Modification history

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| Release | Comments |
| Release 1 | This version released with FBP Food, Beverage and Pharmaceutical Training Package Version 2.0 and meets the Standards for Training Packages 2012. |

| FBPPHM3004 | Clean and sanitise facilities and equipment |
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| Application | This unit of competency describes the skills and knowledge required to plan, prepare, clean and sanitise processing facilities and equipment in a pharmaceutical manufacturing facility.  The unit applies to individuals who apply good manufacturing practice (GMP) requirements and operating principles to the cleaning and sanitising of facilities and equipment 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. Plan and prepare to clean pharmaceutical processing areas and equipment | 1.1 Obtain cleaning task requirements, including job specifications and workplace procedures for sampling and testing cleaning outcomes  1.2 Identify surfaces and soil and dirt types, and select cleaning techniques  1.3 Select and prepare cleaning chemicals required for task  1.4 Select and check cleaning equipment and consumables for serviceability and compliance with cleaning and sanitation requirements of Good Manufacturing Practice (GMP) cleaning program  1.5 Rectify or report faults before starting work  1.5 Confirm services are available and ready for operation  1.6 Source and fit personal protective equipment (PPE) according to work health and safety requirements  1.7 Obtain cleaning consumables to meet anticipated usage patterns  1.8 Select and install signs and barricades according workplace procedures  1.9 Set the plant for cleaning cycle if automated or initiate a manual clean |
| 2. Remove waste | 2.1 Collect and dispose of waste according to workplace procedures and legislative, environmental, and work health and safety requirements  2.2 Clean and sanitise rubbish bins according to workplace procedures, and insert new replacement bin liners |
| 3. Clean and sanitise pharmaceutical processing surfaces | 3.1 Change status label of area and equipment and check status prior to cleaning  3.2 Remove loose dirt and debris from pharmaceutical processing surfaces prior to applying cleaning treatment  3.3 Follow cleaning steps according to workplace procedures  3.4 Apply cleaning chemicals to pharmaceutical surfaces according to manufacturer specifications and workplace procedures  3.5 Thoroughly rinse and dry surfaces according to workplace procedures  3.6 Apply chemical disinfectants and sanitisers to surfaces according to workplace procedures  3.7 Report practices inconsistent with GMP according to workplace procedures |
| 4. Clean and sanitise pharmaceutical processing equipment | 4.1 Clean and sanitise processing equipment according to GMP requirements and workplace procedures  4.2 Monitor the cleaning process according to workplace procedures  4.3 Identify and report deviations from requirements  4.4 Inspect and confirm equipment cleanliness status, identify and take appropriate action to rectify non-conformance to acceptance criteria  4.5 Confirm relevant sampling/test methods including sampling/test points, types of samples and measurements requirements  4.6 Take, collect, store and transport samples according to sampling plan, relevant methods and/or standards  4.7 Return equipment to operating order  4.8 Record and certify data and information relating to equipment cleaning and sanitising, including cleaning status, sampling and testing according to workplace procedures to meet GMP requirements |
| 5. Return plant to operating condition | 5.1 Remove signs and barricades according to workplace procedures and work health and safety  5.2 Clean, check and store cleaning equipment and PPE according to manufacturer specifications, environmental and work health and safety requirements  5.3 Store and dispose of unused chemicals according to manufacturer specifications, and work health and safety requirements  5.4 Order and replenish cleaning consumables  5.5 Document tasks completed 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 and follow signs, symbols, checklists, production schedules, cleaning schedules and other technical information relevant to cleaning and sanitising facilities and equipment * Identify and follow workplace information, specifications and safety data sheets (SDS) * Identify and interpret Good Manufacturing Practice codes relevant to cleaning and sanitising facilities and equipment |
| Writing | * Complete checklists, standard forms and reports relating to practices inconsistent with Good Manufacturing Practice |
| Oral communication | * Use clear language to report contamination risks and practices inconsistent with Good Manufacturing Practice * Participate in verbal exchanges to respond to questions and clarify information |
| Numeracy | * Interpret measurements and numerical symbols in safety data sheets (SDS) * Record data and information using mathematical symbols and conventions |
| Navigate the world of work | * Recognise and follow workplace requirements, including safety requirements and Good Manufacturing Practice, associated with own role and area of responsibility |

| 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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| Cleaning equipment and consumables must include at least one of the following: | * Clean In Place spray balls * Bottle brushes * disinfecting solutions * non-shedding wipes. |
| Services must include at least two of the following: | * electricity * potable water * purified water * steam * compressed and instrumentation air * vacuum. |
| Personal Protective Equipment (PPE) must include the following: | * one of the following: * protective gown * scrubs * smocks * statcoats * cleanroom coveralls * disposable coveralls * all of the following: * disposable overshoes or cleanroom boots * hair net * goggles or safety glasses. |
| Waste must include at least three of the following: | * cleaning material or product waste * biological waste * sharps * general processing and laboratory waste. |
| Chemical disinfectants and sanitisers must include at least one of the following: | * alcohol * aldehydes * hypochlorites * iodophors * quaternary ammonium compounds * acid-anionic surfactants * fogging agents * fumigants such as gases or hydrogen peroxide vapour. |
| Processing equipment must include at least one of the following: | * liquid mixing vessels and their component parts, such as: * blades * mixing shafts * impellors * solid blenders and their component parts, such as: * ribbon blenders * intensifiers * driers, including: * fluid bed driers * oven driers * freeze driers * bag filters * intermediate bulks container * ancillary equipment such as sampling tools. |
| Monitor the cleaning process must include at least one the following: | * chemical strength * cycle time(s) * temperature * contact time * rinse water quality. |
| Sampling/test methods must include at least one of the following: | * visual inspection * pH tests of final rinse water * swabbing of surfaces for presence of contamination. |

