Role of Industrial Engineer in Compliance with FDA Regulations

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To protect consumers and enhance public health by maximizing compliance of FDA regulated products and minimizing risk associated with those products.
The US Food and Drug Administration regulates a wide range of products, including foods, cosmetics, pharmaceutical and veterinary drugs, medical devices, and veterinary products, among others.
FDA offices in Puerto Rico are located in four different locations:

- San Juan District (central office): Investigations, Compliance, and Laboratory Branches
- Aguada Resident Post
- Ponce Resident Post
- Virgin Island Resident Post (St. Thomas)
There are approximately 1,500 FDA-regulated establishments in Puerto Rico and USVI.
Duties of the Industrial Engineer

- Review production schedules, engineering specifications, process flows, and other information to understand methods and activities in manufacturing and services.
- Figure out how to manufacture parts or products, or deliver services, with maximum efficiency.
- Develop management control systems to make financial planning and cost analysis more efficient.
- **Enact quality control procedures to resolve production problems or minimize costs**.
- Work with customers and management to develop standards for design and production.
- **Design control systems to coordinate activities and production planning to ensure that products meet quality standards**.
- Confer with clients about product specifications, vendors about purchases, management personnel about manufacturing capabilities, and staff about the status of projects.

Source: US Department of Labor
Bureau of Labor Statistics
CFR - Code of Federal Regulations Title 21

Part 211: The regulations in this part contain the minimum current good manufacturing practice for preparation of drug products for administration to humans or animals.

Part 820: The requirements in this part govern the methods used in, and the facilities and controls used for, the design, manufacture, labeling and packaging of all finished devices intended for human use.
Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:

1. **Analyzing** processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems;

2. **Investigating** the cause of nonconformities relating to product, processes, and the quality system;

3. **Identifying the action(s) needed** to correct and prevent recurrence of nonconforming product and other quality problems;

4. **Verifying or validating** the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device;

5. **Implementing** and recording changes in methods and procedures needed to correct and prevent identified quality problems.
This regulation provides a source for the control and action to be taken on devices distributed, and those not yet distributed, that are suspected of having potential nonconformities.

FDA cannot dictate in a regulation the degree of action that should be taken because each circumstance will be different, but FDA expects the manufacturers to develop:

- procedures to assess the risk;
- the actions that need to be taken for the different levels of risk;
- how to correct/prevent the problem from recurring depending on the risk assessment
Each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system. Quality audits shall be conducted by individuals who do not have direct responsibility for the matters being audited. Corrective action(s), including a reaudit of deficient matters, shall be taken when necessary.
Without the feedback provided by the quality audit and other information sources, such as complaints and service records, manufacturers operate in an open-loop system with no assurance that the process used to produce devices is operating in a state of control.
Each manufacturer shall establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements.

(a) **Evaluation of suppliers, contractors, and consultants.** Each manufacturer shall establish and maintain the requirements, including quality requirements, that must be met by suppliers, contractors, and consultants. Each manufacturer shall:

1. Evaluate and select potential suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements. The evaluation shall be documented.
2. Define the type and extent of control to be exercised over the product, services, suppliers, contractors, and consultants, based on the evaluation results.
3. Establish and maintain records of acceptable suppliers, contractors, and consultants.
Quality System Regulation

21 CFR Part §820.50 - Evaluation of Suppliers, Contractors, and Consultants

The failure to implement adequate purchasing controls has resulted in a significant number of recalls due to component failures. Most of them due to unacceptable components provided by suppliers. FDA does not regulate component suppliers. This is a responsibility of the finished device manufacturer.

The specifications for the finished device cannot be met unless its individual parts meet specifications. The most efficient and less costly approach is to ensure that only acceptable products and services are received.
Subpart E--Control of Components and Drug Product Containers

(a) There shall be written procedures describing in sufficient detail the receipt, identification, storage, handling, sampling, testing, and approval or rejection of components and drug product containers and closures; such written procedures shall be followed.

(b) Components and drug product containers and closures shall at all times be handled and stored in a manner to prevent contamination.

(c) Bagged or boxed components of drug product containers, or closures shall be stored off the floor and suitably spaced to permit cleaning and inspection.

(d) Each container or grouping of containers for components or drug product containers, or closures shall be identified with a distinctive code for each lot in each shipment received. This code shall be used in recording the disposition of each lot. Each lot shall be appropriately identified as to its status (i.e., quarantined, approved, or rejected).
Subpart F--Production and Process Controls

(a) There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include all requirements in this subpart. These written procedures, including any changes, shall be drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by the quality control unit.
Subpart J– Records and Reports

Master production and control records

(a) To assure uniformity from batch to batch, master production and control records for each drug product, including each batch size thereof, shall be prepared, dated, and signed (full signature, handwritten) by one person and independently checked, dated, and signed by a second person. The preparation of master production and control records shall be described in a written procedure and such written procedure shall be followed.
Thanks!

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