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## Overview

This standard covers the competences you need to implement quality improvement of projects and processes in a biomanufacturing environment, in accordance with approved procedures and practices. You are required to take prompt and appropriate action to rectify any quality problems. 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 ensuring the successful improvement of quality, 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 understand research planning principles and process, data analysis methods, and evaluation methods, which will enable you to assess the effectiveness of the quality improvement principles and systems, whilst ensuring compliance with your company organisational procedures and systems. You will also be conversant with organisational specifications, details and formats, and resource management principles, in sufficient depth to enable you to carry out the quality improvement activities to the required standard.

You will be fully aware of any health, safety and environmental requirements, and the appropriate legislative and regulatory frameworks, applicable to your area of responsibility. You will be required to ensure that safe working practices are maintained throughout, and will understand the responsibility you owe to 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 work safely at all times, complying with health and safety and other relevant regulations and guidelines
- P3 wear the appropriate personal protection equipment (PPE) when working in the biomanufacturing environment
- P4 plan the introduction of improvements to the quality of manufactured products or processes
- P5 specify clearly the improvements that should be implemented
- P6 confirm that conditions are suitable to implement the improvements
- P7 provide clear and accurate instructions to all the relevant people
- P8 control the use of resources to achieve the most effective results
- P9 ensure that the improvements are implemented according to plan, are recorded, and comply with all relevant regulations and guidelines
- P10 identify and solve any implementation problems that occur
- P11 assess the impact of the improvements on the quality of laboratory products or processes

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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 biomanufacturing product and batch process tracking and records system
- K8 the types of handling and sorting system, and the procedures used for biomanufacturing products undergoing processing in the biomanufacturing facilities
- K9 the importance of correct identification, and any unique organisational or biomanufacturing 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 quality criteria that could be used for different types of biomanufacturing projects or processes
- K14 how to obtain and interpret records, charts, specifications, equipment manuals, history/technical support reports and other documents needed for the implementation of quality improvements
- K15 the laboratory processes and standard operating procedures in the area associated with the quality issues
- K16 the types and effects of quality improvements, and their impact
- K17 the factors that have to be taken into account when selecting the solution to a manufacturing quality problem
- K18 the techniques used to obtain information
- K19 methods and techniques involved in quality improvement implementation
- K20 methods and techniques involved in evaluating information
- K21 how to obtain and interpret legislative and regulatory documentation
- K22 how to obtain and interpret company policy and personnel procedures
- K23 organisational reporting procedures and documentation, and their application
- K24 whom to inform of actions taken, and by what means
- K25 how to retrieve the necessary data from company information systems
- K26 the types of impact assessment systems/techniques available, and their application

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## Scope/range

1. carry out all of the following activities:
  - 1.1. plan the implementation of quality improvements so as to minimise disruption to normal working
  - 1.2. identify and use suitable quality improvement methods, techniques and procedures
  - 1.3. control the use of resources for the implementation of the quality improvements
  - 1.4. carry out the quality improvements in accordance with the implementation plan
  - 1.5. solve any problems that occur during the implementation
  - 1.6. assess the impact of the improvements on the quality of products or processes
2. plan the introduction of quality improvement for one of the following:
  - 2.1. new project/process
  - 2.2. revisions to existing project/process
  - 2.3. legal/legislative requirement
  - 2.4. international/national standards requirements
  - 2.5. company standard operating procedures
3. specify quality improvements to a project or process, to include three of the following:
  - 3.1. biological/chemical output
  - 3.2. equipment
  - 3.3. materials
  - 3.4. checking procedures
  - 3.5. services
  - 3.6. systems
4. obtain information to improve quality from all of the following:
  - 4.1. quality assurance department procedures
  - 4.2. manufacturing team requirements
  - 4.3. availability of resources
  - 4.4. product specifications
  - 4.5. regulations and guidelines
  - 4.6. international/national standards
  - 4.7. customer specifications
  - 4.8. legal/patented information
  - 4.9. preparation of site
  - 4.10. company documentation/authorisation
5. ensure that quality improvements conform to all of the following:
  - 5.1. organisational standard operating procedures
  - 5.2. equipment operation specification
  - 5.3. health, safety and environmental requirements
  - 5.4. laboratory log book/record keeping
  - 5.5. recognised compliance agency/body's standards
  - 5.6. customer standards and requirements
  - 5.7. aseptic/sterilisation requirements

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5.8. FDA, EMEA or MHRA standards

6. control the use of three of the following resources to ensure effective results:

- 6.1. people
- 6.2. materials
- 6.3. facilities
- 6.4. utilities
- 6.5. equipment
- 6.6. finance

7. assess the outcome of the quality improvement implementation, to include two of the following:

- 7.1. impact of the improvements on the quality of products or processes
- 7.2. cost effectiveness of the process/actions
- 7.3. effect of changes to quality assurance methods or procedures
- 7.4. quality of data held on the company information system
- 7.5. effectiveness of reporting procedures
- 7.6. lessons learned

8. record details of work done, and communicate the details to the appropriate people, using:

8.1. verbal report

Plus one method from the following:

- 8.2. written or typed report
- 8.3. specific company documentation
- 8.4. computer-based record
- 8.5. electronic mail

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