

## Solve engineering problems in a biomanufacturing environment

---

### Overview

This standard identifies the competences you need to solve engineering problems in a biomanufacturing environment, in accordance with approved procedures. You are required to take prompt and appropriate action to rectify the engineering problem. 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 engineering 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 problem solving procedures. You will have an understanding of the engineering problem solving principles used, in adequate depth to provide a sound background for carrying out the 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.

## Solve engineering problems in a biomanufacturing environment

---

### 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 take prompt action to diagnose and rectify the operational problems, and keep all relevant people informed of progress
- P4 obtain all relevant information relating to the problems
- P5 identify correctly the nature and extent of the problems
- P6 evaluate all realistic engineering solutions to rectify the problems
- P7 identify the most effective engineering solution for rectifying the problems
- P8 ensure that engineering solutions are implemented correctly and promptly
- P9 ensure that the rectification complies with all relevant regulations and guidelines
- P10 communicate the required information about the work done, to senior management and other authorised people, in accordance with organisational procedures.

## Solve engineering problems in a biomanufacturing environment

---

### 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 the standard operating procedures, as set down in local biomanufacturing operating manuals
- K3 the importance of following equipment manufacturers' operating instructions
- K4 the principles of Good Manufacturing Practice (GMP) applied in the workplace
- K5 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
- K6 the manufactured product and batch process tracking and records system
- K7 the types of handling and sorting system, and the procedures used for products undergoing processing in the manufacturing facilities
- K8 the importance of correct identification, and any unique organisational or manufacturing numbers
- K9 the organisational requirements for maintaining the security of the workplace
- K10 the lines of communication and responsibilities in your department, and their links with the rest of the organisation
- K11 the limits of your own authority and to whom you should report if you have problems that you cannot resolve
- K12 how to obtain details of engineering problems
- K13 the criticality of different types of problem, and how to prioritise the problems to be solved
- K14 how to obtain and interpret drawings, charts, specifications, manufacturers' manuals, history/maintenance reports and other documents needed for the problem solving process
- K15 the engineering processes and operating procedures within the area of your responsibility
- K16 the engineering principles and processes within the engineering function where the problem exists
- K17 how to obtain any necessary ancillary equipment to support the investigation or solution to the problem under investigation
- K18 the types and effects of engineering problems in the biomanufacturing environment
- K19 the factors that have to be taken into account when selecting the solution to a problem
- K20 the techniques used to obtain information on problems, and the sources of information
- K21 the methods and techniques involved in problem solving
- K22 the methods and techniques involved in evaluating information
- K23 how to obtain and interpret legislative and regulatory documentation
- K24 how to obtain and interpret company policy and personnel procedures
- K25 how to retrieve necessary data from company information systems
- K26 the types of monitoring systems/techniques available, and their application

## Solve engineering problems in a biomanufacturing environment

## 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 problem
  - 1.3. identify and evaluate possible solutions, considering temporary, short term and long term solutions
  - 1.4. communicate the proposed solution to the relevant people, obtaining feedback where appropriate
  - 1.5. prepare a plan of action for implementation of the appropriate solution
  - 1.6. ensure that the agreed solution is implemented in an effective and timely manner
  - 1.7. ensure that the agreed solution complies with appropriate regulations and guidelines
  - 1.8. monitor the implementation of the solutions and make necessary revisions to the plan of action

2. take action to resolve engineering problems arising from four of the following:

- 2.1. packaging quality problem
- 2.2. material handling devices
- 2.3. equipment malfunction
- 2.4. ergonomic related
- 2.5. utilities supply (gas, electricity, water, air, etc)
- 2.6. safety related
- 2.7. personnel problem
- 2.8. external contractual problem
- 2.9. lack of resources/materials
- 2.10. environmental problem
- 2.11. change to customer requirements
- 2.12. design related
- 2.13. deviation from standard operating procedures
- 2.14. change in regulatory requirements
- 2.15. 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. obtain and use information on the problem from four of the following:

## Solve engineering problems in a biomanufacturing environment

---

- 4.1. statistical data
  - 4.2. historic records (such as maintenance/shift logs)
  - 4.3. quality audits
  - 4.4. external sources
  - 4.5. feedback from users or colleagues
  - 4.6. operating procedures/manufacturing manuals
  - 4.7. company standard operating procedures
  - 4.8. health and safety information
  - 4.9. environmental monitoring documents
  - 4.10. observation
5. implement engineering solutions that comply with:
- 5.1. regulatory requirements
- For two of the following timescales:
- 5.2 temporary (interim solution)
  - 5.3 short term (which require further action)
  - 5.4. long term (permanent solution)
6. record details of the problem solving work, and communicate the details to the appropriate people, using:
- 6.1. verbal report
- Plus one method from the following:
- 6.2. written or typed report
  - 6.3. specific company documentation
  - 6.4. computer-based record
  - 6.5. electronic mail

## Solve engineering problems in a biomanufacturing environment

Developed by	Cogent
Version Number	2
Date Approved	30 Mar 2017
Indicative Review Date	29 Mar 2019
Validity	Current
Status	Original
Originating Organisation	SEMTA
Original URN	12
Relevant Occupations	Associate Professionals and Technical Occupations, Engineering and Manufacturing Technologies, Manufacturing Technologies, Science, Science and Engineering Technicians, Science and Mathematics Science
Suite	Scientific Manufacture
Keywords	production; problem-solving; manufacturing; biomanufacturing; engineering; science