

Overview

This standard covers the competences you need to obtain biomaterial in biomanufacturing downstream processing operations using lysis of cells, in accordance with approved procedures. You are required to check the readiness of the manufacturing area and equipment to be used. 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 be required to present records and details of your biomanufacturing work to the appropriate people.

You will be required to check that the work area and equipment are ready for use, and that the appropriate resources and services are available, as stated in the instructions and standard operating procedures you are given. You will separate biomaterial using lysis of cells for downstream processing (DSP). You will be required to lyse cells in accordance with instructions and procedures.

You will also complete all the required documents and paperwork in accordance with these same instructions and procedures.

Your responsibilities will require you to comply with health and safety requirements and organisational policy and procedures for the biomanufacturing work that is undertaken. You will be required to report any problems with the health and safety procedures 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 cell lysis procedures. You will have an understanding of the cell lysis process, 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 wear the appropriate personal protection equipment (PPE) when working in a biomanufacturing environment
- P3 prepare reagents, according to specifications, in the correct quantities
- P4 obtain biomaterial from the appropriate source
- P5 dispose of waste in the correct manner and location, and tidy and clean the work area, in accordance with established procedures
- P6 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 importance of following equipment manufacturers' operational instructions
- K5 the principles of Good Manufacturing Practice (GMP) applied in the workplace
- K6 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
- K7 the biomanufacturing materials and batch process tracking and records system
- K8 the types of handling and sorting system, and the procedures used for materials undergoing processing in the manufacturing facilities
- K9 the importance of correct identification, and any unique organisational or manufacturing numbers
- K10 the organisational requirements for maintaining the security of the workplace
- K11 the lines of communication and responsibilities in your department, and their links with the rest of the organisation
- K12 the limits of your own authority and to whom you should report if you have problems that you cannot resolve
- K13 the main principles of different cell lysis methods (detergent, mechanical disruption, liquid homogenisation, sonication, freeze/thaw, mortar and pestle)
- K14 the advantages and disadvantages of the different cell lysis methods
- K15 how to prepare working reagents for cell lysis methods correctly
- K16 how to collect biomaterial from a centrifuge and aseptic container
- K17 how to prepare cell lysates from adherent cells
- K18 how to prepare cell lysates from suspension cells
- K19 how and where to store harvested cell lysates for further downstream processing

Scope/range

1. prior to entering the clean room, carry out all of the following:
 - 1.1 use the correct issue of job instructions and specifications
 - 1.2 follow risk assessment procedures and COSHH regulations
 - 1.3 use personal protective equipment for the work being done
 - 1.4 use the correct aseptic techniques and practices
 - 1.5 prepare cell lysates using the lysis method and procedures
 - 1.6 harvest cell debris and collect biomaterial into aseptic containers for downstream processing
 - 1.7 store filled aseptic containers in the correct location for further processing
 - 1.8 store records of your activities, in accordance with appropriate procedures
2. use three of the following types of protective clothing and equipment:
 - 2.1 laboratory coat/overalls
 - 2.2 gloves
 - 2.3 head/hair covers
 - 2.4 safety shoes/shoe covers
 - 2.5 safety glasses/visors
 - 2.6 other (please specify)
3. obtain biomaterial from both of the following sources:
 - 3.1 centrifuge
 - 3.2 aseptic containers
4. obtain biomaterial using one of the following cell lysis methods:
 - 4.1 detergent
 - 4.2 freeze/thawing
 - 4.3 liquid homogenisation
 - 4.4 sonication
5. obtain cell lysates from two of the following biomaterial types:
 - 5.1 suspension cells
 - 5.2 adherent cells
 - 5.3 other (please specify)
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 3 specific company documentation
 - 6.5 electronic mail

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