COGSCIM4_09

Contribute to team feasibility review for product development in a biomanufacturing environment

Overview

This standards identifies the competences you need to supervise existing/new biological product manufacturing for development purposes, in accordance with approved procedures and practices. 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.

Your responsibilities will require you to comply with organisational policy and procedures for supervising existing/ new biological product manufacturing for development purposes, and to report any problems that you cannot personally resolve to the relevant authority.

Your underpinning knowledge will provide a good understanding of general and discipline-specific biomaterial development principles and processes, and you will also be fully conversant with organisational procedures and systems. 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. You will be expected to work to verbal/written instructions and standard operating procedures, and to report against your departmental goals set by senior management, 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 supervising existing/new biological product manufacturing for development purposes, in accordance with approved procedures and practices. 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.

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 establish biological manufacturing process targets with laboratory R&D colleagues
P4 ensure that the laboratory process is satisfactorily converted into the biological manufacturing process
P5 build collaborative partnerships and maintain effective liaison with others who should have an input into the manufacturing process
P6 assure the supply and quality of the raw materials
P7 confirm the suitability of raw materials and processes from information supplied on laboratory trials, ensuring that any required changes are accommodated in the development manufacturing plan
P8 take appropriate action in the event of abnormal occurrences, and consult relevant others as appropriate
P9 ensure that the requirements of the development manufacturing plan are fulfilled to time, quantity and quality
P10 document the development biomanufacturing activities and any changes made to the development manufacturing plan
P11 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 the requirements of relevant quality, health, safety and environmental legislation and guidelines and your organisation's policies and procedures
K14 sources of information (including primary literature and biological abstracts), and how to use specialist search engines appropriate to your organisation
K15 the scope of the biological manufacturing targets for quantity, quality standards, deadlines and any other special requirements
K16 the types of laboratory trial that may be used to confirm the suitability of raw materials and manufacturing processes
K17 how to apply practical techniques to your chosen experiment
K18 whom to consult, and the nature of their interest
K19 how to define manufacturing targets
K20 how to interrogate the results against the biological manufacturing process targets
K21 the effects of scale-up, and the limitations of the biological manufacturing equipment
K22 the principles of the process that you are supervising
K23 the limitations of the available equipment
K24 any budgetary flexibilities and constraints

K25 the different ways in which you might assure the quality of raw materials for biological manufacture (including maintaining a constructive dialogue with suppliers)

Scope/range

1. carry out all of the following activities:
1.1. discuss/consult with the relevant people involved in the existing/new biological product manufacturing process
1.2. gather information from appropriate sources to help supervise the chosen 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 chosen manufacturing method
1.5. ensure that the chosen solution complies with the regulatory and quality control requirements
1.6. amend the appropriate standard operating procedures for the chosen manufacturing method

2. supervise new biological manufacturing processes in both of the following work situations:
2.1. working alone
2.2. working as part of a team

3. supervise new biological manufacturing processes in both of the following:
3.1. test quantities
3.2. commercial quantities

4. record details of the preparation work, and communicate the details to the appropriate people, using:
4.1. verbal report
Plus one method from the following:
4.2. written or typed report
4.3. specific company documentation
4.4. computer-based record
4.5. electronic mail

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