



Meeting FDA Requirements: Subpart H-Holding and Distribution

This short article reviews “how to” approaches for compliance with GMP regulations 211.42-Warehousing Procedures and 211.50 Distribution Procedures. Key points include quarantine of drug products, temperature-sensitive products, humidity and light, first-in-first out and recalls. Suggestions for auditing a firm’s state of compliance with these regulations are reviewed.

ARTICLE EXCERPT

Introduction

The holding and distribution of drug products under established written procedures is a Good Manufacturing Practice (GMP) requirement. GMP regulations under Subpart H - Holding and Distribution require that there be procedures and systems in place that provide for the holding of drug products prior to release by the Quality Unit and proper storage conditions consistent with product labeling. These GMP regulations also require the oldest inventory be distributed first, and that the product can be easily traced in event of a recall.

211.142 – Warehousing Procedures

Introduction

There are two key points to GMP regulation 211.142 that must be considered. The first involves holding finished drug products in quarantine, until released by the Quality Unit. The other involves maintaining both quarantined and released drug products under conditions that reflect the storage conditions listed on the product label. If there are diverse storage conditions involved, then the warehouse must accommodate them.

Warehouse Procedures

This regulation requires written procedures for the warehousing of drug products. These procedures must address the holding of drug products in a quarantine area until release for distribution by the Quality Unit. There must also be written procedures that assure that drug products are kept in temperature and humidity conditions that reflect product labeling. Should product labeling state “Store at room temperature,” storage conditions are simple. This is storage under ambient conditions, which require no real controls. Ambient temperature is the temperature of current outdoor conditions. As temperature requirements become more restricted, maintaining storage requirements become more complex.



Quarantine of Drug Products

GMP regulation 211.142 requires that drug products awaiting release by the Quality Unit be quarantined. This can be done physically or electronically or both. Both would be considered Best Practice because two controls are involved. Physical quarantine areas must be clearly identified with each lot of drug product being adequately segregated. This also applies to electronic quarantine.

END OF ARTICLE EXCERPT



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