SFLGDP5 - HP98 04

Manage resources to ensure compliance with the requirements of Good Distribution Practice

Overview

What this standard is about

This standard is about managing resources to ensure compliance with the requirements for Good Distribution Practice. The organisation will be engaged in the distribution of medicinal products to ensure product integrity and compliance with the current legislation, regulations and guidelines

You will be responsible for managing the premises, staff and equipment to ensure the storage and delivery environments for medicinal products meet the manufacturers and regulatory guidelines.

Who this standard is for

This standard is for the nominated Responsible Person and all relevant staff engaged in the distribution of medicinal products.

Performance criteria

You must be able to:

1. Manage premises, equipment and other resources including security, access and environment to ensure compliance with the requirements of **Good Distribution Practice**
2. Ensure premises and equipment can store and deliver **medical products** according to the conditions specified by the manufacturer
3. Ensure areas for the receipt of goods provide protection in line with the requirements of **Good Distribution Practice**
4. Confirm arrangements for product segregation comply with the relevant regulatory, manufacturer requirements and **Good Distribution Practice**
5. Manage premises to ensure they are kept clean and pest free in line with regulations and the requirements of **Good Distribution Practice**
6. Confirm all monitoring equipment is correctly calibrated
7. Manage the maintenance of all equipment to the standard required to ensure compliance with the requirements of **Good Distribution Practice**
8. Keep documented records of all repairs, maintenance, calibration and validation activity
9. Ensure Standard Operational Procedures (SOPs) are followed at all times and any deviations are correctly documented, investigated and resolved
10. Ensure the roles, responsibilities and inter-relationships of key personnel are clearly documented and communicated including arrangements for deputising
11. Ensure adequate numbers of competent personnel are available for distribution activities at all times

Knowledge and understanding

You need to know and understand:

1. How to manage premises, equipment and other resources to ensure compliance with the requirements of **Good Distribution Practice**
2. Methods to ensure premises and equipment can store and deliver **medical products** according to the conditions specified by the manufacturer
3. Methods to ensure areas for the receipt of goods provide appropriate protection in line with the requirements of **Good Distribution Practice**
4. How to ensure that arrangements for product segregation comply with the requirements of relevant regulations, manufacturers and **Good Distribution Practice**
5. How to manage premises to ensure they are kept clean and pest free in line with relevant regulations and the requirements of **Good Distribution Practice**
6. Methods to ensure all monitoring equipment is correctly calibrated
7. Ways of maintaining equipment to the required standard to ensure compliance with the requirements of **Good Distribution Practice**
8. Types of documented records relevant for all repairs, maintenance, calibration and validation activity
9. The importance of ensuring Standard Operational Procedures (SOPs) are followed at all times and that deviations are correctly documented, investigated and resolved
10. Methods to ensure the roles, responsibilities and interrelationships of key personnel are clearly documented and communicated including arrangements for deputising
11. Ways to ensure that adequate numbers of competent personnel are available for distribution activities at all times

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 who 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

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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