Elements of a Quality System Regulation

Day 2. The Value of Quality Management Systems-
IVD Manufacturing Industry

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Objectives

- Provide a Background to the FDA Quality System Regulation as an example of a Regulatory Body's expectations of a Manufacturer's Quality Management System

- Provide Appropriate Definitions (throughout presentation and in glossary)

- Review the FDA's Quality System and Subsystems Approach to help Control Product Consistency and Quality

- Demonstrate the Advantage to an IVD Product Manufacturer and to the Product end-user of a well maintained Manufacturer's Quality Management System

Background

The FDA Quality System Regulation

- Provides a framework of basic requirements for manufacturers to follow
- Is not prescriptive and is flexible
- Is harmonized with ISO 13485: Medical Devices- Quality Management Systems- Requirements for Regulatory Purposes

Definitions

Quality System

Means the organizational structure, responsibilities , procedures, processes and resources for implementing quality management

Definitions

Quality Control

To test/inspect components/finished products vs. intended and approved specifications

Quality Assurance

To manufacture “quality” into a product

Definitions

Establish.. refers to the 3 D's:

This means define, document (in writing or electronically), and implement

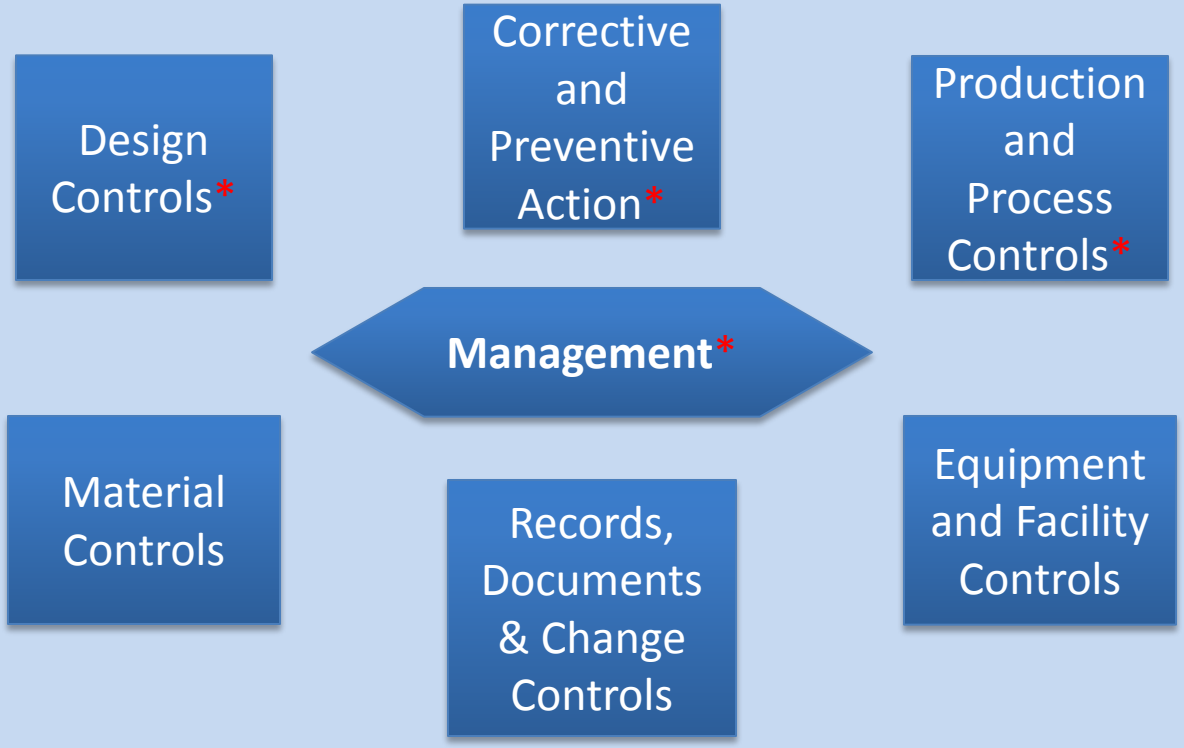
- **D**efine
- **D**ocument, **D**ocument, **D**ocument...
- **D**o i.e., Implement

Fact…

By Regulation, a diagnostic test manufacturer must develop a Quality Management System that aligns with….

- The complexity of its product(s) and manufacturing processes
- The size and complexity of its manufacturing sites , and
- Which assures that it has the ability to design, and manufacture all of its products consistently as intended

The 7 Subsystems of the FDA Quality Management System



There are 4 Major Control Subsystems (*)

- Management Controls
- Design Controls
- Production and Process Controls
- Corrective and Preventive Action (CAPA)

Management Controls Subsystem

What is the Objective of this Subsystem?

