COGREG-07

Prepare submissions to regulatory authorities for approval of products in a Life Science Environment

Overview

This standard covers the competencies you need to support 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 ensure regulatory applications for a medicinal products including any documentation or information submitted to a regulatory agency for review or approval, using appropriate formats including paper or electronic, or both.

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 scientific rationale and data in preparation for submissions to regulatory marketing authority (MA)
P2 support the writing of study reports and compilation and assembling of information in preparation for submission
P3 plan the submission to ensure applications contain the appropriate information using checklists for examples standard operating procedures (SOPs)
P4 use standardised templates to ensure consistency and schedule (project) planners to ensure timelines are maintained
P5 Prepare in accordance to template requirements and submit in accordance to application process
P5 identify the benefits and types of risks associated with the product or process being submitted
P6 ensure all applications are submitted in accordance to up to date regulatory requirements using acceptable format, process and route of application submission forms
P7 ensure all submissions use data that is reliable, of high quality and integrity
P8 maintain effective and efficient communication with regulatory authorities throughout the submission process, including pre and post submission
P9 maintain effective and efficient communication within the regulatory, quality and manufacturing teams

Knowledge and understanding

You need to know and understand:

K1 the life science regulatory environment in which the organisation operates
K2 the scientific knowledge and expertise that relate to the product and or process being considered in any submission to MA
K3 the up-to-date regulations and how to keep abreast with the latest regulatory environment
K4 the planning and project management process involved in new products application to MA
K5 the principles of good manufacturing practice (GMP)
K6 how to develop standing operating procedure (SOPs)
K7 the principles of problem solving and able to resolve issues or escalate to appropriate persons
K8 the formats and methods of submissions to the MA including paper and electronic systems
K9 how to communicate to the internal and external organisation, MA and other stakeholder parties when required
K10 how to analyse, collate and prepare data and information to write technical reports and submission

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