COGSCIM4_05

Determine the manufacturing methods for a biomanufacturing environment

Overview

This standard identifies the competences you need to determine the methods for manufacturing biomaterial, selecting from established practices and procedures, in accordance with approved procedures. 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 investigate the problem, obtaining all the necessary information to enable you to identify and evaluate possible solutions, and their effects on both the biomanufacturing process and the people involved. You will also be expected to decide on a plan of action, and to communicate this to the relevant people.

Your responsibilities will require you to comply with health and safety requirements and organisational policy and procedures for the problem solving 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 applying problem solving procedures. You will have an understanding of the manufacturing methods and principles used, 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.

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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 the biomanufacturing environment
P3 review historical manufacturing data for similar products made in the past
P4 establish manufacturing methods, techniques and equipment for manufacturing the product to be made
P5 check the work area and availability of the equipment needed to make the product
P6 determine the costs, quality required and production times needed for the product to be made
P7 define the sequence of operations for the product to be made
P8 communicate the required information about the work done, to senior management and other authorised people, in accordance with 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 manufactured product and batch process tracking and records system
K8 the types of handling and sorting system, and the procedures used for products 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 obtain and interpret drawings, charts, specifications, manufacturers' manuals, historical manufacturing reports and other documents needed for the determining the manufacturing method(s)
K14 the range of materials and technology used in the manufacture and processing of biomaterials
K15 how to determine the relevant manufacturing methods for the products to be manufactured

K16 production planning, control and scheduling techniques
K17 how to establish the costs of manufacturing, and the procedures used for calculating them
K18 the quality control techniques and standards used in manufacturing

Scope/range

1. carry out all of the following activities:
1.1. discuss/consult with the relevant people on the nature and extent of the problem
1.2. gather information from appropriate sources to help identify and define the manufacturing method
1.3. communicate the proposed solution to the relevant people, obtaining feedback where appropriate
1.4. prepare a plan of action for implementation of the appropriate manufacturing method
1.5. ensure that the agreed solution complies with the regulatory and quality control requirements
1.6. identify the appropriate standard operating procedures for the determined manufacturing method

2. determine manufacturing methods involving ten of the following:
   2.1. packaging quality
   2.2. material handling devices
   2.3. upstream processing equipment
   2.4. downstream processing equipment
   2.5. secondary manufacturing equipment
   2.6. utilities required
   2.7. safety requirements
   2.8. people needed
   2.9. steaming in place/cleaning in place requirements
   2.10. external resource requirements
   2.11. cryostorage materials required
   2.12. environmental controls needed
   2.13. standard operating procedures required
   2.14. regulatory requirements
   2.15. quality requirements
   2.16. other (please specify)

3. evaluate possible solutions to the problems, by considering all of the following:
   3.1. operational effectiveness
   3.2. ease of implementation
   3.3. timescale for implementation
   3.4. financial impact
   3.5. functionality of the system
   3.6. environmental impact
   3.7. staffing implications
   3.8. conformity with regulations
   3.9. health and safety implications
   3.10. other (please specify)

4. review historical data from four of the following sources:
   4.1. statistical data

4.2. manufacturing records
4.3. quality audits
4.4. external sources
4.5. feedback from users or colleagues
4.6. regulatory requirements
4.7. operating procedures/manufacturing manuals
4.8. company standard operating procedures
4.9. health and safety information
4.10. environmental monitoring documents
4.11. other (please specify)

5. record details of the proposed method, 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. specific company documentation
5.4. computer-based record
5.5. electronic mail

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