

Subpart K – Returned and Salvaged Drug Products

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This six (6) page article reviews the basics of the subject matter below:

- 211.204 Returned Drug Products & 211.208 Drug Product Salvaging
- Written procedures
- Receipt and quarantine
- Inspection and testing
- Disposition
- Basic documentation
- Products that can be returned to inventory for resale
- Products that must not be returned to inventory for resale

ARTICLE EXCERPT BEGINS

211.204 – Returned Drug Products

Introduction

Drug product returns can be defined as any product that has been returned for reasons ranging from incorrect product shipped to products with quality and safety issues. The reason for the return determines how the returned products must be handled.

Drug Product Returns

Most product returns are not the result of quality or safety issues. Common examples are an over-shipment of product (too much), shipment of an incorrect product to a customer, or the customer could not sell the product (overstocked). The drug products must be returned in their original shipping containers before most companies will even consider returning them to inventory.

There are times when drug products are returned due to complaints or quality or safety issues. For example, a customer complains that two different types of tablets are in a bottle of product. This requires an investigation by the Quality Unit to determine if the complaint is valid. Should the complaint be valid in this case, all of the product that was distributed would have to be recalled and destroyed. GMP regulation 211.204 specifies FDA requirements for the processing and disposition of returned drug products for both quality and non-quality issues.

Written Procedures

Written procedures are required for all phases of the handling of drug product returns, and therefore must be included in a company's Standard Operating Procedures (SOP) system. Here are examples of the types of procedures that must be present and followed.

Receipt and Quarantine

Procedures must list the actions required for proper identification, initial inspection and storage of products returned to the manufacturing facility.

All returned drug products must be inspected. Also, documentation received with the returned products should be reviewed to determine the reason for the return, and conditions under which the products were held, stored and shipped. The returned products are then placed in a designated quarantine area.

ARTICLE EXCERPT ENDS



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