COGSCIM2_09 - SQA Unit Code F802 04
Harvesting biomaterial into sterile containers from a bioreactor for biomanufacturing downstream processing

Overview

This unit covers the competences you need to harvest biomaterial into sterile containers for biomanufacturing downstream processing operations, 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 stop pH control, cool the fermentation vessel and stop oxygen control for upstream processing. You will be required to connect harvest bags and containers, and to fill them, 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. You will be expected to work to verbal/written instructions and standard operating procedures, with a high level of supervision, taking personal responsibility for your own actions and for the quality and accuracy of the work that you 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 the use of harvesting procedures. You will have an understanding of the harvest process from a fermentation vessel, 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 wear the appropriate personal protection equipment (PPE) when working in a biomanufacturing environment
- P3 prepare the fermentation vessel for harvesting biomaterial, in accordance with established practices and procedures
- P4 harvest biomaterials in sealed sterile containers for downstream processing (DSP), in accordance with established practices and procedures
- 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

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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 importance of following equipment manufacturers' operational instructions
K5 the principles of Good Manufacturing Practice (GMP) applied in the workplace

Organisation specific

You need to know and understand:

K6 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
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

Equipment/Process specific

You need to know and understand:

K13 how to prepare the bioreactors for harvesting biomaterials
K14 the different sizes and types of sterile container (including bags) used in the harvesting process
K15 how to connect and remove the various types of sterile container to/from the bioreactor in an aseptic manner
K16 how to operate the bioreactor valves to harvest the biomaterial
K17 the correct aseptic techniques to be used during in the harvesting process

K18 how and where to store the harvested material, in preparation for further processing upon completion of operations

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Additional Information

Scope/range related to performance criteria

You must be able to:

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 the bioreactor for harvesting operations
   - 1.6 harvest biomaterial into sterile containers from the bioreactor
   - 1.7 store the harvested biomaterial 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. prepare the fermentation vessel for harvesting biomaterial, by carrying out **all** of the following:
   - 3.1 stopping pH control
   - 3.2 cooling the vessel
   - 3.3 stopping oxygen control
4. harvest biomaterial in **both** of the following container types:
   - 4.1 sealed sterile bag
   - 4.2 sealed sterile container
5. record details of the work done, and communicate the details to the appropriate people, using:
   - 5.1 verbal report

   Plus **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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