



GMP Pharmaceutical Regulations: An Introduction to Interpretation and Enforcement

by John Stromp

The pharmaceutical industry is regulated by the Food and Drug Administration (FDA). One of the more difficult issues with which we grapple with is that of compliance. The requirements of these regulations are enforced by the FDA. They cannot be avoided and cannot be overlooked.

Maintaining compliance with Good Manufacturing Practice (GMP) regulations is an ongoing process. FDA regulation requirements, their application and interpretation are continually changing to reflect the increased expectations of our society, and the ever-changing level of technological advancement that affect all areas of our industry

In this article, you will be introduced to drug GMP regulations, their main focus interpretation, and enforcement.

ARTICLE EXCERPT BEGINS

Food and Drugs - CFR Title 21

“...Title 21 is divided into three chapters; each chapter is divided into Parts. Chapter 1, Parts 1-1299, applies to the FD&C Act, which includes drugs, biologics, and medical devices. Chapter 2, Parts 1300-1399, applies to the Drug Enforcement Agency (DEA) and Chapter 3, Parts 1400-1499, applies to National Drug Policy.

The following are the CFR Parts that apply to the GMP regulation of drugs, biologics, and devices:

- Drugs – Parts 210 and 211 (21 CFR 210 and 21 CFR 211)
- Biologics – Part 606 (21 CFR 606)
- Devices – Part 820 (21 CFR 820)

Harmony within the Regulations

Regulations always supplement each other; they never conflict. There are statements within the regulations themselves that indicate that when two or more regulations comment on the same subject, the more specific regulation will take precedence over the more general one, unless the regulations specifically state otherwise. For example, a drug can be packaged in a plastic bottle. The regulation states only that a drug product container must be non-reactive. Title 21 of the Code has regulations for plastics that are much more specific and prove non-reactivity. Therefore, the plastic used to contain drug product must comply with the more specific requirements under the regulations for plastics.

GMP Focal Points

The goals of GMP regulations are to prevent mistakes and mix-ups and to ensure that only safe, effective, and high-quality products reach the consumer. Once these goals are understood as primary, it becomes apparent how each of the GMP areas of focus contribute to achieving these goals.



Training

FDA requires adequate and appropriate GMP training for personnel involved in the manufacture, testing, and distribution of a drug, medical device, or biologic. Personnel must also have an appropriate combination of education and experience. If an individual does not meet these criteria, then all their work is subject to question. Appropriate personnel training directly affects the product being manufactured. Inadequate training could cause the FDA to declare the subject product adulterated under the FD&C Act. This means that the product cannot be distributed or sold. To do so, would be a violation of Federal Law.

GMP regulations contain specific requirements for documentation and recordkeeping. There must be established systems for the control of detailed documentation, compilation, and storage of records related to the manufacture and testing of each batch of product. Good documentation and recordkeeping procedures help ensure the production and distribution of a safe, high quality, and effective product.

Process Control

Process control entails having established systems that consistently produce a quality product. Validation of processes is documented proof of process control-proof that the process does what it purports to do. FDA regulations require validated processes, because validated process methods will consistently produce safe and effective products.

Equipment

Properly installed, well-maintained, and properly cleaned equipment will produce products that meet their intended specifications. There are specific GMP regulations that address all three of the areas involving equipment. These regulations can be located in Subpart D of 21 CFR 211...”

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