



Meeting FDA Requirements: Subpart D-Equipment

This article offers numerous approaches and considerations for successfully complying with GMP regulation Subpart D-Equipment. Requirements reviewed for the following regulations include:

- 211.63 Equipment Design, Size, and Location
- 211.65 Equipment Construction
- 211.67 Equipment Cleaning and Maintenance
- 211.68 Automatic, Mechanical, and Electronic Equipment
- 211.72 Filters

Auditing applications for each regulation are also included.

ARTICLE EXCERPT

Location

How equipment is located in relation to manufacturing a product is another GMP compliance issue. The purpose of this requirement is to minimize the possibility of a mix-up and assure that adequate space is given to facilitate equipment cleaning and maintenance.

Product flow through the manufacturing process should be evaluated to determine how best to place the equipment, so that there are no “cross-overs” that could lead to a mix-up.

Cross-overs are instances where different products, or products in different stages of manufacture, come into close proximity of each other. A good example would be unlabeled products passing through an area that already contains labeled products. A mistake here could result in unlabeled products being shipped to the marketplace, which would result in a recall.

Another consideration of placement of equipment is providing sufficient space, so that maintenance and cleaning can be easily done. It is important that the equipment not be too close to walls, pillars or beams, which can result in making maintenance and cleaning difficult. When lack of space make maintenance and cleaning difficult, parts cannot be properly lubricated and “hard-to-reach” places will not be properly cleaned.



211.65 – Equipment Construction

Introduction

GMP regulation Subpart D states that equipment and lubricants, coolants and other fluids associated with their operation cannot have an impact that will damage product purity or safety. This regulation discusses the materials of construction of the equipment and the materials necessary for equipment operation.

Materials of Construction

GMP requires those parts of manufacturing equipment that come in direct contact with components, containers and closures, in-process materials and finished product be made of materials that are not reactive, additive or absorptive. Reactive means that there is something in the material in a part of that machine, like a gasket, that will cause a chemical reaction with the product that will produce a contaminant that could impact product purity or safety. Additive means that some part in that equipment, like a plastic hose in liquid filling equipment, will allow substances to be extracted out by the product or its components. Absorptive is when a material used in the construction of the equipment absorbs some component of the product. It could be a filter that absorbs some of the active ingredients, thus lowering the potency of the drug. To address these issues, most direct contact materials used in the construction of equipment will be made of stainless steel, polypropylene plastics or other materials known to be inert.

END OF ARTICLE EXCERPT



This article excerpt is compliments of the FDA Compliance Learning Community of enKap (<http://www.enkap.com>). This article has been published in its entirety in the March 2010 Issue of the FDA Compliance Digest.