Australian Government

Assessment Requirements for 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.

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
- 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.

Links

Companion Volume Implementation Guides are found in VETNet: - https://vetnet.gov.au/Pages/TrainingDocs.aspx?q=78b15323-cd38-483e-aad7-1159b570a5c4