Modification history

|  |  |
| --- | --- |
| 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. |

| FDFPHM3XXX | Clean and sanitise facilities and equipment |
| --- | --- |
| 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 environment.  The unit applies to individuals who work in pharmaceutical manufacturing facilities of different sizes, producing various pharmaceutical products under broad direction and taking 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 |
| --- | --- |
| 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 Access, interpret and apply to planning workplace information applicable to the area and equipment, including sampling and testing  1.2 Identify by observation surfaces and soil and dirt types, and cleaning techniques  1.3 Select and prepare cleaning chemicals required for task  1.4 Select and check cleaning equipment for serviceability and compliance with cleaning and sanitation requirements of Good Manufacturing Practice (GMP) cleaning program, and 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 workplace health and safety requirements  1.7 Obtain cleaning consumables to meet anticipated usage patterns  1.8 Select and install signs and barricades according workplace information  1.9 Set the plant for cleaning cycle |
| 2. Remove waste | 2.1 Collect and dispose of waste according to workplace information and legislative, environmental, and workplace health and safety requirements  2.2 Clean and sanitise rubbish bins according to workplace information, and insert new replacement bin liners |
| 3. Clean and sanitise pharmaceutical processing surfaces | 3.1 Conduct physical movement in pharmaceutical processing according to GMP and workplace information  3.2 Remove loose dirt and debris from pharmaceutical processing surfaces prior to applying cleaning treatment  3.3 Follow cleaning steps according to workplace information  3.4 Apply cleaning chemicals to pharmaceutical surfaces according to manufacturer specifications and workplace information  3.5 Thoroughly rinse and dry surfaces according to workplace information  3.6 Apply chemical disinfectants and sanitisers to surfaces according to workplace information  3.7 Report practices inconsistent with GMP according to workplace information |
| 4. Clean and sanitise pharmaceutical processing equipment | 4.1 Clean and sanitise processing equipment according to GMP requirements and workplace information  4.2 Monitor the cleaning process according to workplace information  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 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 information to meet GMP requirements |
| 5. Return plant to operating condition | 5.1 Remove signs and barricades according to workplace information and workplace health and safety  5.2 Clean, check and store cleaning equipment and PPE according to manufacturer specifications, environmental and workplace health and safety requirements  5.3 Store and dispose of unused chemicals according to manufacturer specifications, and workplace health and safety 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. | |
| --- | --- |
| 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 material safety data sheets (MSDS) * 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 specifications and material safety data sheets (MSDS) * Record data and information |
| 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. | |
| --- | --- |
| Workplace information must include at least one of the following: | * company quality policies, procedures, protocols and instructions * safety and security policies, procedures and guidelines * specifications and material safety data sheets (MSDS) * signs and symbols * workplace procedures, instructions and protocols * production cleaning schedules * approved workplace checklists standard forms. |
| Surfaces must include: | * floors * benches * outer surfaces of equipment * door handles and door frames * light switches * lockers * vents * grills * pass-through cabinets. |
| Soil and dirt types must include at least one of the following: | * physical (dust and fiber) particulates from equipment, environment or personnel * chemicals from other products or ingredients, including decomposition products and preservatives * microbial contamination from: * materials * equipment * environment * personnel * difficult to remove residues including cleaning chemicals, and biological residues such as: * proteins * lipids * simple and complex sugars * salts * heat denatured residues. |
| Cleaning chemicals must include at least one of the following: | * alkaline, neutral or acidic cleaners * aerosol, gel, liquid, powder or tablet forms * cleansers * strippers * degreasers * detergents * abrasives * emulsifiers and suspending agents * ready-to-use or concentrates * wetting agents. |
| Cleaning equipment must include at least one of the following: | * mops, including cleanroom mops * buckets, including cleanroom mop bucket and wringer * vacuum cleaners. |
| Good Manufacturing Practice (GMP) must include: | * conformance to site-wide manufacturing quality systems for ensuring that products are consistently produced and controlled according to quality standards. |
| Services must include at least one of the following: | * power * water: * potable * purified * steam * compressed and instrumentation air * vacuum. |
| Personal Protective Equipment (PPE) must include the following: | * protective gown, scrubs, smocks, statcoats, cleanroom coveralls or disposable coveralls * surgical masks * surgical gloves * disposable overshoes * hair net * cleanroom undergarments * cleanroom boots * goggles. |
| Cleaning consumables must include at least one of the following: | * cleaning solutions * disinfecting solutions * wipes, including cleanroom wipes. |
| Cleaning cycle must include at least one of the following: | * equipment shutdown and/or taken off line for cleaning * equipment and related valves and pipework are configured to confirm readiness for cleaning * pre-rinsing * cleaning * rinsing * sanitation * drying. |
| Waste must include at least one of the following: | * biological waste * sharps * chemicals * general processing and laboratory wastes such as: * paper * glassware * consumables. |
| Cleaning steps must include at least one of the following: | * cleaning of all work surfaces in a controlled environment * vacuuming (where allowed) of the floors and work surfaces * emptying of appropriate trash and waste * cleaning of the doors, door frames and lockers in pre-staging and gowning areas * mopping gowning and cleanroom floors * changing tacky mats. |
| 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 the following: | * chemical strength * cycle time(s) * temperature * time * storage tank levels * rinse water quality. |
| Sampling/test methods must include at least one of the following: | * visual checks * pH tests of final rinse water * swabbing of surfaces for presence of contamination. |
| Data and information must include at least one of the following: | * cleaning status cards * cleaning logs * cleaning records * incident reports. |

