Modification history

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| Release | Comments |
| Release 1 | This version released with FBP Food, Beverage and Pharmaceutical Training Package Version 3.0. |

| FBPPHM30XX | Operate a sterilisation process using an autoclave |
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| Application | This unit of competency describes the skills and knowledge required to set up, operate, adjust and shut down a sterilisation process using an autoclave.  The unit applies to individuals who apply Good Manufacturing Practice (GMP) and operating principles to the terminal sterilisation of product and sterilisation of goods for aseptic processing using an autoclave. Individuals work 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. Prepare and initiate operation of equipment | 1.1 Confirm autoclave is operational and the sterilisation load is available  1.2 Prepare the sterilisation load according to standard operating procedure  1.3 Load autoclave and position temperature load probe according to load pattern requirements detailed in the standard operating procedure  1.4 Run pre start leak test cycle and select the correct sterilisation cycle as per the standard operating procedure  1.5 Initiate the autoclave cycle |
| 2. Review autoclave printout at end of cycle | 2.1 Review the autoclave cycle printout or electronic report and confirm correct cycle was run with no faults or alarms detected.  2.2 Complete documentation according to standard operating procedures |
| 3. Remove items and follow shut down procedures | 3.1 Confirm the autoclave cycle is complete and autoclave is safe to open as per standard operating procedures  3.2 Remove items from autoclave and check contents as per standard operating procedure  3.3 Check chemical indication has been activated and confirm items are dry and sterilised  3. Complete records according to standard operating 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 and interpret requirements for the sterilisation process |
| Writing | * Complete workplace documentation using appropriate language and in required format |
| Numeracy | * Confirm number of items according to loading pattern * Interpret time and temperature specifications for cycle parameters * Confirm post cycle results meet sterilisation requirements |

| 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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| Pre-start checks must include: | * carrying out required area or line clearances * inspecting equipment condition to identify signs of wear * confirming all safety equipment is in place and operational * confirming that equipment is clean or sanitised * confirming that equipment is correctly configured for processing requirements. |

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| Unit Mapping Information | | | |
| Code and title current version | Code and title previous version | Comments | Equivalence status |
| FBPPHM30XX Operate a sterilisation process using an autoclave | FBPPHM3016 Operate a sterilisation process using an autoclave | Major changes to Performance Criteria  Foundation skills amended  Performance Evidence revised  Knowledge Evidence clarified  Assessment Conditions clarified | Not equivalent |

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| Links | Companion Volumes, including Implementation Guides, are available at VETNet https://vetnet.gov.au/Pages/TrainingDocs.aspx?q=78b15323-cd38-483e-aad7-1159b570a5c4 |

| TITLE | Assessment requirements for FBPPHM30XX Operate a sterilisation process using an autoclave |
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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 sterilisation process using an autoclave, including:   * accessed standard operating procedure information to confirm sterilisation requirements * confirmed supply of product or materials are available for the sterilisation process * prepared items by stacking the autoclave dolly with product for terminal sterilisation or wrapping, taping, or sealing in an autoclave bag product for aseptic processing * ensure marking with temperature-sensitive tape or chemical indicators are located on the bags * positioned any moveable load probe and loaded items in correct orientation according to standard operating procedures and validated load pattern requirements * conducted pre-start checks required for safe operation of the autoclave, including: * carrying out required area or line clearances * inspecting equipment condition to identify signs of wear * confirming all safety equipment is in place and operational * confirming that equipment is clean or sanitised * confirming all pre-start cycles have been run, including a leak test * confirming that equipment is correctly configured for processing requirements * selecting the correct sterilisation cycle as per the standard operating procedures * reviewing the cycle print out to confirm the cycle was completed satisfactorily with no alarms or faults * taken corrective action in response to a non-conformance * opened autoclave and removed items from autoclave according to workplace procedures * safely shut down the process according to workplace procedures * cleaned and maintained work area to meet workplace cleaning standards and environmental requirements * completed records according to standard operating 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 requirements for autoclaving for microbial reduction/sterility * stages of the sterilisation process, including: * principles of heat transfer * properties of saturated steam * the relationship between time, temperature and pressure as they affect the kill rate * variables that impact the effectiveness of sterilisation * the nature of items to be sterilised using an autoclave, the different cycle types used and related handling and preparation requirements, including: * porous loads * non-porous loads * position of probes * the nature of wrapping materials suitable for use, including: * methods used to wrap or bag items * methods used to monitor whether time and temperature parameters are met (including heat-sensitive tape or markers) * the significance of validated loading patterns in achieving effective sterilisation * basic operating principles of equipment, requirements and parameters of autoclave, including: * main equipment components including filters, vacuum pumps, condensers and the autoclave chamber * service requirements for a GMP autoclave including compressed air, electricity, town water, steam supply and cooling water * time and temperature parameters required to achieve 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 * status and purpose of guards * equipment operating capacities and applications * purpose and location of sensors and related feedback instrumentation * corrective actions required where operation is outside of specified parameters * calibration schedule and procedures to confirm that instruments are within calibration * 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 * pre-start checks requirements, including: * carrying out required area or line clearances * inspecting equipment condition to identify signs of wear * confirming all safety equipment is in place and operational * confirming that equipment is clean or sanitised * confirming that equipment is correctly configured for processing requirements * evaluation and in-process monitoring of sterilisation process indicators, including: * biological * chemical * physical * methods used to monitor the sterilisation process, including: * inspecting * measuring * testing * requirements of different shutdowns, including: * emergency and routine shutdowns * procedures to follow in the event of a power outage * isolation, lock out and tag out procedures and responsibilities * operating principles of process control * Good Manufacturing Practice (GMP) requirements associated with a sterilisation process and related control measures * environmental issues and controls relevant to the sterilisation process including 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 workplace or an environment that accurately represents workplace conditions * resources, equipment and materials: * autoclave and handling equipment * loading in bags or wrapping materials and tape/heat sensitive markers * materials for sterilisation * test equipment * cleaning materials and equipment associated with sterilisation process * record keeping system * specifications: * sterilisation specifications, control points and processing parameters * recording requirements and procedures * workplace documentation relating to sterilisation process and procedures that comply with GMP and Good Documentation Practice (GDP) requirements * load pattern requirements * sampling schedules and test procedures * cleaning procedures associated with sterilisation 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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