
Overview

This standard covers the competences you need to prepare culture media and solutions for biomanufacturing operations, in accordance with approved procedures. You are required to check the readiness of the manufacturing area and equipment that is 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 area and equipment are clear, cleaned and prepared correctly, and that the appropriate services are available, as stated in the instructions and standard operating procedures you are given. You will remove the culture media from cryostorage, revive it and scale up the media to specification for upstream processing. 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 the preparation procedures. You will have an understanding of the preparation of culture media and solutions, 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 check that the laminar flow hood work area to be used is clean, tidy and ready for use
- P4 remove the culture from cryostorage to the work area, in accordance with established procedures
- P5 revive the culture for scale-up in the correct manner
- P6 measure liquids in the correct quantities/batch sizes for scale-up of the culture
- P7 grow the culture in growth solution and scale up in the correct manner
- P8 take samples to ensure that the correct specifications have been reached
- P9 dispose of waste in the correct manner and location, and tidy and clean the work area, in accordance with established procedures
- P10 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
- K13 the methods used for storing and removing culture media in cryostorage (including low pressure liquid nitrogen)
- K14 how to revive cultures from cryostorage, using room temperature
- K15 how to revive cultures from cryostorage, using a water bath
- K16 how to check that a pipette is clean and ready for use
- K17 how to measure out aliquots of solutions, using a pipette for small quantities (less than 2ml) and large quantities (greater than 50ml)
- K18 the correct aseptic techniques to be used in the preparation of culture media for upstream processing
- K19 how to use incubators, with and without shaker, for the scale-up of culture material
- K20 the procedures for taking aseptic samples during the scale-up of cultures for measurement

- K21 how to measure and test samples of cultures, using optical density
- K22 how to measure and test samples of cultures, using physical cell count (including hemocytometer)

Scope/range

1. carry out all of the following operations:
 - 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 measure culture and growth media into sterile containers in an aseptic manner
 - 1.6 incubate and grow cultures to the required volume
 - 1.7 perform tests to show that the culture has reached the required specification
 - 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. revive culture media, using two of the following methods:
 - 3.1 using room temperature
 - 3.2 using a water bath
 - 3.3 other (please specify)
4. measure out aliquots of solutions, using both of the following:
 - 4.1 pipettes measuring less than 2ml
 - 4.2 pipettes measuring greater than 50ml
5. incubate culture media, using both of the following:
 - 5.1 incubator with shaker
 - 5.2 incubator without shaker
6. measure samples by both of the following methods:
 - 6.1 optical density
 - 6.2 physical cell count, using a hemocytometer
7. scale up the culture, as specified by both of the following categories:
 - 7.1 final volume
 - 7.2 final cell count
8. record details of the work done, and communicate the details to the appropriate people, using:
 - 8.1 verbal reportPlus 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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