



The Compliance Program and Meeting Challenges of Extreme Weather

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Operations

FDA Locations

- Office of Regulatory Affairs (ORA)
 - » ORA Headquarters in Silver Spring, MD
 - » 5 Regional U.S. offices
 - » 20 District offices located in 5 regions
- Center for Devices and Radiological Health (CDRH)
 - » Headquarters in Silver Spring, MD
- FDA currently has staff posted in seven countries
 - » China, India, Mexico, Costa Rica, Belgium and United Kingdom
- Specific addresses and contact information for all locations available at www.fda.gov

FDA Premarket Device Classes

Risk-Based Approach

- **Class I: Low Risk, General Controls**
 - » Usually exempt from pre-market notification
- **Class II: Moderate Risk, Special Controls**
 - » Usually 510(k), Pre-market notification
- **Class III: Higher Risk**
 - » Usually Pre-Market Approval

FDA's Authority to Conduct Inspections

- Section 704(a) of the FD&C Act
 - » (1) ...officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized
 - (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, tobacco products, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, tobacco products, or cosmetics in interstate commerce; and
 - (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein.

Establishing Inspectional Priorities

- A search is performed in:
 - » FDA's registration database to identify medical device manufacturers.
 - » FDA's listing database to identify what devices the medical device manufacturer distributes in the US.

Establishing Inspectional Priorities

- Prioritization is performed based on:
 - » Risk of the device (Class III life sustaining/life supporting devices, Class II)
 - » Inspectional history of the manufacturer
 - Date of last inspection
 - Previous inspection findings (violative or non-violative)
 - » New devices or new firms



Establishing Inspectional Priorities

Guidance for Industry, Third Parties and Food and Drug Administration Staff - Medical Device ISO 13485:2003 Voluntary Audit Report Submission Pilot Program

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm212795.htm>

Document issued: March 19, 2012

ISO 13485 Voluntary Audit Report Submission Program

- The Food and Drug Administration Amendments Act of 2007 (FDAAA) mandated that FDA would accept voluntary submission of ISO reports:
 - » “For the purpose of setting risk-based inspectional priorities, the Secretary shall accept voluntary submissions of reports of audits assessing conformance with appropriate quality system standards set by the International Organization for Standardization (ISO) ...”

Why does FDA accept ISO 13485 reports?

- Risk-based planning and efficient use of FDA inspectional resources:
 - » More inspections are performed to ensure conformity to ISO 13485 than FDA is able to perform for 21 CFR 820
 - » Many ISO 13485 audits are performed domestically and internationally
- Harmonization efforts with other countries