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| Unit Mapping Information | | | |
| Code and title current version | Code and title previous version | Comments | Equivalence status |
| FBPPHM3004 Clean and sanitise facilities and equipment | Not applicable | New unit | No 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 FBPPHM3004 Clean and sanitise facilities and equipment |
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| Performance Evidence | |
| An individual demonstrating competency must satisfy all of the elements and performance criteria in this unit.  There must be evidence that, the individual has cleaned and sanitised facility surfaces and equipment of at least one manufacturing environment, including:   * accessed workplace information, such as the cleaning schedule to identify cleaning requirements * read and interpreted workplace procedures applicable to cleaning operations, including pictorial and written signs/instructions * identified soil types present in the following work surfaces, and selected cleaning equipment and agents required to clean the surfaces: * floors * walls * ceilings * benches * outer surfaces of equipment * door handles and door frames * light switches * lockers * vents * grills * pass-through cabinets * replenished different types of consumables used in cleaning processes * selected and prepared cleaners and sanitisers as required according to workplace procedures * selected, fitted and used personal protective equipment (PPE) as required by work tasks * applied correct cleaning and sanitising procedures to a range of equipment and surfaces commonly encountered in pharmaceutical manufacturing sites * identified and controlled hazards and risks, including contamination hazards encountered in pharmaceutical manufacturing environments * taken samples and conducted tests according to workplace procedures * confirmed supply of necessary cleaning and sanitising equipment and services * prepared equipment for cleaning according to manufacturer instructions, including: * rendered equipment safe to clean * cleared product and waste materials * covered motors and instrumentation where steam or water hoses are used * dismantled and reassembled equipment parts for cleaning according to operation and maintenance manual * inspected equipment to identify equipment condition and cleanliness * stored cleaners, sanitisers and related equipment according to workplace 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:   * responsibilities of cleaning staff and procedures for cleaning teams * common types of microbiological, physical and chemical contaminants in pharmaceutical processing facilities * the GMP requirements and role of cleaning and sanitising in preventing contamination of materials and products, and in the protection of personnel including, maintenance personnel and other external contractors * risks associated with cleaning and sanitising operations and cross contamination prevention * personal hygiene, clothing and footwear requirements, clothing storage and disposal for working in and moving between work areas * terminology relating to chemical cleaning and decontamination, including: * cleaners * disinfectants * sanitisers * sterilants * fogging * fumigation * types of cleaning equipment suitable for use in a pharmaceutical processing environment, including their use and storage, types of cleaning equipment include: * Clean in place (CIP) spray balls * Bottle brushes * disinfecting solutions * non-shedding wipes * hygienic vs unhygienic design features of facilities and equipment, including inserts and dead legs * different cleaning methods: * CIP methods * Clean-Out-of Place (COP) methods * manual cleaning * the difference between: * cleaning * disinfecting * sanitising * sterilising * different levels of cleaning requirements depending on the reason for cleaning, and whether equipment is dedicated or shared * the influence of the time between manufacture and cleaning (dirty hold time), and the time between cleaning and use (clean hold time) on a cleaning process * acceptance criteria used to evaluate cleaning quality, including: * how cleaning is measured * commonly used sampling and testing * purpose of keeping records and the recording requirements of GMP, including the legal significance of certifying and verifying GMP records * advantages and disadvantage of automated and semi-automated CIP systems * the different types and properties of cleaning and sanitising agents * considerations when choosing and using cleaning chemicals including: * the correct selection of chemicals for the surface being cleaned * the chemical and physical properties of the soils or residues to be removed * the interactions between cleaning chemicals and the surfaces they may adhere to * the solubility of the soil/residue in the cleaning solution * the need to rotate sanitisers * the frequency of cleaning and sanitising * manual, semi-automated and fully automated cleaning methods * purpose and basic principles of CIP, including the use and functions of caustic and acid solutions, and cleaning sequence and stages * the variable factors that influence cleaning effectiveness and performance * critical parameters in a cleaning and sanitising process including: * time * temperature * concentration * GMP requirements for the validation of cleaning processes * procedures for responding to out-of-limits or unacceptable performance or outcomes * waste collection, recycling and handling procedures relevant to own work responsibilities * common practices inconsistent with GMP found in cleaning and sanitising operations, including: * damage to plant or equipment * failure of cleaning regime * signs of pest infestation * missing or inaccurate records * failure to follow workplace procedures. |

| Assessment Conditions |
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| Assessment of skills must take place under the following conditions:   * physical conditions: * skills must be demonstrated in a commercial pharmaceutical or complementary medicine manufacturing workplace setting or an environment that accurately represents workplace conditions * resources, equipment and materials: * personal protective clothing and equipment * equipment and surfaces to be cleaned * chemicals and/or automated chemical addition system services * data collection forms and information recording systems * specifications: * Australian Code of Good Manufacturing Practice * GMP workplace procedures * cleaning procedures and related advice on equipment operation, including advice on safe work practices and environmental requirements * safety data sheets * cleaning schedule and related standard operating procedures * advice on environmental management issues relevant to work responsibilities * data collection and information recording requirements and procedures * relationships: * team members/supervisors * timeframes: * according to the job requirements.   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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