

EUCOMED Position Paper

Good Distribution Practice (GDP)

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1. Introduction

To maintain the quality of the products and the quality of the service offered by distributors, EUCOMED has developed these guidelines to provide distributors with recommendations on Good Distribution Practice.

2. Principle

The European medical device industry operates at a high level of quality assurance, achieving its objectives by establishing and maintaining quality management systems, which are normally certified to EN ISO 9001 and EN ISO 9002 and to EN 46001 and EN 46002, for the manufacture of devices. This policy ensures that products released for distribution are of appropriate quality.

Quality management systems should be established and maintained throughout the supply chain to ensure the quality of medical devices is not adversely affected during their distribution and to ensure that appropriate records are kept.

Distributors of medical devices should ensure that those products that they handle have been placed on the market in accordance with European and national legislation, that correct storage conditions are observed at all times, including during transportation and that contamination from other products is avoided. They should also ensure that there is adequate turnover and stock rotation and that where the distributor is responsible for stock levels these are appropriate to support demand. Products must be stored in appropriately safe and secure areas. In addition, distributor's quality management systems should ensure that the right products are delivered to the right addressee within a satisfactory time period. Appropriate records must be kept and these should include, where relevant, records of the customers to which particular batches of product (or in appropriate cases, individually identified products) were sent. Adverse incidents must be properly reported to the manufacturer.

3. Personnel

A management representative should be appointed in each distribution location, who should have defined authority and responsibility for ensuring that a quality system is implemented and maintained. He should fulfil his responsibilities personally. Such managers should be appropriately trained and experienced and should be retrained at appropriate intervals.

Key personnel involved in the warehousing of medical devices should have the appropriate ability and experience to ensure that the products are properly stored and handled.

Personnel should be trained in the duties assigned to them, particularly regarding vigilance, and records to be maintained.

4. Documentation

Although the Medical Devices Directive (93/42/EEC) does not place a specific requirement on distributors with regard to any documentation from distributors, local law may differ.

5. Procedures

The distributor's quality management system should include written procedures appropriate to the different operations carried out by the distributor including vigilance, receipt and checking of deliveries, storage, cleaning and maintenance of the premises. This includes recording of the storage conditions, security of stocks on site and of consignments in transit, withdrawals from saleable stocks, records, including records of clients' orders, returned products, recall trends, pest control, etc. These procedures should be approved, signed and dated by the responsible person.

6. Records

Records should be made at the time each operation is carried out, and in such a way that all significant activities or events are traceable. Records should be clear and readily available. They should be retained for a period of 10 years or expected lifetime of the product unless indicated otherwise by the supplier. Records should be kept of each purchase and sale (including loan and consignment devices), showing the date of purchase or supply, name of the medical device, quantity received or supplied and

name and address of the supplier or consignee. For transactions between manufacturers and distributors and between distributors, records should ensure the traceability of the origin and destination of product, for example by use of batch numbers, so that all the suppliers and consignees can be identified.

7. Premises and Equipment

Premises and equipment should be suitable and adequate to ensure proper conservation and distribution of medical devices. Premises should be constructed and maintained so as to protect materials from potentially harmful influences. Monitoring devices, where appropriate, should be calibrated.

8. Receipt

Receiving bays should protect deliveries from bad weather during unloading. The reception area should be separate from the storage area. Deliveries should be examined on receipt, in order to check that containers are not damaged and that the consignment corresponds to the order.

Medical devices subject to specific storage measures should be immediately identified and stored in accordance with manufacturers' instructions.

9. Storage

Medical devices should normally be stored apart from other goods and under the conditions specified by the manufacturer, in order to avoid any deterioration by light, moisture or temperature. The storage areas should be sufficiently large and should have physically separated zones so that orderly, segregated storage is possible.

Temperature should be monitored and recorded periodically where appropriate.

Storage areas should be cleaned and accumulated waste removed at regular intervals. The frequency and methods of cleaning the premises and areas should be recorded.

Smoking, eating and drinking should be permitted only in segregated areas, and not in those areas used for storage and handling of the product.

Adequate toilet and changing facilities should be provided. These should be isolated from the main storage area.

Adequate precautions should be taken against spillage or breakage and contamination.

There should be a system to ensure stock rotation (first in, first out or first expiration date), with regular checks that the system is operating correctly. Products beyond their expiry date or shelf life should be separated from usable stock and neither sold nor supplied.

Medical devices with broken seals, damaged packaging, or suspected of possible contamination should be withdrawn from saleable stock, and if not immediately destroyed, they should be kept in clearly separated areas, so that they cannot be sold in error or contaminate other goods.

10. Deliveries to Customers

For all supplies to customers a document must be enclosed, making it possible to ascertain the date, the name of the medical device, the quantity supplied, the lot number and the name and address of the supplier and addressee. Proof of delivery transactions should be used.

Medical devices should be transported in such a way that:

- their identification is not lost;
- adequate precautions are taken against spillage, contamination or theft;
- they are secure and not subject to unacceptable degrees of heat, cold, light, moisture or other adverse influence, nor to attack by micro-organisms or pests;
- medical devices requiring controlled temperatures and storage should also be transported by appropriate means.

11. Returns of Non-defective Medical Device Products

Non-defective medical devices, which have been returned should be kept apart from saleable stock to prevent from further distribution until a decision has been reached regarding their disposal.

Products which have left the care of the distributor should only be returned to stock if:

- the goods are in their original and sealed containers and in good condition;
- it is known that the goods have been stored and handled under proper condition;
- the remaining shelf life period is acceptable;
- they have been examined and assessed by a person authorised to do so. This assessment should take into account the nature of the product, any special storage conditions it requires and the time elapsed since it was issued. Special attention should be given to products requiring special storage conditions. As necessary, advice should be sought from the manufacturer of the product;
- records of returns should be kept. The responsible person should formally release goods to be returned to stock. Products returned to saleable stock should be placed so that the first in, first out, first expiry system operates effectively.

12. Emergency Plans and Recalls

A recall procedure should be described in writing. Any recall operation should be carried out only after full consultation with the manufacturer and should be recorded at the time it is carried out and records should be made available promptly to the manufacturer.

In order to ensure the efficacy of the recall procedure, the system of recording of deliveries should enable all those involved in the supply chain to be identified and contacted. In the case of recall, distributors may decide in consultation with the manufacturer to inform either all their customers of the recall or only those having received the batch to be recalled.

All customers to whom the product was distributed should be informed with the appropriate degree of urgency. This includes customers in other Member States.

The message should request that the recalled products be removed immediately from usable stock and stored separately in a secure area until they are disposed of in accordance with the manufacturers' instructions.

13. Internal Audits

Internal audits should be conducted and recorded in order to monitor the implementation of and compliance with this guideline.

EUCOMED has taken reasonable care in preparing these guidelines but does not present them as being legal or commercial advice to members. Accordingly, EUCOMED accepts no liability for any consequence arising from the use of these guidelines. Members should seek advice from professional advisers as appropriate.

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