COGREG-01

# Analyse the Life Science business operations and identify the regulatory compliance needs

## Overview

This standard covers the competencies you need to analyse the business operations to ensure compliance to regulatory and site licensing requirements in accordance to current Good Manufacturing Practice (GMP) and Good Distribution Practice(GDP) to maintain compliance with the UK Statutory and EU Directives.

You will be required to demonstrate that systems are in place to ensure compliance to the appropriate regulators, site licenses, internal and external procedures for carrying out life science operations within the manufacturing and quality 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 the regulatory and license requirements that affect the manufacturing and operating processes within the organisation
P2 systematically review source information, data and documents related to regulatory and compliance requirements
P3 identify the commercial objectives of the organisations and how those are affected by the regulatory and license requirements
P4 use techniques to analyse compliance needs and assess the operating risks in the work areas
P5 assess the wider external market risks of the work areas
P6 use of best practice, including GMP and GDP to ensure compliance systems are effective
P7 define and document the responsibility, authority and interrelation of key personnel in regulatory control.
P8 establish an agreed balance between your organisation's commercial objectives and key requirements of regulation in consultation with senior management
P9 identify regulatory issues and trends which will impact on current and future business performance
P10 analyse and structure information to develop the organisations knowledge that can be communicated and shared internal and external to the organisation

## Knowledge and understanding

*You need to know and understand:*

K1 the life science regulatory environment in which the organisation operates
K2 detailed regulatory requirements that affect the process and manufacturing compliance requirements
K3 the commercial objectives of your organisation and how those are affected by the regulatory and compliance requirements
K4 the nature of different risks that must be considered when establishing the regulatory and compliance systems
K5 how to reach agreement with senior management about the commercial and regulatory balances within the business
K6 your organisation's practice and procedures for applying the regulatory and legislative requirements common to all employers/sectors
K7 your organisation's practice and procedures relating to the application of industry regulation, standard codes of practice and product license requirements
K8 your organisation's practice and procedures relating to the recognition, promotion and application of ethical standards.
K9 problems solving and improvements techniques

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| **Developed by** | Cogent |
| **Version Number** | 1 |
| **Date Approved** | March 2019 |
| **Indicative Review Date** | March 2024 |
| **Validity** | Current |
| **Status** | Original |
| **Originating Organisation** | Cogent |
| **Original URN** | COGREG-01 |
| **Relevant Occupations** | Science; Science and mathematics Science; Science Professionals |
| **Suite** | Regulatory Compliance Life Science |
| **Keywords** | Compliance, Regulatory, Life Science quality assurance, quality control |