- Designed to ensure adequate resources are available for manufacturing and quality teams
- To ensure and monitor that a quality system is established and is effective
- To establish appropriate responsibility and authority to make product quality decisions
- Ensure that management reviews are conducted during product development and post marketing stages

Management Controls are….

Designed to:

- Establish Management approved Quality Plan and Quality System procedures
- Ensure that quality audits are conducted
- Ensure that a Company has enough well trained and experienced employees that understand the Quality System and its objectives

Design Controls Subsystem

What is the Objective of this Subsystem?

- To control and make sure the design of the product meets user need, all intended uses and specified requirements

How does a Company achieve this Goal?

- By developing a plan describing all design and development activities, including review meetings and to include the following items….

Design Controls are Used to...

- Develop product “design inputs” and “design outputs” and verify that design outputs meet design inputs in final product
- Validate and verify the design of the final product
- Control any product design changes during manufacturing
- Transfer final validated product design to full production
- Create and maintain a Design History File

Design Controls: Additional Definitions and Questions for a Manufacturer

Design Verification

- *Are the product specifications being met and can I the manufacturer prove it?*

Design Validation

- *Is the product meeting user needs and intended uses for all specifications, and can I the manufacturer prove it?*

Design Validation vs. Process Validation

Process Validation

- *Does the manufacturing process consistently produce a product meeting predetermined specifications and can I the manufacturer prove it?*

Note: A company should be using known Risk Analysis and Risk Management Tools to help develop their Design Control Process so that they can answer these questions

Production and Process Controls Subsystem

What is the Objective of this Subsystem?

- To make sure that products meet predetermined specifications, manufacturers need to…..
  - Develop adequate processes
  - Validate those processes
  - Monitor and control the manufacturing processes

Other Activities Included in the Production and Process Controls Subsystem?

- Purchasing
- Acceptance Activities
- Buildings and Equipment
- Calibration
- Personnel
- Identification
- Labeling
- Handling, Storage and Distribution
- Installation and Servicing

Purchasing Controls Documentation Includes…

- Auditing and evaluation of suppliers, contractors to make sure their products and services conform with predetermined specifications that apply to a specific product

Verification/Validation of Changes to a Product Specification, Method, Process…

Does the manufacturer check and validate any changes made to product specifications, manufacturing methods or processes before implementation ?

Why is this important to a manufacturer?

- Helps to avoid new product performance issues and possible product recalls

Corrective and Preventive Action (CAPA) Subsystem

What is the Objective and Value of this Subsystem?

- A manufacturer should continuously collect and analyze information on the post-market performance of its commercial diagnostic products

Why?

- Helps identify and investigate any product quality problems early and to quickly identify effective "corrective" and "preventive" actions

Subsystem-Related Definitions

“Corrective Action”

An action that will eliminate the causes of a product that is not performing correctly or has other quality problems

“Preventive Action”

The elimination of the cause of a potential product performance or other quality problems

CAPA Subsystem Procedures Help a Manufacturer…

Identify and eliminate the causes of real and potential product quality and performance problems.

How?

What Sources of “Internal Feedback” can Help Identify a Product Problem?

Company Product Acceptance Activities

- Analysis of product component in-process & final testing records
- Ongoing Monitoring of Manufacturing Processes
- Process control data, control charts etc.
- Calibration of equipment and maintenance records
- Change Control records
- Quality audit reports
- Supplier audits

What Sources of "External Feedback" can Help Identify a Product Performance Problem?

- Incoming customer complaints and Medical Device Records (MDRs)
- Instrumentation Servicing Records from Field Service reports
- Product recalls - Includes information from all countries where distributed
- Legal claims from patients

The Manufacturer obtained “Internal and External Feedback” What Next?

Uses all Quality Management System Resources to…

- Analyze the Problem in depth to find the source(s)
- Develop an Action Plan
  - Consider the impact (public health and customer satisfaction) and need for action
  - Decide what are the immediate, short and long term corrective actions that need to be taken

Verification and Validation of Identified Corrective Actions

- A thorough analysis of all input data may lead to more than one solution to the problem. Validation and verification steps are needed to assure proposed solution(s) are appropriate
- Implementation of all corrections should be tracked carefully
- The manufacturer must follow up to check if the corrective action is effective and must document, document, document all corrective action findings

In Summary

In this Presentation we Covered:

- The basic elements of a recognized Quality Management System
- The value and importance to both an *in-vitro* diagnostic product manufacturer and the product end user of maintaining a Quality Management System to continuously track product development and manufacturing processes for quality and consistency, and…
- To use this well documented information to help determine the possible source(s) of a post-market product performance issue and put in place validated changes to prevent it occurring again

Thank You