COGSCIM3_17

Monitor the concentration and diafiltration of harvested biomaterial in downstream processing using tangential flow filtration

Overview

This standard covers the competences you need to monitor the concentration and diafiltration of harvested biomaterial in biomanufacturing downstream processing operations using tangential flow filtration, in accordance with approved procedures. You are required to check the readiness of the manufacturing area and equipment that is 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 also 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 concentrate and diafiltrate biomaterial in downstream processing operations. 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 biomanufacturing activities 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 application of procedures for the monitoring of tangential flow filtration. You will have an understanding of harvesting by the 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 the biomanufacturing environment
P3 prepare the tangential flow filtration system in accordance with established practices and procedures
P4 correctly sterilise equipment in accordance with established practices and procedures
P5 pump biomaterial through the filtration system, monitoring and adjusting flow-rate according to specification
P6 collect filtered biomaterial in the correct sterile containers and quantities
P7 dispose of waste in the correct manner and location, and tidy and clean the work area, in accordance with established procedures
P8 monitor and lead the quality and delivery of the above outcomes for yourself and your team
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' operating 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 to monitor and lead the quality and delivery of concentrated and diafiltrated harvested biomaterial in biomanufacturing downstream processing operations using tangential flow filtration
K14 the basic principles of tangential flow filtration (TFF) operation
K15 how to set up a TFF system, insert the membrane and torque it correctly
K16 the procedure for preparing the TFF system using cleaning in place (CIP)
K17 the different methods that can be used for doing CIP
K18 how to conduct a clean water flux measurement test
K19 how to equilibrate the TFF system membrane with the appropriate buffer solution
K20 how to add biomaterial to the TFF system tank, and how to operate the system correctly
K21 how to calculate trans-membrane pressure (TMP)
K22 how to recover biomaterial from the TFF system and membrane
K23 how to dispose of waste material correctly

K24 how to store filled biomaterial containers for further processing.

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 set up the filtration system, insert the membrane and torque correctly
1.5 prepare the system using cleaning in place (steam in place (SIP), hot water or chemicals)
1.6 conduct a clean water flux measurement test
1.7 equilibrate the system membrane with the appropriate buffer solution
1.8 add biomaterial to the system tank, and start up the filtration process correctly
1.9 monitor the system instruments and adjust controls to optimal settings
1.10 process biomaterial to the required concentration
1.11 run diafiltration to required volumes
1.12 switch off correctly and recover biomaterial from the system into sterile containers
1.13 store filled biomaterial containers in the correct location and quantities for further processing
1.14 rinse the membrane to recover biomaterials, and clean the system for next use
1.15 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. monitor and adjust system settings for all of the following:
   3.1 pressure
   3.2 pump setting
   3.3 flow

4. complete all of the following procedures:
   4.1 monitor retentate pressure
   4.2 calculate trans-membrane pressure
   4.3 monitor permeate pressure

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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