SFLGDP1- HP97 04

Develop, implement and maintain a quality system to control the distribution of medicinal products

Overview

What this standard is about

This standard is about developing, implementing and maintaining a quality system to control the distribution of medicinal products.

You will be responsible for developing the quality system and ensuring colleagues understand their role and responsibilities as well as monitoring the implementation to ensure it complies with legislative requirements.

The quality system should include: the supply chain activities of procuring, holding, supplying or exporting medicinal products, excluding supply to the public, to ensure product integrity and compliance with the current legislation, regulations and guidelines.

Who this standard is for

This standard is for the nominated Responsible Person engaged in the distribution of medicinal products.

Performance criteria

You must be able to:

1. Confirm your **quality system** relates to the control of the distribution of **medicinal products** including roles and interrelationships, organisational charts and all processes and risk management principles
2. Develop, implement and update a **quality system** to control the distribution of **medicinal products**
3. Confirm that all distribution activities are clearly defined and systematically reviewed to ensure relevant quality standards are met
4. Monitor the effectiveness of the **quality system** and take appropriate corrective and preventative action (**CAPA**) as necessary to ensure management of distribution processes
5. Update colleagues about their roles and responsibilities in meeting relevant quality standards
6. Ensure the size, structure and complexity of the distributor's activities are fully considered when developing or modifying the **quality system**
7. Implement an effective and proportionate **change control system** in the quality system
8. Ensure the **quality system** is **formally documented** and includes an internal process management review
9. Ensure the **quality system** covers outsourced activities
10. Ensure the **quality system** incorporates quality risk management (QRM) which is based upon scientific knowledge and is linked to the protection of the patient
11. Maintain the quality system ensuring it meets relevant legislative and organisational requirements

Knowledge and understanding

You need to know and understand:

1. Your organisation's **quality system** in relation to the distribution of **medicinal products**
2. The responsibilities, roles and inter-relationships in your organisation
3. All activities of your organisation in relation to the distribution of **medicinal products**
4. The importance of keeping up to date with current developments, tools and techniques in quality management, customers' and other stakeholders' quality expectations
5. The importance of keeping colleagues up to date about their role in meeting **Good Distribution Practice** quality standards in line with relevant legislation and organisation needs
6. How to take, and the scope of, appropriate corrective and preventative action **(CAPA)**
7. The importance of ensuring systems and plans are in place to meet quality standards
8. The importance of communicating information accurately
9. The **formal documentation** required for your organisation's **quality system** and the internal management review process
10. The appropriate **corrective and preventative action (CAPA)** in response to deviations from established procedures and why these should be investigated
11. The importance of documenting **corrective and preventative action (CAPA)** in line with the relevant standards and legislation
12. The scope and boundaries of outsourced activities
13. How to develop, implement and maintain a **quality system** to control the distribution of **medicinal products**

Scope/range related to performance criteria

Quality system includes all items as per the MHRA rules and guidance:

- Clearly specified management responsibilities
- Delivery to the right recipients within a satisfactory time period
- Making records contemporaneously
- Documentation and investigation of deviations from established procedures
- Taking appropriate CAPA, in line with the principles of quality risk management, where there are deviations from established procedures
- Maintaining written job descriptions for key positions and the arrangements for deputising
- Appointed Responsible Person (RP)

Scope/range related to knowledge and understanding

Formal documentation for the quality system should include:

- Achievement of quality system objectives
- Assessment of Key Performance Indicators (KPIs) including: complaints, deviations, CAPA, changes to processes, outsourced activities, self-assessment processes (risk assessments and audits), external assessments (inspections, findings and customer audits)
- Emerging regulations, guidance and quality issues
- Innovations to enhance the quality system
- Changes to the business environment and objectives
- Quality manual

Glossary

Good Distribution Practice
Is the part of quality assurance which ensures that the quality of medicinal products is maintained through all stages of the supply chain. This refers to the procurement, holding, storage or distribution of medicinal products to retailers, pharmacies, wholesale dealers or person authorised to supply medicinal products that must be in possession of the relevant authorisation issued by the Secretary of State. The distribution of medicinal products includes those for both human and veterinary use and must comply with the EU rules and guidelines on Good Distribution Practice.

CAPA
Corrective and Preventative Action

Change control system (incorporating QRM principles)
The common or shorthand name in the industry for the "Rules and Guidance for Pharmaceutical Distributors" which is published and kept up to date by the Medicines and Healthcare products Regulatory Agency (MHRA).

Medicinal products
Any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or animals is likewise considered a medicinal product.

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