

## Manage projects in biomanufacturing operations

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### Overview

This standard identifies the competences you need to manage projects in biomanufacturing operations, 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 managing projects in biomanufacturing operations, 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 biomanufacturing 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 managing projects in biomanufacturing operations, 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.

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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 determine the scope of the project, and the processes required to achieve it
  - P4 develop a full project plan which accurately identifies the project aims and objectives
  - P5 develop project objectives, work plans and schedules that are realistic and achievable, and that will meet the overall project aims
  - P6 form the project team, comprising the correct mix of subject and technical experts to deliver the project
  - P7 determine and agree individual roles and responsibilities within the project team
  - P8 develop and manage a monitoring process to review the progress of the project, adjusting the project plan as required
  - P9 obtain authority and support for the release of the necessary resources to carry out the project
  - P10 conduct and manage the project in accordance with the plan, consulting with subject experts and specialists according to the needs of the project
  - P11 report project progress to relevant parties, at the agreed stages
  - P12 deal effectively with problems within your control and report any that cannot be solved
  - P13 communicate the required information about the work done, to senior management and other authorised people, in accordance with organisational procedures.

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### 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 key principles for project management success
  - K14 the different project management methods that can be used, and how to select the methods appropriate to your own circumstances
  - K15 the information that should be included in project plans to allow the project progress to be monitored and measured (including aims and objectives of the project, timescales, quality, cost and delivery requirements, resource requirements)
  - K16 how to arrive at an estimate of timescales for the project, and the need to set milestones for achievements
  - K17 the tools and techniques available for project planning and monitoring (including spreadsheets, graphs, Gantt charts, critical path analysis)
  - K18 how to allocate specific tasks and responsibilities to the project team members, according to individual skills and abilities
  - K19 how to monitor and evaluate the project progress effectively
  - K20 how to prepare the plans (to include the structure, style, clarity and compliance with relevant standards)
  - K21 how to conduct a project meeting, and the importance of obtaining team

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members' agreement to changes in plans

K22 how to monitor progress of the project in terms of delivery on time, to budget and within agreed levels of quality

K23 how to report project closure, completion and final status to management, teams and customers

K24 how to solve problems and overcome barriers/difficulties encountered during the life of the project

K25 with whom to liaise and from whom to obtain relevant and specific information, to support and assist you in running the project

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### Scope/range

1. develop project plans that identify all of the following:
  - 1.1. the project aims and objectives
  - 1.2. milestones and deliverables to be met
  - 1.3. individual tasks within the project
  - 1.4. any special requirements that must be met
  - 1.5. quality, cost and delivery outcomes
  - 1.6. estimate resources required (eg, people)
  - 1.7. start time required for the project
  - 1.8. completion date of the project
  - 1.9. the full cost of the project
  
2. consult with appropriate people in order to secure the release of four of the following resources:
  - 2.1 people who have the required skills and knowledge
  - 2.2. the relevant documentation and information
  - 2.3. raw materials and consumables
  - 2.4. equipment (eg, bioreactor, centrifugation, filtration, autoclaving, lifting and handling equipment)
  - 2.5. work space/work area
  - 2.6. any outside support services
  - 2.7. special/specific safety equipment
  
3. monitor the progress of the project to ensure that all of the following are met:
  - 3.1. project deliverables on time
  - 3.2. project achieved within budget
  - 3.3. level of quality that is acceptable
  
4. produce reports on project progress using two of the following:
  - 4.1. spreadsheet
  - 4.2. Gantt charts
  - 4.3. critical path analysis
  - 4.4. project schedule
  - 4.5. event calendar
  - 4.6. other (please specify)
  
5. record details of the project work, and communicate the details to the appropriate people, using:
  - 5.1. verbal reportPlus 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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