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LAKSHMI NARAIN COLLEGE OF PHARMACY, BHOPAL

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Subject: Quality Assurance (BP-606T)

Unit: IV

Topic: *DISTRIBUTION AND DISTRIBUTION RECORDS*

DISTRIBUTION AND DISTRIBUTION RECORDS

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DISTRIBUTION PROCEDURES

- Written procedures shall be established, and followed, describing the distribution of drug products.

- They shall include:

1. A procedure whereby the oldest approved stock of a drug product is distributed first. Deviation from this requirement is permitted if such deviation is temporary and appropriate.

2. A system by which the distribution of each lot of drug product can be readily determined to facilitate its recall if necessary.

- Distribution records must be constructed and procedures established to facilitate recall of defective product.

- A requisite of the system is approval and specific release of each lot of drug by the quality control function before distribution can occur. This control of finished goods for shipment allows only those drugs into commerce that have been shown by testing to confirm to appropriate requirements.

- The manufacture must maintain records of all distribution transactions involving in-process or finished goods.

- All records should be indexed by either the manufacturing batch-lot number of the packaging control number as a means of accountability until the shipment passes from the direct control of the manufacturer.

- This type of indexing permits an efficient determination of the receiver of a lot to be recalled since only one shipment record need be examined.

- Depending on the marketing procedure of the individual company, distribution records may list shipments to consignees for packaging or labeling, or to an independent distributor, a wholesaler, a retail pharmacist, a physician, or possibly the ultimate consumer.

- A variety of distribution recording systems may be utilized. Two of the more commonly used approaches are

  1. To record the lot or control number on the retained copies of the shipping invoices
  2. To record the dates on which each lot commenced distribution.

- This later approach has disadvantages in that it does not readily accommodate the redistribution of small amounts of returned goods or the occasional need to distribute part lots out of sequence.

- Many U.S. companies also distribute products to their foreign affiliates. The distribution records should also include these transactions.

- This can become complicated if distribution from the United States is to a central international distribution center and the U.S. operation has no records of the final distribution. In these situations the U.S. QA function should evaluate and audit the central international distribution center operation and confirm the adequacy of its systems and controls.

- The distribution process also includes other considerations. It must be arranged so that a first in/ first out movement of product occurs. This requirement is consistent with the intent of the stability and expiration dating policy.

- The distribution system must include provisions in order that this movement is achieved. Exceptions to this requirement that may be permitted should be described in written procedures.

- All distribution records should be maintained for a minimum 3-year period after the distribution process for any control number has been completed.

- If expiration date is used for a product, distribution records must be maintained at least for 1 year past the expiration date of the product.

DISTRIBUTION RECORDS

- Distribution records shall contain the name and strength of the product and description of the dosage form, name and address of the consignee, date and quality shipped, and lot or control number of the drug product. For compressed medical gas products, distribution records are not required to contain lot or control numbers.

- The primary purpose is to ensure that adequate data are available to access trade customers should a recall be initiated. The recording of lot number to each order will certainly accomplish this purpose.

- The recordings of dates on which a specific lot of product commenced and ceased distribution may be used. All customers receiving the product between these dates could then be contacted.

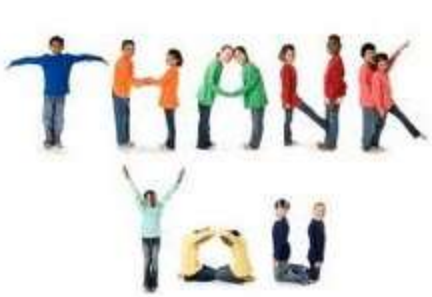
- Obviously on the first and last days of distribution, some of the customers may have received product from the end of previous lot or the beginning of the next lot.

- This overlap should in no way adversely impact on the effectiveness of a recall.

- Whatever system is used, it must accommodate the reintroduction of returned goods into the distribution chain.

- Distribution records include a wide range of documentation such as invoices, bills of lading, customers' receipts, internal warehouse storage and inventory records.

- The information required need not be on every document. Also customer codes and product codes may be used as alternates to customer names and address and product names.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