
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 demonstrate that systems are able to gather information and guidance and ensure this information is available, delivered and used to meet organisational compliance ensure compliance to the appropriate regulators, site licenses, internal and external procedures for carrying out science operations within the business 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 determine the extent of the information and guidance required to support the regulatory compliance needs
 - P2 ensure the requirements for health, safety and security in the work environment are identified
 - P3 identify the legal, license and regulatory requirements relevant to your area of work responsibility
 - P4 work to and implement best practices including Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP)
 - P5 identify the social , environmental and ethical responsibilities
 - P6 obtain accurate interpretations of legal and regulatory requirements from specialists in your area of work internal and external to the organisation
 - P7 identify the organisation structure of accountability for legal, regulatory and quality responsibilities in your organisation
 - P8 identify the risks involved in non-compliance or non-conformance to regulatory or license requirements
 - P9 provide accessible, up-to-date information to the organisation and appropriate teams to ensure compliance and regulatory needs are met
 - P10 agree organisational responsibilities with decision makers, key people and stakeholders how they will be demonstrated
 - P11 develop clear and accessible plans for how your area of responsibility will comply with its legal, regulatory and license requirements
 - P12 ensure that systems are developed to monitor and maintain regulatory compliance and license requirements
 - P13 evaluate information and feedback about how your area of work performs in complying with responsibilities
 - P14 provide information to decision makers about how your area of work complies with its responsibilities
 - P15 make recommendations about changes or improvements to regulatory and compliance systems or processes
 - P16 provide feedback and reports on regulatory compliance information, including non-compliance data

Knowledge and understanding

You need to know and understand:

- K1 the European, UK and country specific legislation, statutory codes, standards, frameworks and guidance relevant to the legal, license and regulatory requirements relevant to your area of work
- K2 how to use and apply best working practices including Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP)
- K3 how to identify, collect, analyse, measure and assess data
- K4 how to promote your organisations legal and regulatory responsibilities
- K5 the requirements of health, safety and security in the work environment
- K6 the social, environmental and ethical responsibilities relevant to your area of work
- K7 the organisation structure of accountability for legal, regulatory and quality responsibilities in your organisation
- K8 the compliance risks involved in work processes and the effects of non-compliance to regulatory or license requirements
- K9 the organisations risk assessment process
- K10 how to identify, collate and communicate information to the organisation and appropriate teams and stakeholders
- K11 how to develop plans and instructions for your area of responsibility
- K12 how develop systems to monitor and maintain regulatory compliance and license requirements
- K11 how to develop or use systems to communication regulatory information and feedback in your area of work
- K13 the organisations change management system
- K14 improvement and problem solving techniques
- K15 how to manage ethical dilemmas and conflicts resulting from promoting organisational responsibilities
- K16 how to obtain accurate and timely reports of your organisations performance in complying with regulatory and license requirements
- K16 how to develop strategies to ensure compliance
- K17 how to manage and promote effective communication with colleagues, individuals and other stakeholders

COGREG-05

Gather, collate and provide information & guidance to meet organisational compliance



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