COGSCIM3_03 - SQA Unit Code F7YK 04
Monitoring and following aseptic procedures in a biomanufacturing environment

Overview

This unit 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. You will be expected to work to verbal/written instructions and standard operating procedures, with a minimum of supervision, taking personal responsibility for your own actions and for the quality and accuracy of the work that you and your team carry out.

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.

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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

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Knowledge and understanding

Sector specific

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

Organisation specific

You need to know and understand:

K5 the importance of wearing protective clothing, gloves and eye protection when handling materials (such as 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

Equipment/Process specific

You need to know and understand:

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 (such as for body, hands, eyes, ears, feet, mouth and face)

K15 hazards associated with working in a clean room or clean work area with biomanufacturing equipment (such as 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 (such as body lotions, makeup, jewellery, contact lenses, footwear, own clothing)

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Additional Information

Scope/range related to performance criteria

You must be able to:

1. monitor **all** of the following clean room protocols:
   - 1.1 use the correct issue of job instructions and specifications
   - 1.2 follow risk assessment procedures and COSHH regulations
   - 1.3 ensure that your team are appropriately dressed and uncontaminated before entering the area
   - 1.4 your team carry out your activities in line with organisational procedures
   - 1.5 store records of your team activities, in accordance with appropriate procedures
2. monitor **all** of the following company clean room/clean work area requirements:
   - 2.1 use appropriate clothing/personal protective equipment (PPE) (such as suits, gowns, coats, hoods, hats, caps, helmets, other headwear, boots, overshoes, other forms of footwear, safety goggles, visors, gloves)
   - 2.2 comply with hazard protection (such as breathing apparatus, gloves, apron/smock, other forms of PPE or clothing required)
   - 2.3 deal appropriately with damaged or dirty clothing/PPE (such as reporting damage, replacement, safe removal and cleaning or disposal, subjected to acid/hazardous substance spills, damaged/dirty labelling)
   - 2.4 store specified clothing/PPE correctly when not in use
   - 2.5 ensure the proper cleaning/laundering/maintenance of clothing/PPE
   - 2.6 dispose of single-use clothing and equipment in the correct location
   - 2.7 report any hazards or breaches of protocol
3. use **three** of the following types of personal protective equipment for clean room working:
   - 3.1 body suit
   - 3.2 gloves
   - 3.3 air supply
   - 3.4 face mask
   - 3.5 respirator
   - 3.6 other (please specify)
4. monitor use of personal protective equipment in **one** of the following clean room environments:
   - 4.1 health/disease screening
   - 4.2 drug development
   - 4.3 biochemical processing
   - 4.4 agro-biotech research
   - 4.5 biotechnology processing

4.6 other (please specify)

5. monitor and follow protocol methods and procedures that satisfy **all** of the following:
   - 5.1 the safety of people
   - 5.2 containment/integrity of the clean room/work area
   - 5.3 containment/integrity of the specimen/product
   - 5.4 appropriate industry standards and protocols
6. record details of the work done, and communicate the details to the appropriate people, using:
   - 6.1 verbal report

   Plus **one** method from the following:
   - 6.2 written or typed report
   - 6.3 computer-based record
   - 6.4 specific company documentation
   - 6.5 electronic mail

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