|  |  |  |  |
| --- | --- | --- | --- |
| Unit Mapping Information | | | |
| Code and title current version | Code and title previous version | Comments | Equivalence status |
| FDFPHM3XXX Clean and sanitise facilities and equipment | Not applicable | New unit | No equivalent unit |

|  |  |
| --- | --- |
| 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 Clean and sanitise facilities and equipment |
| --- | --- |
| Performance Evidence | |
| An individual demonstrating competency must satisfy all of the elements and performance criteria in this unit.  There must be evidence that, on at least one occasion, the individual has cleaned and sanitised facilities and equipment, including:   * accessed workplace information, such as the cleaning schedule to identify cleaning requirements * read and interpreted relevant instructions and labels applicable to cleaning operations, including pictorial and written signs/instructions * identified type of surfaces and soil typically present in the work area selected cleaning equipment required for the task * replenished different types of consumables used in cleaning processes * selected and prepared cleaners and sanitisers as required according to typical workplace procedures * selected, fitted and used personal protective equipment (PPE) as required by work tasks * applied correct cleaning procedures to a range of surfaces (facilities) commonly encountered in pharmaceutical manufacturing sites * applied correct cleaning and sanitising procedures to a range of equipment commonly encountered in pharmaceutical manufacturing sites * identified and controlled hazards, including contamination hazards, typically encountered in pharmaceutical manufacturing environments before commencing cleaning, and taken steps to prevent identified hazards * carried out typical cleaning checks and inspections * taken samples and conducted tests according to typical workplace procedures * completed forms and incident reports according to GMP and workplace rules * maintained housekeeping standards to meet GMP requirements * confirmed supply of necessary cleaning and sanitising equipment and services * prepared equipment for cleaning, such as: * rendered equipment safe to clean * cleared product and waste materials * covered motors and instrumentation where steam or water hoses are used * simple dismantle of equipment parts * returned equipment to operating order (this may involve basic assembly of equipment parts) * inspected equipment to identify equipment condition and cleanliness * stored cleaners, sanitisers and related equipment. | |

| Knowledge Evidence |
| --- |
| 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 importance of maintaining a tidy facility and how good housekeeping practices contribute to a safe and efficient workplace * housekeeping requirements and responsibilities relating to own work * responsibilities of general cleaning staff and how to work with a cleaning team * common types of microbiological, physical and chemical contaminants relevant to the work process * the 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 * the GMP requirements for cleaning and sanitation of pharmaceutical processing facilities and equipment * risks associated with cleaning and sanitising operations * personal hygiene, and the clothing and footwear requirements for working in and moving between work areas * personal clothing use, storage and disposal requirements * use and storage of housekeeping cleaning equipment * terminology relating to chemical cleaning and decontamination, including: * cleaners * disinfectants * sanitisers * sterilants * fogging * fumigation * the different types of cleaning equipment suitable for use in a pharmaceutical processing environment * hygienic vs unhygienic design features of facilities and equipment, including inserts and dead legs * different cleaning methods: * Clean-In-Place (CIP) methods * Clean-Out-of Place (COP) * 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 the cleaning process * acceptance criteria determining what is clean, and how cleaning is measured, including 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 * points to consider when choosing and using cleaning chemicals including: * 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, and * 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 the 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 observed 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 |
| --- |
| 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: * equipment to be cleaned * chemicals and/or automated chemical addition system services * personal protective clothing and equipment * 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 * material safety data sheets * cleaning schedule and related standard operating procedures * housekeeping standards and procedures * advice on environmental management issues relevant to work responsibilities * data collection and information recording requirements and procedures * relationships: * team member(s)/supervisors or realistic scenarios or role plays * 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. |

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