

Overview

This standard identifies the competences you need to monitor and follow aseptic or clean room protocols in a biomanufacturing work environment, in accordance with approved procedures. You are required to check the application of aseptic procedures in the manufacturing area. You will be required to work to the relevant standard operating procedures, legislation and organisational policy, and to follow Good Manufacturing Practice (GMP). You will also be required to present records and details of your biomanufacturing work to the appropriate people.

Your responsibilities will require you to ensure compliance with aseptic procedural requirements and organisational policy and procedures for the biomanufacturing work that is undertaken. You will be required to report any problems with the biomanufacturing activities that you cannot personally resolve, or that are outside your permitted authority, to the relevant people.

Your underpinning knowledge will be sufficient to provide a sound basis for your work, and will enable you to adopt an informed approach to preparing for work and working in clean rooms. You will have an understanding of the attributes and behaviours required for clean room working, in adequate depth to provide a sound background for carrying out the biomanufacturing activities to the required specification.

You will understand the safety precautions required when carrying out the biomanufacturing activities for scientific operations and processes. You will be required to demonstrate safe working practices throughout, and will understand your responsibility for taking the necessary safeguards to protect yourself and others in the workplace.

This activity is likely to be undertaken by someone whose work role carries out Science/Bio manufacturing work activities. This could include individuals working in the following industries, Chemical, Pharmaceutical and Life Science industries.

Performance criteria

You must be able to:

P1 ensure that your work is carried out in accordance with standard operating procedures

P2 dress in the appropriate personal protection equipment (PPE) required for the clean room or clean work area environment, in accordance with the correct procedure

P3 carry out visual quality checks on your personal protection equipment prior to entering the working environment

P4 follow the correct procedures for entering and exiting the clean room or clean work area

P5 follow aseptic techniques in the work place

P6 remove personal protection equipment on completion of clean room or clean work area activities, and dispose/store in line with the correct procedure

P7 monitor and lead the quality and delivery of the above outcomes for yourself and your team

P8 communicate the required information about the work done, to authorised people, in accordance with departmental and organisational procedures

Knowledge and understanding

You need to know and understand:

- K1 the health and safety requirements of the area in which you are carrying out the biomanufacturing activities
- K2 the implications of not taking account of legislation, regulations, standards and guidelines when conducting biomanufacturing activities
- K3 the standard operating procedures, as set down in local biomanufacturing operating manuals
- K4 the principles of Good Manufacturing Practice (GMP) applied in the workplace
- K5 the importance of wearing protective clothing, gloves and eye protection when handling materials (including biochemical substances, biological pathogens and/or antigens), and the equipment used to contain and process them
- K6 the manufactured materials and batch process tracking and records system
- K7 the types of handling and sorting system, and the procedures used for materials undergoing processing in biomanufacturing facilities
- K8 the importance of correct identification, and any unique organisational or manufacturing numbers
- K9 the organisational requirements for maintaining the security of the workplace
- K10 the lines of communication and responsibilities in your department, and their links with the rest of the organisation
- K11 the limits of your own authority and to whom you should report if you have problems that you cannot resolve
- K12 how to monitor the application of aseptic procedures and practices for biomanufacturing operations
- K13 the specific safety precautions to be taken when working in a clean room or clean work area environment
- K14 the correct fitting and use of clothing and personal protective equipment that must be worn in a clean room or clean work area (including body, hands, eyes, ears, feet, mouth and face)
- K15 hazards associated with working in a clean room or clean work area with biomanufacturing equipment (including heat, radiation, chemicals, static electricity, high voltages, trapping points on equipment)
- K16 how to put on clean room clothing and footwear correctly
- K17 the scrub-up procedures
- K18 the procedures for entering and exiting the clean room or clean work area, and the

authority needed to do so

K19 the classification of the relevant clean room or clean work area, and how this impacts upon you

K20 the industry standards/classifications for clean rooms and clean work areas

K21 the company requirements for clothing and personal protective equipment required, and the reasons why such clothing and equipment must be used

K22 the procedures and methods for maintaining issued clothing and personal protective equipment

K23 how to apply procedures for dealing with damaged or dirty clothing and personal protective equipment

K24 how to store issued clothing and personal protective equipment correctly

K25 the laundering/cleaning/maintenance procedures relating to the issued clothing and personal protective equipment

K26 the aseptic techniques used in the laboratory

K27 how to dispose of single-use personal protective equipment correctly

K28 the policy and procedures relating to personal items (including body lotions, makeup, jewellery, contact lenses, footwear, own clothing)

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Monitor and follow aseptic procedures in a biomanufacturing environment



Scope/range