COGREG-04

Maintain Pharmacovigilance in the Life Science Environment

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 the use of systems, procedures and processes to maintain compliance to the regulatory requirements in maintaining Pharmacovigilance, including the use of appropriate product and packaging labels and dealing with complains and product recalls.

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 use and maintain the marketing authorisation holder's pharmacovigilance system
P2 monitor medicinal product safety profiles and any emerging safety concerns
P3 ensure the conditions or obligations of the marketing authorisations relating to safety or the safe use of the products
P4 consider and apply risk minimisation measures
P5 monitor risk management plans
P6 support the review and sign-off of protocols of post-authorisation safety studies
P7 use and support the submission of all pharmacovigilance-related documents in accordance with the legal requirements
P8 ensure the necessary quality, correctness and completeness, of pharmacovigilance data
P9 respond to any request from the competent authorities for the provision of additional information necessary for the benefit-risk evaluation of a medicinal product
P10 provide input into the preparation of regulatory action in response to emerging safety concerns
P11 maintain oversight over the functioning of the system in all relevant aspects, including its quality system
P12 maintain awareness of the validation status in any database used in the process, including any failures and corrective actions that have been taken to address the failures
P13 ensure the labelling of products and packaging meets the information, format and style in accordance to the regulatory requirements for the safe use of the medicine
P14 ensure all labelling is consistent and meets regulatory requirements regardless of the packaging medium, for example small containers or blister packs
P15 follow the procedures in response to receiving a complaint, taking appropriate actions to resolve, handle or escalate the issue to appropriate persons
P16 use the organisations record system to record all complaints, actions and resolutions
P17 follow special procedures in the event of suspected quality issues related to falsified products
P18 facilitate, support and communicate internal or external quality defect and regulatory investigation
P19 ensure the appropriate use of GMP to ensure that patient and animal safety is maintained

P20 ensure recall operations are capable of being initiated promptly and at any time to protect public or animal health prior to establishing the root cause(s) and full extent of the quality defect
P21 develop and communicate a final report on completion of complaint or recall issue

Knowledge and understanding

You need to know and understand:

K1 the UK & European legal, license and regulatory requirements relevant to your area of work
K2 the marketing authorisation (MA) holder's pharmacovigilance system
K3 the conditions or obligations of the marketing authorisations relating to safety or the safe use of the products
K4 use and monitor risk management system and plans
K5 the review and sign-off of protocols of post-authorisation safety studies
K6 how to support the submission of all pharmacovigilance-related documents in accordance with the legal requirements
K7 how to maintain the necessary quality, correctness and completeness, of pharmacovigilance data
K8 the required response to regulatory actions emerging from safety concerns
K9 the functions and operation of the organisations quality system
K10 how to maintain awareness of the validation status of the database, including failures and corrective actions
K11 the labelling of products and packaging regulations in accordance to the regulatory requirements for the safe use of the medicinal product
K12 how to deal with the receipt of a complaint and the actions to resolve, handle or escalate the issues
K13 the use of the organisations record system to record all complaints, actions and resolutions
K14 the quality issues related to falsified products
K15 the communication process for internal or external quality defect and regulatory investigation
K16 the appropriate use of Good Manufacturing Practice (GMP) to ensure patient safety is maintained
K17 the product recall procedures and operations in accordance to regulatory requirements
K18 how to develop and communicate reports on completion of complain or recall issue

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