

Overview

This standard covers the competences you need to provide feedback to supervisors and team members working in a quality assurance environment.

You will be required to demonstrate that you can ensure the implementation, monitor and review the effectiveness of systems, procedures and practices for quality assurance and control within your organisation. Ensuring systems comply with all internal and external regulations.

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, implement and review the effectiveness of systems, procedures and practices within your organisation
 - P2 ensure systems comply with legal, internal and external regulations
 - P3 ensure members of the quality team and other workers relevant to the control and assurance of quality, are aware of the quality systems and their responsibilities
 - P4 support the development of quality standards and ensure that they are implemented, maintained, and improved when necessary
 - P5 identify appropriate key performance indicators and use these to ensure quality assurance measures and controls are being followed and monitored
 - P6 ensure all quality systems, procedures, practices and resources are effectively utilised and followed, reporting and responding to any deviation or non-conformances
 - P7 ensure deviations and non-conformances to the quality systems are reported, recorded and resolutions are acted upon
 - P8 provide support to the quality team, making sure the team is competent in the execution of their quality related responsibilities
 - P9 provide or support training and development to the quality team using an appropriate competency management system to identify and deliver appropriate training
 - P10 ensure relevant information is available to the team to ensure their effective contribution to quality assurance and control process
 - P11 support and encourage others in the development and implementation of and new ideas and improvements proposals
 - P12 take appropriate action to ensure adequate resources are available to support your actions
 - P13 record and report on quality assurance and control audits and self-inspections
 - P14 evaluate feedback from people, workers and relevant others to monitor and review the effectiveness of quality systems, procedures and practice
 - P15 provide support and advise to other areas of the organisation normally outside the area of responsibility, providing audit and inspections in accordance to procedures

Knowledge and understanding

You need to know and understand:

- K1 the organisations quality systems and procedures and the compliance needs to meet legal and regulatory requirements
- K2 the roles, responsibilities and accountability of others in quality assurance control team
- K3 the manufacturing and, or other process operations that produce products or service within the organisations operation
- K4 how to support and develop and implement new and improved quality standards and procedures
- K5 how to development key performance indicator to monitor and milestone improvements within the quality assure and control systems
- K6 how to use corrective action system to report, record and generate resolutions to issues and problems
- K7 how to support the training and development of others in the team, understanding how us the organisations competence system and processes to ensure competence in the workplace
- K8 how to select and support document management systems to support the activities of the quality assurance and control processes, these can be paper or computer or combined systems
- K9 the human resource systems within the organisation to appraise, develop and monitor performance of the quality team
- K10 the audit and inspection procedures within the organisations quality assurance and control system and how these can be supported, reported upon and recorded
- K11 commercial awareness of pharmaceutical products and overall science sector

Manage and Coordinate Quality Assurance Team Work Activities

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