COGREG-06L

Ensure compliance and respond to issues or deviation from standards or best practice in a Life Science Environment LEGACY

Overview

This standard covers the competencies you need to support the business operations to ensure the effective handling of complaints, issues and non-conformance to maintain compliance with regulatory UK Statutory and EU Directives and site licensing requirements in accordance to current Good Manufacturing Practice (GMP).

You will be required to support the resolution of non-compliance, or deviation from standard or best practice, record, liaise and communicate externally with the regulators and internally with business management as a result of issues or complaints.

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 work in accordance to organisational procedures and documentation for non-compliance issues
P2 work in accordance to organisational procedures and best practice to action corrective or preventative work
P3 consider historical compliance issues to develop new strategies and standard operating procedures (SOPs) to prevent reoccurrence of problems
P4 ensure validation processes are in place and appropriately monitored and reviewed in line with SOPs
P5 maintain routine monitoring and auditing requirements as specified by SOPs and in accordance to GMP
P6 keep and maintain good quality and compliance records
P7 check that equipment used in manufacturing or testing is performing correctly and safe to use
P8 ensure an appropriate escalation process is in place for consideration of corrective and preventive actions outside the areas of your responsibility
P9 identify non-compliance to relevant standards or deviation from approved procedures
P10 report non-compliance to relevant standards or deviation from approved procedures to appropriate persons or department for further action
P11 take appropriate corrective and or preventative action in response to compliance issues
P12 communicate appropriately internally and or externally to the organisation any corrective and or preventative actions in response to compliance Issues
P13 monitor compliance improvement work through inspection, meetings and correspondence
P14 develop communication channels with internal teams and external regulatory groups, including the Inspection Action Group (IAG) to ensure expedient handling of issues and non-conformance
P15 support the development of good practices, including the support in writing of appropriate SOPs to ensure maintenance of quality systems and regulatory compliance
P16 plan and conduct regular audits and inspections of systems, process and procedures
P17 support the audit process conducted by external bodies, including the regulatory inspector**

Knowledge and understanding

You need to know and understand:

K1 the life science regulatory environment in which the organisation operates
K2 the Principles of Good Manufacturing Practice and associated guidelines and standards
K3 the relevant organisations Standard Operating Procedures (SOPs) relevant to compliance, quality control and regulatory requirements
K4 your personal responsibilities and accountabilities
K5 the scientific knowledge and expertise that relate to the product and or process non-conformance being reported to Marketing Authority (MA)
K6 the up-to-date regulations and how to keep abreast with the latest regulatory environment
K7 the principles of problem solving and able to resolve issues or escalate to appropriate persons
K8 the formats and methods of submitting non-conformance applications to regulatory authority including paper and electronic systems
K9 how and when to communicate to the internal and external organisations, regulator, MA and other stakeholder parties in the event of issues or nonconformities
K10 how to analyse, collate and prepare data and information to write technical reports and submission
K11 how to consider previous conformance issues in the past and how to develop new procedures and strategies to prevent reoccurrence

Glossary

Preventive action: to eliminate the cause of potential nonconformity or other undesirable potential situation

- There can be more than one cause for a potential nonconformity
- Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent recurrence

Corrective action: to eliminate the cause of a detected nonconformity or other undesirable situation

- There can be more than one cause for a nonconformity
- Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence
- There is a distinction between correction and corrective action

Correction: to eliminate a detected nonconformity

- A correction can be made in conjunction with a corrective action
- A correction can be, for example, rework

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