

Subpart E- Control of Components and Drug Product Containers and Closures

by John Stromp

This eight (8) page article discusses the following subject matter below related to Subpart E, including:

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ARTICLE EXCERPT BEGINS

211.84 – Testing and Approval or Rejection of Components and Drug Product Containers and Closures

Introduction

GMP regulation 211.84 of Subpart E contains GMP requirements for the testing and approval or rejection of components and drug product containers and closures. 211.84 addresses approval and release procedures, sampling requirements and testing. There must be written procedures for these activities and they must be followed.

Quality Unit

The responsibilities of the Quality Unit are clear in this regulation. The Quality Unit is required to sample, examine or test components, containers and closures prior to their being released for use in drug product manufacturing. These materials must be held in quarantine until the Quality Unit has completed these tasks. The Quality Unit is required to sample, examine or test materials per established procedures and methods to assure compliance to established specifications of suitability, quality and purity. Upon completion of all required testing, Quality is responsible to approve (release) or reject the component or container or closure.

Sampling

211.84 emphasizes that representative samples must be taken for the examination or testing of each lot of components, drug product containers and closures being held in quarantine prior to use. It is extremely important to understand what a representative sample is in order to comply with this GMP regulation. 21 Code of Federal Regulations (CFR) states a *“representative sample means a sample that consists of a number of units that are drawn based on rational criteria such as random sampling, and intended to assure that the sample accurately portrays the material being sampled.”* An effective way to comply with requirements for a representative sample is to use established sampling plans published by a source recognized by industry and FDA. The American Society for Quality (ASQ) is a good example. Their sampling plans are used in many industries, including pharmaceuticals, and are acceptable to FDA. Such established sampling plans are based on statistical criteria, such as variability, confidence levels, degree of precision and quantity of units needed.

In addition to representative samples of each lot of materials, regulations also require a representative sample of each lot of active ingredient be retained as reserved samples. These are needed for testing because of complaints, product failures, or investigations.

ARTICLE EXCERPT ENDS



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