COGREG-02

Analyse audits and inspections to ensure compliance to regulations in a Science Environment

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) to maintain compliance with the UK Statutory and EU Directives.

You will be required to analyse audits and inspections to ensure compliance to regulations in a Science Environment and demonstrate that systems are in place to ensure compliance to the appropriate regulators, site licenses, internal and external procedures for carrying out 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 analyse the results of audits, inspections and checks to ensure they are within the regulatory and product license requirements
P2 respond to deficiencies, discrepancies or non-conformance identified in the process of quality checking and auditing
P3 monitor batch and continuous production records for deviations in manufacturing, equipment, operations, distribution, and product quality
P4 maintain accurate records of all audits and actions related to compliance and non-compliance to regulatory requirement
P5 instigate and communicate actions for corrective and preventative actions (CAPA) as a result of non-conformance or quality issues
P6 maintain regulatory and quality practices in line with Manufacturing & Good Distribution Practices (GMP & GDP) and Good Documentation Practice (GDocP).
P7 ensure all relevant documentation provided by suppliers and other external agents is complete and accurate in accordance to supply chain procedures
P8 ensure issues outside your authority are escalated to the appropriate level to enable action in resolving issues
P9 monitor actions and activities
P10 monitor and record information in line with internal audit procedures and supplier auditing requirements
P11 identify where regular inconsistencies in supplies occur and ensure resolution to these issues
P12 make recommendations to colleagues and technical staff where failure against specifications suggests that a new source of supply is needed
P13 make recommendations to colleagues and technical staff regarding the suitability of the criteria used as a measure of acceptance

Knowledge and understanding

You need to know and understand:

K1 the policies, guidelines and legislation relating to sources and supply of raw materials relevant to the workplace and products within manufacturing and storage
K2 your organisation's supply chain assurance guidelines, policies, audit requirements, and how they are applied
K3 the principles of corrective and a preventative action process (CAPA)
K4 the principles and implementation of GMP, GDP and GDocP
K5 the types and sources of raw materials, intermediates items and products manufactured or distributed by the organisation
K6 the control and sampling methods appropriate to type and source of supply or manufactured products
K7 the potential methods, sources and types of product contamination that can be encountered during product manufacture, transportation and delivery
K8 how contamination during transportation and delivery can be identified
K9 the range of checks that can be applied to ensure that delivered is safe
K10 the recording systems that are in place to record data related to accepted and declined deliveries
K11 the impact that external audit requirements have upon the acceptance
K12 the range of data that is used to support external audits
K13 the requirements for certificates of conformity
K14 the procedures to ensure product and manufacturing traceability K15 the product specifications for raw materials and supplies
K16 the corrective actions to be taken when an item is received that does not conform with product specification

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Developed by	Cogent
Version Number	2
Date Approved	30 Mar 2025
Indicative Review Date	30 Mar 2030
Validity	Current
Status	Original
Originating Organisation	Cogent
Original URN	COGREG-02
Relevant Occupations	Science, Science and Mathematics Science, Science Professionals
Suite	Regulatory Compliance Life Science
Keywords	Compliance, Regulatory, Life Science quality assurance, quality control