmental guidelines |
| 3. Remove items and follow shut down procedures | 3.1 Remove items from autoclave  3.2 Shut down 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 terminal sterilisation process requirements |
| Writing | * Complete records according to workplace guidelines using paper based and/or electronic media |
| Numeracy | * Load items according to loading pattern |
| 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 confirm all water has drained * pulling a vacuum to remove air from autoclave * selecting appropriate settings to meet sterilisation requirements * cancelling isolation or lock outs * confirming that equipment is clean and operational * positioning sensors and controls correctly * ensuring all safety guards and signs 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 a terminal sterilisation process | FDFPH2014A Operate a terminal sterilisation 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 a terminal sterilisation 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 a terminal sterilisation process, including:   * accessed workplace information to identify sterilisation requirements * selected, fitted and used personal protective clothing and equipment * confirmed supply of necessary materials and services * prepared items by wrapping and marking with temperature-sensitive tape or material and ensured clothing is folded correctly * loaded items in accordance with loading pattern * conducted all pre-start checks on the autoclave that are required for safe operation * started, operated and monitored the autoclave to confirm that required outcomes are achieved, including monitoring time, temperature and pressure gauges * identified out-of-specification results and taken appropriate corrective action within level of responsibility * followed procedures to open autoclave and remove items from autoclave to maintain sterility and personal safety * responded to and reported equipment failure in accordance with workplace procedures * located emergency stop functions on equipment * followed isolation, lock out and tag out procedures, to take the process off-line in preparation for cleaning or maintenance * completed workplace records in required format * maintained work area in accordance with workplace housekeeping standards * used process control systems in accordance with workplace procedures * collected samples and conducted tests 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:   * purpose and basic principles of terminal sterilisation, including principles of heat transfer, properties of saturated steam, and the relationship between time, temperature and pressure as they affect the kill rate * the nature of items to be sterilised using an autoclave and related preparation requirements, including handling and preparation requirements for porous and non-porous loads * the nature of wrapping materials suitable for use, methods used to wrap items, methods used to monitor whether time and temperature parameters are met (typically heat-sensitive tape or markers), and the significance of loading patterns in achieving effective sterilisation * basic operating principles of equipment including main equipment components, status and purpose of guards, equipment operating capacities and applications, the purpose and location of sensors and related feedback instrumentation, and where relevant, the calibration schedule and procedures to confirm that instruments are within calibration * services required and actions to take if they are unavailable * time and temperature parameters required to achieve terminal sterilisation and corrective actions required where operation falls outside specified 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 sterilisation process, including inspecting, measuring and testing * inspection or test points (control points) and related procedures and recording requirements * possible causes of variation in outcomes and corrective actions * work health and safety hazards related to autoclave operation and associated control measures, including working with superheated steam and hot surfaces, manual handling and steam leaks * purpose and limitations of personal protective equipment * emergency and routine shutdown procedures and procedures to follow in the event of a power outage * isolation, lock out and tag out procedures and responsibilities * procedures and responsibilities for recording and reporting information on autoclave performance * environmental issues and controls including waste collection, rework collection and handling procedures * basic operating principles of process control, including the relationship between control panels and systems and physical equipment * cleaning and sanitation procedures. |

| 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 * autoclave equipment and services * wrapping materials and tape/heat sensitive markers * materials handling equipment * test equipment * cleaning materials and equipment associated with terminal sterilisation process * specifications: * work procedures, including advice on safe work practices, GMP, quality and environmental requirements * information on equipment capacity and operating parameters * sterilisation schedule and instructions * specifications, control points and processing parameters * sampling schedules and test procedures * documentation and recording requirements and procedures * cleaning procedures associated with terminal sterilisation 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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