COGSCIM2_08

Produce biomaterial using bioreactors in biomanufacturing upstream processing

Overview

This standard covers the competences you need to produce biomaterial using bioreactors in biomanufacturing upstream processing operations, in accordance with approved procedures. You are required to check the readiness of the manufacturing area and bioreactor 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 weigh and measure materials correctly, sterilise equipment in place (where applicable), add growth media, add culture and set growth parameters to specification for upstream processing. You will be required to make regular checks of growth parameters during fermentation, to regularly take and samples, add additional media when required and to harvest in accord withinstructions 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 biomanufacturing procedures. You will have an understanding of the fermentation 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 the biomanufacturing environment
P3 correctly sterilise equipment, in accordance with established practices and procedures
P4 prepare the bioreactor, in accordance with established practices and procedures
P5 correctly add culture and growth media, in the correct quantities and at required levels in the bioreactor
P6 establish growth parameters and correctly set controls for the required production run
P7 monitor and run the bioreactor, in accordance with established practices and procedures, until the required biomaterial specifications are reached
P8 dispose of waste in the correct manner and location, and tidy and clean the work area, in accordance with established procedures
P9 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 how the fermentation vessel operates, its controls and main competent parts
K14 the safety equipment, and procedures to follow, when sterilising a bioreactor using steaming in place (SIP)
K15 how to sterilise an empty bioreactor correctly, and the steps to be followed
K16 how to pump culture and growth media into a bioreactor
K17 how to set and check growth parameters on a bioreactor (including pH, dissolved oxygen, stirrer speed, temperature and pressure)
K18 the procedures for taking biomaterial samples for measurement during the growth cycle
K19 how to measure and test samples of biomaterial, using optical density
K20 how to measure and test samples of biomaterial, using physical cell count and a hemocytometer
K21 how to make additions to the bioreactor during the production run

Scope/range

1. 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 sterilise the bioreactor, using steaming in place (SIP)
1.6 pump in growth media and culture media
1.7 check the growth parameters during the production cycle
1.8 perform regular sampling and tests until the biomaterial has reached the required specification
1.9 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. sterilise the fermentation vessel for two of the following circumstances:
   3.1 vessel empty (eg, mammalian growth)
   3.2 other (please specify)
   3.3 vessel full (eg, microbial growth)

4. fill the fermentation vessel to the required levels, measuring by both of
   the following controls:
   4.1 sight glass
   4.2 automatic level indicators

5. set and check four of the following growth parameters:
   5.1 pH
   5.2 stirrer speed
   5.3 pressure
   5.4 dissolved oxygen (DO2)
   5.5 temperature
   5.6 other (please specify)

6. measure samples by both of the following methods:
   6.1 optical density
   6.2 physical cell count, using a hemocytometer

7. ferment biomaterial in both of the following categories:
   7.1 no additional media required during fermentation
   7.2 additional media required at a fixed point

8. record details of the work done, and communicate the details to the appropriate people, using:
   8.1 verbal report
   Plus one method from the following:
   8.2 written or typed report
   8.3 computer-based record
   8.4 specific company documentation
   8.5 electronic mail

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