

## Develop a Control Strategy for a Biomanufacturing Process

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### Overview

This standard identifies the competences you need to develop a Process Control Strategy for a biomanufacturing process.

You will be required to identify appropriate solutions for the control of a biomanufacturing process, in accordance with approved procedures and practices. You will need to develop a control strategy that ensures that the process remains always under a state of control and that the quality of the final bioproduct meets all the requirements of the manufacturing licence.

Your underpinning knowledge of process engineering and biochemistry will enable you to identify the critical aspects of the bioprocess that need to be controlled and adopt an informed approach to identifying appropriate process control protocols.

This activity is likely to be undertaken by someone whose work role carries out process engineering work activities in a biochemical environment. 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 review and interpret the regulations, directives and guidelines relevant for a biomanufacturing process
  - P2 work to the relevant standard operating procedures, legislation and organisational policy, and to follow Good Manufacturing Practice (GMP).
  - P3 obtain accurate information on the requirements of a control system for the biomanufacturing process
  - P4 identify any unique or specific features of the biomanufacturing process that need consideration to ensure that it can operate under aseptic conditions
  - P5 identify the critical aspects of the biomanufacturing process: the Critical Process Parameters, the Critical Material Attributes and the Critical Quality Attributes
  - P6 identify the control operations to be carried out and determine their sequence
  - P7 establish a data management, analysis and storage strategy as part of the Control Strategy
  - P8 produce a detailed Control Strategy for the biomanufacturing process that complies with all relevant regulations, standards directives or codes of practice
  - P9 ensure that the Control Strategy addresses all the critical aspects of the biomanufacturing process and agree the defined scope of controls with the relevant personnel
  - P10 determine the specific equipment that is critical to the process control and any special testing, calibration and maintenance to enable the bioprocess to be compliant with the continuing regulations, directives and guidelines
  - P11 review the results of the Control Strategy and make improvements where appropriate and gain approval for the improvements
  - P12 communicate the Control Strategy to relevant people in accordance with organisational procedures confirm
  - P13 maintain full, accurate and legible records of information and store in line with current legislation, guidelines, local policies and protocols
  - P14 work within your level of competence, responsibility and accountability

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### Knowledge and understanding

- You need to know and understand:*
- K1 the principles of process engineering and how they apply in an aseptic environment
  - K2 the regulations, standards, directives and codes of practice that are relevant in a biomanufacturing environment, and any implications they have on process control
  - K3 the principles of Good Manufacturing Practice (GMP) applied in the workplace
  - K4 the biomanufacturing process and how to determine the critical aspects - the Critical Process Parameters, the Critical Material Attributes and the Critical Quality Attributes
  - K5 the principles of operation of the instrumentation and control equipment being used, including Process Analytical Technology (PAT), its intended use, capabilities and limitations
  - K6 the information that can be gathered from process control equipment and its uses
  - K7 the process control data required to ensure the bioproduct quality
  - K8 how to determine the process parameter ranges to ensure the bioprocess is in a state of control
  - K9 the quality control techniques and standards used in manufacturing biochemical products
  - K10 the organisational requirements for the action to be taken when results are out of specification
  - K11 the testing, calibration and maintenance requirements for the control equipment to ensure the bioprocess is compliant with the continuing regulations, directives and guidelines
  - K12 the risks to production in failure of the process control equipment
  - K13 how to review the outcome of the control strategy and verify the compliance to statutory requirements for process control equipment
  - K14 how to compare the results with appropriate specifications and to determine the action required
  - K15 information and document systems and the need for effective document and data control and the implications if these are not applied
  - K16 the lines of communication and responsibilities in your department, and their links with the rest of the organisation
  - K17 the limits of your authority and why it is important to adhere to them

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