SFLGDP6 - HP96 04

Receive and store medicinal products in a warehouse environment to meet Good Distribution Practice

Overview

What this standard is about

This standard is about the receiving and storage of medicinal products into a warehouse environment to meet Good Distribution Practice. Particular attention is paid to the relevant legal requirements that relate to the Pharmaceutical sector and the various storage conditions that are required to ensure that medicinal products and medicinal appliances remain fit for purpose and stored in a secure environment.

Operatives will work within their own organisational requirements that relate to the way in which pharmaceutical storage services are provided in the workplace. Users of this standard will need to ensure that practice reflects up to date information and policies.

Personnel should be familiar with the particular requirements and organisational procedures involved with working with medicinal products and how legislation regarding Good Distribution Practice relates to everyday duties and work roles.

Who this standard isfor

This standard is relevant to all warehousing and storage operatives in logistics operations who deal with the safe storage and receipt of medicinal products and goods.

Operatives could, for example, be working with medicinal products in warehousing and storage, transportation, or import or export forwarding

Performance criteria

You must be able to:

1. Confirm tasks, priorities and responsibilities with colleagues and the person setting them
2. Follow health and safety and **Good Distribution Practice** procedures related to **Personal Protective Equipment** when moving, handling, receiving and placing goods in correct storage area
3. Confirm the area used to receive the medicinal products is clean and contains no obstructions or hazards
4. Carry out relevant checks confirming deliveries against the delivery note, original notification and control data
5. Carry out relevant checks on load condition, vehicle temperature and recording equipment during transit
6. Identify the correct **storage areas or locations** and special storage requirements for received goods
7. Follow organisational procedures for quarantine and sampling requirements
8. Place received goods into the correct **storage areas or locations** taking account of security procedures, special storage requirements and stock rotation
9. Notify the **responsible person** of the availability of stock where the goods are for a special or outstanding order using the appropriate process
10. Follow own organisational procedures for safe storage and control of **products** related to maintenance and disposal of **medicinal products** and **Good Distribution Practice**
11. Carry out checks of **storage areas or locations** at regular intervals to ensure they continue to meet organisational guidelines, product requirements, correct environmental conditions and remain fit for purpose
12. Carry out stock checks at regular intervals following organisational guidelines to ensure **medicinal products** and stock information remains accurate and fit for purpose
13. Manage requests for **recalls or alerts** following agreed organisational and manufacturer guidelines
14. Complete all relevant documentation in accordance with organisational procedures for received goods, stock rotation, stock checks, damaged goods and authorised disposals
15. Carry out organisational checks to avoid falsified or counterfeit products entering the storage facility

Knowledge and understanding

You need to know and understand:

1. Requirements for **Personal Protective Equipment,** standards of appearance and methods for maintaining your equipment and work area
2. Own organisational procedures, manufacturers guidance and relevant legal requirements for safe and secure storage of **medicinal products**
3. How to follow your organisational procedures and manufacturers guidance related to receiving, storing, disposing and maintaining **medicinal products**, including only receiving stock identified on the original order, expiry dates and batch numbers
4. Specific health and safety requirements related to receiving, maintaining and disposing of **medicinal products**
5. The procedures and actions to take when alerts and company or manufacturer recalls are received and the importance of doing so immediately
6. How to identify and maintain safe **storage areas or locations** and secure storage environments
7. The storage requirements for different types of products and why they are important
8. The role and purpose of an effective stock taking program, the checking of expiry dates, lot and batch codes required for audit trace and how this affects daily operations
9. The importance of recording stock information and to whom this should be reported
10. The importance of taking special storage information and security requirements into consideration
11. The action to be taken if stock is unavailable due to it being beyond expiry date, damaged, contaminated or has an inconsistent batch number or a batch number for which **recalls or alerts** have been issued
12. The organisational procedure for inputting and retrieving stock data
13. Methods of checking for possible falsified or counterfeit products, what to do if this occurs and who to notify if suspicions arise

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.

Personal Protective Equipment (PPE)
Personal protective clothing and equipment.

Storage area or location: including caged/secure work areas, sole medicinal product storage facilities and partially medicinal product facilities.

Responsible Person: the nominated person who is held accountable for delivering the requirements of GDP as defined in European Guidelines 2013/C 68/01 and:
• Should be continuously contactable
• Should fulfil responsibilities personally
• Can delegate *duties* but not *responsibilities*

Products
Could include hazardous and non hazardous products, medicinal gases, combustibles, flammable liquids and solids, radioactive and temperature sensitive products etc.

Recalls or alerts: including manufacturers, governmental, health service, or potential forgery information/bulletins

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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