SFLGDP6

Receive and store medicinal products in a warehouse environment to comply with the requirements of Good Distribution Practice

Overview

This standard is about receiving and storing medicinal products in a warehouse environment to comply with the requirements of Good Distribution Practice (GDP). Good Distribution Practice (GDP) includes the legal requirements for the pharmaceutical sector, and the storage conditions that are required for medicinal products and medicinal appliances.
Operatives will follow organisational requirements relating to pharmaceutical storage, and maintain practice that reflects up-to-date information and policies.
Operatives should be familiar with the particular requirements and organisational procedures for working with medicinal products, and how legislation regarding Good Distribution Practice (GDP) relates to everyday duties and work roles.

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.

Performance criteria

You must be able to:

1. confirm the tasks, priorities and responsibilities for receiving and storing medicinal products in a warehouse environment with the relevant colleagues
2. comply with the relevant health and safety and Good Distribution Practice (GDP) procedures relating to Personal Protective Equipment (PPE) when moving, handling, receiving and placing medicinal products in storage areas or locations
3. confirm the area being used to receive medicinal products is clean and contains no obstructions or hazards
4. check deliveries against the delivery note, original notification and control data
5. sign for the received delivery, once all have been confirmed as received and matched against the original notification
6. undertake the relevant inspections on load condition, vehicle temperature and recording equipment for received medicinal products
7. follow the organisational procedures when checking medicinal products to avoid falsified or counterfeit products entering the storage facility
8. confirm the storage areas or locations and storage requirements for received medicinal products are in accordance with organisational guidelines, product requirements and environmental conditions
9. follow the relevant organisational procedures for quarantine and sampling requirements
10. place received medicinal products into the storage areas or locations, according to organisational security procedures, storage requirements and stock rotation
11. notify the Responsible Person of the availability of stock where the medicinal products are for an urgent or outstanding order
12. follow the organisation’s procedures relating to the maintenance and disposal of medicinal products and Good Distribution Practice for the safe storage and control of products
13. undertake checks of the storage areas or locations and the storage requirements, in accordance with organisational guidelines, to ensure their continued suitability for the medicinal products
14. undertake stock checks, in accordance with organisational guidelines, to maintain and check medicinal products and stock information

15. manage requests for recalls or drug alerts following the agreed organisational and manufacturer's guidelines
16. complete documentation in accordance with organisational procedures for received medicinal products, stock rotation, stock checks, damaged goods and authorised disposals
17. comply with organisational procedures and the relevant legal, environmental, health and safety, bio-security and operating requirements relating to the receipt and storage of medicinal products

Knowledge and understanding

You need to know and understand:

1. how to receive and store medicinal products in a warehouse environment to comply with the requirements of Good Distribution Practice (GDP)
2. the requirements for Personal Protective Equipment (PPE), standards of appearance and methods for maintaining your equipment and work area
3. your organisation's procedures, manufacturers' guidance and the relevant legal requirements for safe and secure storage of medicinal products
4. how to follow organisational procedures and manufacturers' guidance for receiving, storing, disposing of and maintaining medicinal products
5. the health and safety requirements relating to receiving, maintaining and disposing of medicinal products
6. how to identify and maintain safe storage areas, or locations, and secure storage environments, where applicable
7. the storage requirements for products and why they are important
8. the role and purpose of a stocktaking programme, expiry dates, lot and batch codes for audit trace, and how these affects daily operations
9. the organisational requirements of recording stock information and to whom this should be reported
10. how to take special storage information and security requirements into consideration
11. how to, and the importance of, undertaking checks of the storage areas or locations
12. how to, and the importance of, undertaking stock checks in accordance with organisational guidelines
13. the procedures and actions to take when recalls or drug alerts are received from the manufacturer
14. the action to be taken with stock that is beyond its expiry date, damaged, contaminated or has an inconsistent batch number, or a batch number for which recalls or drug alerts have been issued
15. the organisational procedure for inputting and retrieving stock data
16. methods of checking for falsified or counterfeit products, what to do if they are found, and who to notify
17. the organisational procedures and the relevant legal, environmental, bio-

security and operating requirements for the receipt and storage of medicinal products

Glossary

Colleagues:

supervisor, line manager, co-worker

Good Distribution Practice (GDP):

the part of quality assurance that 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 the 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:

a substance or combination of substances administered to humans or animals through injection, application, oral ingestion, inhalation, and so forth, whose purpose is to treat or prevent disease

Personal Protective Equipment (PPE):
personal protective clothing and equipment, branded workwear

Products:

hazardous and non-hazardous products, medicinal gases, combustibles, flammable liquids and solids, radioactive and temperature sensitive products, etc

Recalls or drug alerts from: manufacturers, the government, the health service, or potential forgery information/bulletins

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*

Storage areas or locations:

caged/secure work areas, sole or partial medicinal product storage facilities

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