



Australian Government

FBPPHM3004 Clean and sanitise facilities and equipment

Release: 1

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Modification History

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

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. 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.

Pre-requisite Unit

Nil

Unit Sector

Pharmaceutical (PHM)

Elements and Performance Criteria

Elements	Performance Criteria
<i>Elements describe the essential outcomes.</i>	<i>Performance criteria describe the performance needed to demonstrate achievement of the element.</i>
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 appropriate cleaning techniques 1.3 Select and prepare cleaning chemicals required for job 1.4 Select and check cleaning equipment and consumables for serviceability and compliance with cleaning and sanitation

Elements	Performance Criteria
<i>Elements describe the essential outcomes.</i>	<i>Performance criteria describe the performance needed to demonstrate achievement of the element.</i>
	requirements of GMP cleaning program 1.5 Rectify or report faults before starting work 1.6 Confirm services are available and ready for operation 1.7 Source and fit personal protective equipment (PPE) according to procedures for health and safety in the workplace 1.8 Obtain cleaning consumables to meet anticipated usage patterns 1.9 Select and install signs and barricades according workplace procedures 1.10 Set the plant for automated cleaning cycle or initiate a manual clean
2. Remove waste	2.1 Collect and dispose of waste according to procedures and legislative requirements for the environment and health and safety in the workplace 2.2 Clean and sanitise rubbish bins and insert new replacement bin liners according to workplace procedures
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 manufacturers' 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 and identify and report deviations from job specifications according to workplace procedures 4.3 Inspect and confirm equipment cleanliness status against acceptance criteria and take appropriate action to rectify

Elements	Performance Criteria
<i>Elements describe the essential outcomes.</i>	<i>Performance criteria describe the performance needed to demonstrate achievement of the element.</i>
	non-conformances 4.4 Confirm relevant sampling or testing methods including sampling or testing points, types of samples and measurements requirements 4.5 Take, collect, store and transport samples according to sampling plan, relevant methods and standards 4.6 Return equipment to operating order 4.7 Record and certify data and information about equipment cleaning and sanitising, including cleaning status, sampling and testing according to workplace procedures and 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 manufacturers' specifications, environmental and workplace health and safety requirements 5.3 Store and dispose of unused chemicals according to manufacturers' specifications, and workplace 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.

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 GMP information relevant to cleaning and sanitising facilities and equipment
Writing	Complete checklists, standard forms and reports relating to practices inconsistent with GMP

Skill	Description
Oral communication	• Use clear language to report contamination risks and practices inconsistent with GMP • Participate in verbal exchanges to respond to questions and clarify information
Numeracy	• Interpret measurements and numerical symbols in SDSs • Record data and information using mathematical symbols and conventions
Navigate the world of work	• Recognise and follow workplace requirements, including safety requirements and GMP, 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.

PPE must include:	• one of the following: • protective gown • scrubs • smock • statcoat • cleanroom coverall • disposable coverall • plus all of the following: • disposable overshoes or cleanroom boots • hair net • goggles or safety glasses.
Waste must include:	• cleaning material or product waste • hazardous waste • general processing and laboratory waste.
Monitoring of the cleaning process must include:	• chemical strength • cycle time(s) • temperature • contact time • rinse water quality.
Sampling or testing	• visual inspection • pH tests of final rinse water

methods must include:	• swabbing of equipment 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

Links

Companion Volume Implementation Guides are found in VETNet: -

<https://vetnet.gov.au/Pages/TrainingDocs.aspx?q=78b15323-cd38-483e-aad7-1159b570a5c4>

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 cleaning schedules or other workplace information to identify cleaning requirements
- 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
 - vents
 - grills
 - pass-through cabinets
- identified hazards and controlled risks, including contamination hazards encountered in pharmaceutical manufacturing environments
- confirmed supply of necessary cleaning and sanitising equipment and services
- replenished different types of consumables used in cleaning processes^[1]_{SEP}
- selected and prepared cleaners and sanitisers according to workplace procedures
- selected, fitted and used personal protective equipment (PPE) required for tasks
- prepared equipment for cleaning according to manufacturers' 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
- applied correct cleaning and sanitising procedures to equipment and surfaces
- taken samples and conducted tests according to workplace procedures
- inspected equipment to identify equipment condition and cleanliness
- stored cleaners, sanitisers and related equipment according to workplace procedures.

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:

- responsibilities of cleaning staff and procedures for cleaning teams
- common types of microbiological, physical and chemical contaminants in pharmaceutical processing facilities
- Good Manufacturing Practice (GMP) requirements and role of cleaning and sanitising in preventing contamination of materials and products, and in the protection of personnel and 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
- services used in a pharmaceutical manufacturing process, including:
 - potable and purified water
 - steam
 - compressed and instrumentation air
- types of cleaning equipment suitable for use in a pharmaceutical processing environment, including their use and storage,
- different cleaning methods:
 - clean-in-place (CIP)
 - clean-out-of place (COP)
 - manual cleaning
- purpose and basic principles of CIP, including the use and functions of caustic and acid solutions, and cleaning sequence and stages

- advantages and disadvantage of automated and semi-automated CIP systems
- types of cleaning equipment include:
 - CIP spray balls
 - bottle brushes
 - disinfecting solutions
 - non-shedding wipes
- hygienic vs unhygienic design features of facilities and equipment, including inserts and dead legs
- the differences between:
 - cleaning
 - disinfecting
 - sanitising
 - sterilising
- properties and functions of different cleaning and sanitising agents for pharmaceutical industry
- 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
- 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
- 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
- waste related to pharmaceutical manufacturing processes, including:
 - cleaning material
 - product waste
 - hazardous waste
 - general processing and laboratory waste

- waste collection, recycling and handling procedures relevant to own work responsibilities
- procedures for responding to out-of-limits or unacceptable performance or outcomes
- 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
- purpose of keeping records and the recording requirements of GMP, including the legal significance of certifying and verifying GMP records.

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:
 - personal protective equipment
 - equipment and surfaces to be cleaned
 - chemicals and/or automated chemical addition system services and their related safety data sheets
 - data collection forms and information recording systems
- specifications:
 - cleaning procedures and related advice on equipment operation that comply with GMP requirements
 - workplace health and safety procedures related to cleaning and sanitising pharmaceutical manufacturing equipment
 - cleaning schedule
 - data collection and information recording requirements and procedures.

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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