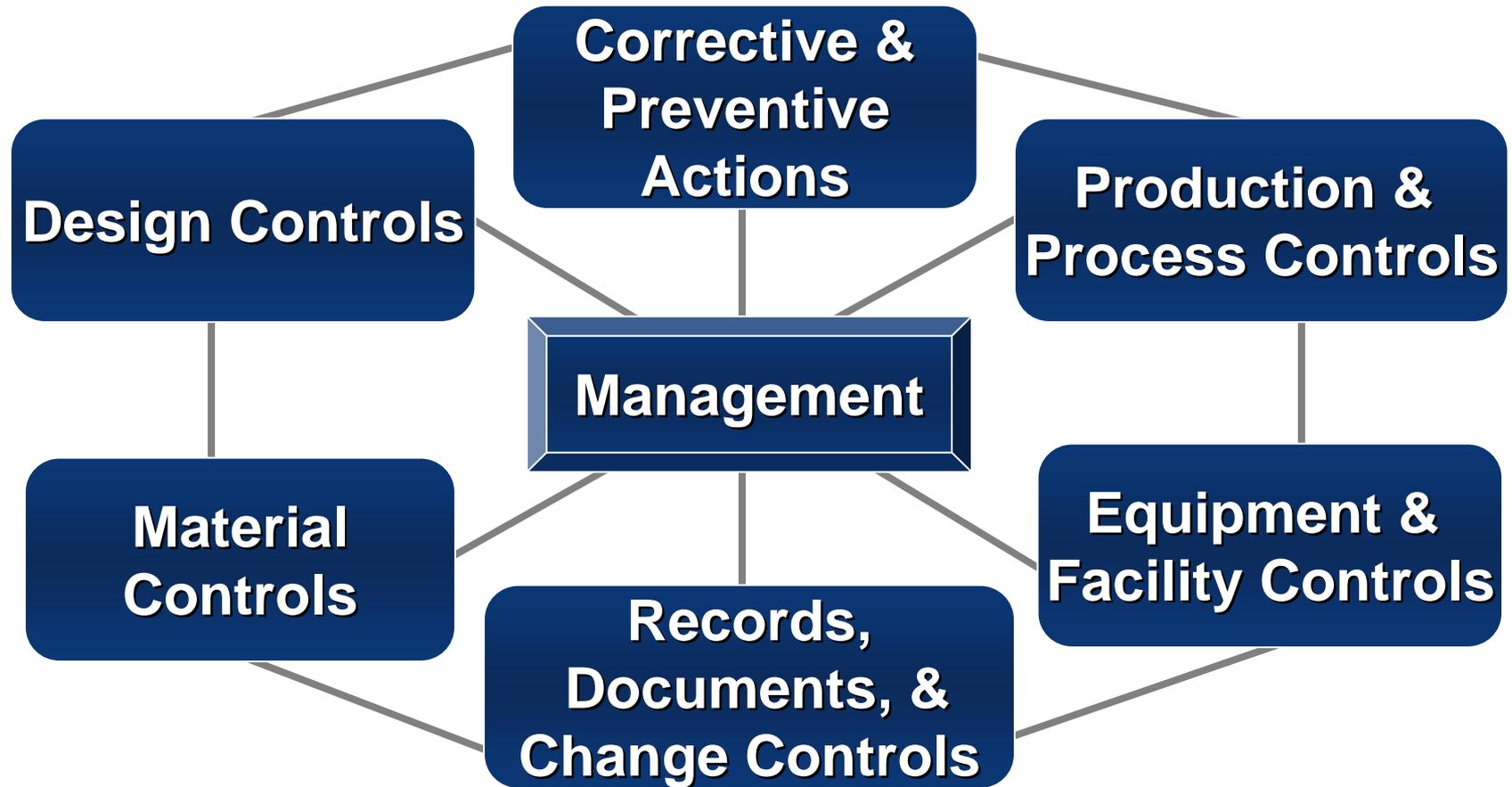
Compliance Program

- Compliance Program 7382.845
“Inspection of Medical Device Manufacturers”
- Part III discusses the inspectional strategies

QSIT Overview

- Quality System Inspection Technique (QSIT)
 - » “Top-down” inspection of a manufacturer’s quality system
- Start by looking at a firm’s “systems” and procedures for addressing quality problems
 - » As opposed to a “bottom-up” review starting with problems
- Developed by FDA and introduced in 1999
 - » “Field investigators may conduct an efficient and effective inspection using this guidance material which will help them focus on key elements of a firm’s quality system.”

QSIT – 7 Subsystems





Compliance Program

7382.845 Part III Inspectional

INSPECTION LEVEL	REASON FOR INSPECTION	QS SUBSYSTEM INSPECTED
1	ABBREVIATED	CAPA PLUS 1 (DESIGN OR PPC)
2	BASELINE	FOUR MAJOR SUBSYSTEMS
3	COMPLIANCE FOLLOW-UP	AS DIRECTED BY GUIDANCE

High Risk Devices in the Compliance Program

- Manufacturers of high risk devices which can be identified by:
 - A. Special Assignment from CDRH;
 - B. Devices with a higher frequency of recalls and MDRs;
 - C. Devices that are driven by software and those with rapidly evolving technological changes
Both of these types of devices are subject to rapid and potentially poorly controlled modifications that could affect their continued safety and efficacy; or,
 - D. New devices

CP 7382.845 Part III

- Selection of manufacturing processes for inspectional coverage should include the following considerations:
 - » Corrective or preventive actions indicators of process problems
 - » Processes used to manufacture high risk products
 - » Processes that have a high risk of causing product failure
 - » Processes that require process validation
 - » Processes that are new to the manufacturer
 - » Processes that cover a variety of process technologies and profile classes
 - » Common processes used in multiple products
 - » Processes not covered during previous inspections

CP 7382.845 Part III

- It is important to thoroughly cover Purchasing Controls, to include outsourced processes as a QSIT linkage under P&PC whenever P & PC is covered.
- Coverage of Purchasing Controls must be documented in the establishment inspection report, especially if the manufacturer contracts a sterilization process or contracts the manufacture of significant components, subassemblies, or processes.

