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## Overview

This standard covers the competences required to maintain and improve the documentation and system processes of a quality system within the science or technology environment.

You will be required to demonstrate that you can evaluate the quality of documents and system processes within sciences or technology related work activity, reporting findings to the appropriate people with recommendations.

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.

## Performance criteria

- You must be able to:*
- P1 monitor and evaluate the quality of documents and system processes in accordance to Good Documentation Process (GDocP) and Good Manufacturing Processes (GMP) within science or technology related work activity.
  - P2 ensure accurate and complete transfer of quality and regulatory information from the manufacturing process to customer and vice versa.
  - P3 respond to the evaluation process, provide feedback and priority actions from the report findings to the appropriate people for change or improvement approval.
  - P4 ensure recommendations and actions are implemented in accordance with organisational policies and procedures.
  - P5 implement approved improvements to the documentation or processes in accordance to the organisations change management process.
  - P6 ensure that conditions are suitable to implement the improvements in accordance to the change management process.
  - P7 ensure all changes to process and procedures are accurately reflected in standard operating procedures (SOPs) and other relevant organisational documents.
  - P8 ensure adequate resources are available to carry out the improvements within the allocated agreed time.
  - P9 provide clear and accurate instructions to all the relevant people to achieve the most effective results.
  - P10 ensure that new or improved documentation or processes are implemented according to the change management plan.
  - P11 record the implementation of the improvements.
  - P12 monitor the new or improved documentation or process to ensure satisfactory implementation.
  - P13 ensure the resolution of any problems arising after implementation, recording information and the notifying all relevant people.
  - P14 assess and record the impact of the improvements on the quality related documentation or processes.

## Knowledge and understanding

- You need to know and understand:*
- K1 the health and safety requirements of the area in which the activities are being carried out.
  - K2 the relevant legislation, regulations, product licence and organisational rules and procedures used in the science or technology related work activities.
  - K3 the importance of using the organisations change management system and the actions and responsibilities required in the change process.
  - K4 the principles of GDocP and GMP when considering changes to documentation of processes.
  - K5 latest technological developments relevant to the sciences or technology industry and how to keep up-to-date with them.
  - K6 how to analyse the impact of bringing in new science technology or processes into the business.
  - K7 the importance of using appropriate documentation control systems and documentation identification and record (paper and computer based systems).
  - K8 the organisational requirements for maintaining the security of the workplace.
  - K9 the organisational structure including roles and responsibilities and lines of communication in your department, and the wider business environment.
  - K10 the limits of your own authority and to whom you should report if you have problems that you cannot resolve.
  - K11 the quality criteria (GDocP, GMP & QMS) that could be used for different types of documentation or processes within the sciences or technology related work activities.
  - K12 how to obtain and interpret records, charts, specifications, equipment manuals, history and technical support reports and other documents needed for the implementation of quality improvements.
  - K13 the science or technology related processes and standard operating procedures (SOPs) in the area associated with the quality issues.
  - K14 the factors that have to be taken into account when selecting the solution to a science or technology manufacturing quality process problem.
  - K15 methods and techniques involved in quality improvement implementation. K16 methods and techniques involved in evaluating information.
  - K17 organisational reporting procedures and documentation, and their application.
  - K18 whom to inform of actions taken, and by what means.
  - K19 how to retrieve the necessary data from company information systems.
  - K20 the types of impact assessment systems and techniques available, and their application.

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Maintain and improve quality documentation and processes for science or technology based industries



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