COGSQP-09

Maintain License Requirements and Good Manufacturing Practice (GMP) to Ensure Compliance

Overview

This standard covers the competencies you need to Maintain License requirements and current Good Manufacturing Practice (GMP) to ensure compliance with the UK Statutory Instruments and EU Directives.

You will be required to demonstrate that you can work with the quality (licensing) team in order to ensure that the appropriate licenses are in place for carrying out life science facilities operations. You will liaise with the licensing authorities to ensure appropriate documents and licenses are available at the time of selling, importing or exporting pharmaceutical products.

This standard has been developed for Qualified Persons working in the medicinal products sector. The Qualified Person is responsible for ensuring that each individual batch is has been manufactured and checked in compliance with laws in force in the Member States where certification takes place, in accordance with the requirements of the marketing authority (MA) and with Good Manufacturing Practice (GMP).

Performance criteria

You must be able to:

P1 identify and evaluate all regulation and legislation needs for licensing activities in accordance to both the organisational premises (site) operating licence and as a marketing authority holder (MAH) licence
P2 design compliance strategies for all relevant businesses areas and activities, including strategy for addressing risks and issues
P3 ensure appropriate licensing activities are implemented for relevant business groups
P4 ensure timely application and approval of licenses and monitor validity and expiry of all licensing documents which are required to carry out export and import operations
P5 monitor and maintain records on all compliance trends, making any recommendations for changes related to company processes and systems
P6 ensure all appropriate reports are completed for medicinal products and manage all communications with licensors
P7 evaluate the effective use of the reporting process and ensure appropriate audits are successfully completed
P8 monitor and review all relevant licensing agreements, communicating and recording compliance and non-compliance in the appropriate organisational record system
P9 maintain and update all distribution lists and manage all correspondence with licensed partners.
P10 review reports to carry out the departmental checks in compliance with rules and regulations and other statutory requirements
P11 review and update departmental functions, including cost structures, manufacturing processes and stock management to ensure compliance with rules and regulations and other statutory requirements
P12 ensure regulatory compliance by identifying any variations or deviation from the regulatory guidelines
P13 provide advice on any corrective actions required to ensure deviations or non-compliance to regulations are resolved
P14 ensure communication of updated information on regulatory and licensing needs to different businesses and stakeholders in a timely manner
P15 obtain and exchange information from across teams and businesses needed to confirm adherence to compliances
P16 establish, ensure and maintain protocol for sharing of regulatory and statutory-related information for licensing to prevent risk issues
P17 ensure and maintain confidentiality of organisational data

Knowledge and understanding

You need to know and understand:

K1 the strategies in your organisation that ensure compliance in all relevant business operations, processes and activities
K2 the principles of Good Manufacturing Practice (GMP) applied in your organisation
K3 the strategies in your organisation for addressing risks and issues in all relevant business operations, processes and activities,
K4 the requirements to meet all relevant internal compliance policies and procedures in your organisation
K5 the requirement to meet all relevant regulatory licensing compliance in your organisation
K6 the documentation policies, templates and any software used in your organisation
K7 the defined procedure for reporting compliance risks and occurrences in your organisation
K8 the range of products and licensing needs associated with them in your organisation
K9 the relationships of your organisation with all other licensors and licensed partners
K10 the communication protocols in your organisation:
K11 the legal and contracting procedures pertaining to the product manufacturing
K12 the supply chain management, operations and business in your organisation
K13 the contracts, tariffs and governments import and export regulation in accordance to the marketing authority holder (MAH) licence
K14 the implications of not complying to defined regulations and license agreements
K15 any supply chain best practices

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