Types of Inspections

- For Cause
 - » MDR trends, complaints, articles in the press, information received in submissions, etc.
- Preapproval/Postmarket
 - » Original PMA or a supplement
- Routine
- BIMO
 - » Clinical investigator, sponsors, monitors, IRBs, etc.
- Compliance Follow Up
 - » Follow up to Warning Letter, injunction, etc.
- Risk Based

Types of Inspection

- For Cause
 - » For Cause inspections are usually initiated at the request of CDRH through ORA headquarters
 - » Regional or District directives
 - » For Cause inspections are dictated by the source of information and may differ from the typical QSIT approach. These inspections are generally more in-depth in particular areas than typical QSIT inspections.

For Cause Inspections

- The inspectional guidance provided by the assignment, the district compliance branch, and/or CDRH will guide the flow of these inspections, however, elements of the QSIT Guide may also be utilized.
- For Cause inspections should be directed towards the quality problem(s) and, if applicable, trace the underlying cause, assuring that appropriate correction(s) and corrective action(s) are initiated.

Risk Based Workplan

- Risk based work plan inspections are initiated at the request of CDRH. These inspections are focused by the Center's analysis and work plan assignment and may differ from the typical QSIT approach. These inspections are generally more in-depth in particular areas than typical QSIT inspections.
- The inspectional guidance provided by the assignment will guide the flow of these inspections; however, elements of the QSIT Guide may also be utilized.

Extreme Weather Considerations

- What processes were affected during the extreme weather event?
 - » Storage?
 - » Shipping?
 - » Validated processes?
 - » Processes performed by suppliers?
- Was appropriate corrective or preventive action taken as a result of an extreme weather event?

Extreme Weather Considerations

- Supplied products
 - » What supplied products or services were affected by the extreme weather event?
 - » How is the finished device manufacturer controlling the supplier to ensure products or services received continue to meet specifications?

FDA Priorities After An Extreme Weather Event

- Inspectional activities after an extreme weather event are:
 - » Food and water
 - » Pharmaceuticals
 - » Other commodities, including medical devices

FDA and Regulatory Strategies

- Warning Letter
- Order to repair, replace, or refund devices
- Notification to users or public
- PMA suspension/ withdrawal
- Device seizure
- Criminal prosecution of company and/ or responsible individuals
- Civil penalties
- Prohibition of import

Summary

- Medical device manufacturers need awareness of FDA organization, especially
 - » Center for Device and Radiological Health
 - » Office of Regulatory Affairs
- FDA has established a risk-based product class scheme
 - » Class I, II, and III
 - » Product classifications encompass over 1700 general device types

Summary

- ORA's inspectional activities after extreme weather events prioritize food and water
- It is imperative that device manufacturers plan for extreme weather events
- If a medical device manufacturer has questions regarding what activities should be taken after an extreme weather event, they should contact their local district office for assistance

References

- Investigations Operations Manual (IOM)
 - » <http://www.fda.gov/ICECI/Inspections/IOM/default.htm>
- Guide to Inspections of Quality Systems: Quality Systems Inspection Techniques (QSIT)
 - » http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074883.htm?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=Quality%20system%20inspection%20technique&utm_content=1
- Compliance Program: CP 7383.001 Medical Device Premarket Approval and Postmarket Inspections, March 5, 2012
 - » <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ComplianceActivities/ucm295572.htm>
- Compliance Program: CP 7382.845 Inspection of Medical Device Manufacturers, February 2, 2011
 - » <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072753.htm>