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## Overview

This standard covers the competences you need to assure quality methods and procedures in a science or technology environment.

You will be required to demonstrate that you can identify suitable quality assurance methods and procedures, ensuring that the specified quality assurance methods and procedures are implemented correctly in accordance authorised procedures.

The activity is likely to be undertaken by someone who carries out work within a science quality related work environment. This could include individuals working in scientific laboratories, chemical, energetic materials and biochemical manufacturing process industries.

**This standard now replaces COGSCIM4-6**

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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 (SOPs), regulatory or license requirements and Good Manufacturing Practices (GMP).
  - P2 work safely at all times, complying with health and safety and other relevant regulations and guidelines.
  - P3 establish clear and precise criteria for assuring the quality of Science manufacturing processes and systems.
  - P4 identify suitable quality assurance methods and procedures.
  - P5 ensure that the specified quality assurance methods and procedures are implemented correctly.
  - P6 obtain accurate information from valid sources on the Science manufacturing projects or processes being quality assured.
  - P7 specify clearly the required quality of Science manufacturing processes.
  - P8 assess accurately and realistically the quality of the Science manufacturing processes.
  - P9 ensure that information on quality is provided to the appropriate people.
  - P10 recommend improvements to quality to the appropriate people.

## 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 science activities.
- K2 the implications of not taking account of legislation, regulations, standards and guidelines when conducting science activities.
- K3 the standard operating procedures, as set down in local science operating instruction documents or manuals (including computer based systems).
- K4 the importance of following equipment manufacturers' operating instructions.
- K5 the principles of Good Manufacturing Practice (GMP) applied in the workplace (if applicable).
- K6 the importance of wearing protective clothing, gloves and eye protection when handling materials including chemical, biochemical substances, and the equipment used to contain and process them.
- K7 the science product and batch process tracking and records system.
- K8 the types of handling and sorting system, and the procedures used for science products undergoing processing in the science facilities.
- K9 the importance of correct identification, and any unique organisational or scientific 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 scientific processes.
- K14 the quality assurance methods that are available.
- K15 statistical methods for recording and analysing scientific processes.
- K16 other non-statistical methods that could be used for obtaining information on scientific processes.
- K17 the relevant sources of valid information on scientific processes.
- K18 who should be involved in the scientific quality assurance process.
- K19 the type of impact that scientific quality assurance could have on the organisation.
- K20 who requires information on scientific quality assurance, and the procedures for informing them.
- K21 how to obtain quality information on resources used by the scientific environment.
- K22 how to determine the resources that are necessary to ensure that quality methods and procedures are applied.

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K23 how to determine the availability and suitability of resources.

K24 the regulations and guidelines relevant to your area of responsibility.

K25 how to obtain and interpret information on regulations and guidelines.

K26 the types of recommendation that could emerge from the quality assurance process.

K27 methods of presenting scientific quality assurance recommendations.

## Scope/range

Carry out all of the following activities:

- 1.1. establish clear criteria as the basis of the quality assurance process
- 1.2. obtain accurate information from appropriate sources for consideration in the process
- 1.3. assess and specify the quality requirements for the scientific projects or processes
- 1.4. identify suitable quality assurance methods, techniques and procedures
- 1.5. assess the implications of implementing the quality assurance procedures
- 1.6. present recommendations for improvements to the quality assurance process to the appropriate people

Develop quality assurance procedures that cover two 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
- 2.5. company standard operating procedures

Obtain accurate information from five of the following sources:

- 3.1. quality assurance department
- 3.2. equipment manuals/specifications
- 3.3. FDA/EMEA/MHRA regulations (and any other relevant industry regulator)
- 3.4. project output specifications
- 3.5. other regulations and guidelines
- 3.6. international/national standards
- 3.7. legal/patented information
- 3.8. company standard operating procedures
- 3.9. customer specifications

Identify suitable quality assurance methods and procedures for four of the following:

- 4.1. manufacturing output specification
- 4.2. material specifications
- 4.3. patents
- 4.4. product quality checks
- 4.5. batch inspection
- 4.6. manufacturing methods

- 4.7. process parameters
- 4.8. technical support procedures
- 4.9. schedule checking
- 4.10. legal requirements
- 4.11. use of international/national standards
- 4.12. company standards operating procedures
- 4.13. other (please specify)

Ensure that the quality assurance methods and procedures comply with four of the following:

- 5.1. organisational standard operating procedures
- 5.2. equipment operation specification
- 5.3. health, safety and environmental requirements
- 5.4. manufacturing record keeping
- 5.5. recognised compliance agency/body's standards
- 5.6. customer standards and requirements
- 5.7. aseptic/sterilisation requirements
- 5.8. relevant standards for example, BS and/or ISO standards

Record details of work done, 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

COGSQO-03

Assure quality methods and procedures in a science or technology environment



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