

Overview

This standard covers the competencies you need to provide information and guidance to meeting organisational compliance in the business and to ensure regulatory and site quality requirements are in place and in accordance to current best practices, including Good Manufacturing Practice (GMP) to maintain compliance.

You will be required to support and input to the development of strategies and systems to ensure products and services meet the requirements of the organisational compliance, appropriate regulatory, product licenses and internal and external procedures for carrying out operations within life science environments.

This standard has been developed for persons responsible for regulatory activities whilst working in the life science sector. You are responsible with other members of the regulatory and quality teams for ensuring that all operations and procedures are processed and maintained in line with appropriate data security, regulatory, site and product license requirements.

Performance criteria

You must be able to:

- P1 identify and evaluate the regulatory and legislative activities required to meet the site operating, product license and marketing authority requirements
- P2 support and input to the development and design of regulatory strategies for relevant product quality and safety activities
- P3 support and input to the development of strategies for addressing risks and license issues
- P4 coordinate, support and communicate the plans for implementing licensing activities for all relevant regulatory business areas
- P5 monitor and maintain records on all change management related to regulatory changes to company processes and systems
- P6 provide reports and documentation in line with an communication strategy with regulatory authorities
- P7 evaluate and ensure the effective use of the reporting process and ensure appropriate audits are successfully completed
- P8 review all relevant licensing agreements, communicating and recording compliance and non-compliance in the appropriate organisational record system
- P9 review process to carry out the departmental checks in compliance with rules and regulations and other statutory requirements
- P10 review and update departmental functions, including cost structures, manufacturing processes and stock management to ensure compliance with rules and regulations and other statutory requirements
- P11 provide advice and support to the organisation in the application of product licensing and registration requirements
- P12 provide information on regulatory and licensing needs to different businesses and stakeholders in a timely manner
- P13 work with teams and individuals within the organisation to ensure all aspects of regulatory and compliance needs are effectively communicated

Knowledge and understanding

You need to know and understand:

- K1 the principles of strategic planning and what a strategic plan should cover
- principles of quality assurance, quality control and the distinction between them
- K2 the legislation, statutory codes, standards, frameworks and guidance appropriate to the organisation's operations and activities
- K3 your own roles, responsibilities and accountabilities with their limits and responsibilities
- K4 how internal and external influences may impact on the work of your organisation
- K5 how to work and communicate with regulatory authorities, agencies, and other stakeholders to maintain site license requirements
- K6 the use of the organisation's risk management and assessment process and reporting systems
- K7 the use of evidence based research relating to product quality and provision of services within the framework of license requirements
- K8 the principle of Good Manufacturing and Distribution Practices (GMP & GDP)
- K9 how to recognise areas for improvement against regulations, standards and best practice (GMP & GDP)
- K10 how to implement, monitor and evaluate systems, practices, policies and procedure
- K11 organisational policies and practices for monitoring and maintaining health, safety and security in the work environment
- K12 legal requirements, policies and procedures for the security and confidentiality of information
- K13 how to record written information with accuracy, clarity, relevance, an appropriate level of detail

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