

Separate harvested biomaterial in biomanufacturing downstream processing using normal filtration

Overview

This standard covers the competences you need to separate harvested biomaterial in biomanufacturing downstream processing operations using normal filtration, 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 from cell debris for downstream processing (DSP). You will be required to separate biomaterial using filtration 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 different filtration procedures. You will have an understanding of the harvesting by the normal filtration 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 the filter unit and connect it to the biomaterial source for downstream processing (DSP), in accordance with established practices and procedures
- P4 pump biomaterial through the filter unit, monitoring and adjusting flowrate according to specification
- P5 collect the filtered biomaterial in the correct aseptic containers, and in the required quantities
- P6 perform a filter unit integrity test, in accordance with established practices and procedures
- P7 dispose of waste in the correct manner and location, and tidy and clean the work area, in accordance with established procedures
- 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 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 different types of filter unit, with and without pre-equilibrate, that are used in manufacturing
- K14 how to assemble and disassemble filter units for biomaterial processing
- K15 how to switch on the pump, vent air from the filter unit and monitor flowrate during processing
- K16 the maximum flow rate for the common filter units used in biomanufacturing
- K17 how to recognise the signs of filter blocking
- K18 how to recover biomaterial from the filter unit by buffer washing
- K19 the main differences between a disposable filter unit and a filter unit with module interchange
- K20 how to store filled biomaterial containers for further 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 assemble and disassemble the filter unit to/from the fermentation vessels or biomaterial containers
 - 1.6 switch on the pump, vent the air and collect biomaterial in a sterile container
 - 1.7 monitor the flow-rate, pressure and output of biomaterial
 - 1.8 wash the filter unit with buffer solution to recover the biomaterial
 - 1.9 store the filled biomaterial containers in the correct location and quantities for further processing
 - 1.10 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. separate biomaterial by one of the following filter types:
 - 3.1 disposable complete filter unit
 - 3.2 filter unit with module interchange
4. use both of the following types of filter unit:
 - 4.1 filters with pre-equilibrate
 - 4.2 filters without pre-equilibrate
5. record details of the work done, and communicate the details to the appropriate people, using:
 - 5.1 verbal reportPlus one method from the following:
 - 5.2 written or typed report
 - 5.3 computer-based record
 - 5.4 specific company documentation
 - 5.5 electronic mail

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