# FDA Medical Device Inspections

**FDA Small Business Regulatory Education for Industry (REdI)**

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Office of Medical Devices & Radiological Health Operations

U.S. Food and Drug Administration

FDA shows up at your door for an inspection, are you ready?

# Learning Objectives

1. Give an Overview of ORA
2. Summarize Preparations for an FDA Inspection
3. Explain Expectations during the Inspection
4. Describe Post Inspectional activities

# Overview of ORA

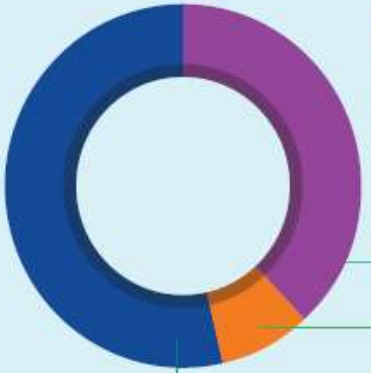
# CDRH and ORA Responsibilities

| Center for Devices and Radiological Health (CDRH) | ORA Office of Medical Device and Radiological Health Ops (OMDRHO) |
| --- | --- |
| • Responsibilities include:<br>– Premarket review<br>– Postmarket surveillance<br>– Policy making and guidance development<br>– Postmarket/Enforcement activities<br>– Public communication and education | • Responsible for medical device field activities:<br>– Establishment Inspections<br>– Investigations<br>– Collect samples for analysis<br>– Monitor recalls<br>– Consumer Complaints |

# Office of Medical Devices and Radiological Health Operations (OMDRHO): 3 geographic divisions

# 2019

## Inspections



**35,029**
Total Inspections

- **14,204** Domestic Inspections
- **3,766** Foreign Inspections
- **17,059** State Inspections

# 2019

## Enforcement

**14,949**
Warning Letters Issued
*Includes 14,607 warning letters issued by the Center for Tobacco Products

**7,893**
Recalled Products

**8**
Injunctions

**2**
Seizures

**212**
Import Alerts

Allow FDA to detain future shipments of potentially violative products without testing or examination

# Preparation

# Preparation for an FDA Inspection

- Know the regulations!

Primary regulations:

- 21 CFR 820 (Quality System regulation)
- 21 CFR 806 (Reports of Corrections and Removals)
- 21 CFR 803 (Medical Device Report or “MDR”)
- 21 CFR 807 (Establishment Registration and Device Listing)

# Other Regulations Covered as Applicable

- **21 CFR 801**: Labeling
  - Unique Device Identification System – UDI
- **21 CFR 821:** Medical Device Tracking
- **21 CFR 11:** Electronic Records; Electronic Signatures

# Other Regulations Covered as Applicable

- **21 CFR 1000-1050:** Electronic Product Radiation Control (EPRC)
- **21 CFR 4:** Regulation of Combination Products

# Preamble

## Preamble to 21 CFR 820

- Issued 1996
- Includes industry comments
- FDA responses/clarifications to industry comments

# Knowledge Check

**The acronym “MDR”, stands for:**

a) Medical Device Regulations
b) Medical Device Report
c) Master Design Regulations
d) Maximum Daily Radiation

# Keys to Inspection Preparation

- Assure your Quality System has been:
  - Defined, Documented and Implemented
- Identify/train your Inspectional team
- Assure records are easily accessible, legible and timely
- Recalls and MDRs clearly documented and reported appropriately
- Quality issues have been identified through CAPA subsystem
- Internal audits have been conducted and completed as required

# Investigator's Preparation

- Review previous Establishment Inspection Report(s) (EIR)
- Review FDA-483 responses and communications between the firm and FDA/Compliance/Center
- Review databases: Registrations, Listings, 510(k)s, PMAs, MDRs and Recalls
- Review of applicable standards and guidance documents

# Inspection Pre-Announcement

- **Purpose:** Facilitate Inspection, assure staffing and record access

- Domestic Inspection: five days advance notice:
  - Set date/estimated duration
  - Inspection type/nature/ potential records for review
  - May request procedures, Quality Manual

- Foreign Inspections are planned further in advance due to country clearance requirements and prep

# Expectations During the Inspection

# Start of the Inspection

1. Present credentials, issue FDA-482, *Notice of Inspection* to top Management Official on site (domestic only)

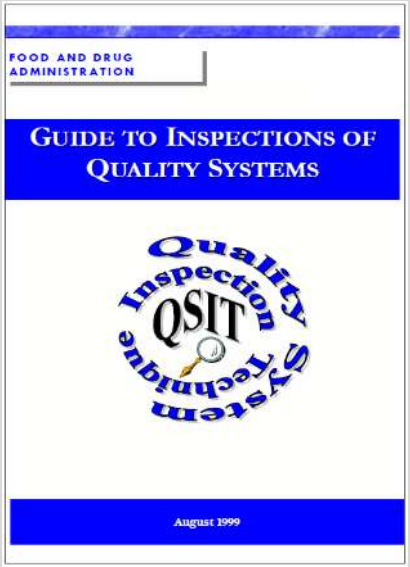
2. Opening meeting to discuss current operations, objectives and responsibilities

3. Typically, perform a facility walkthrough

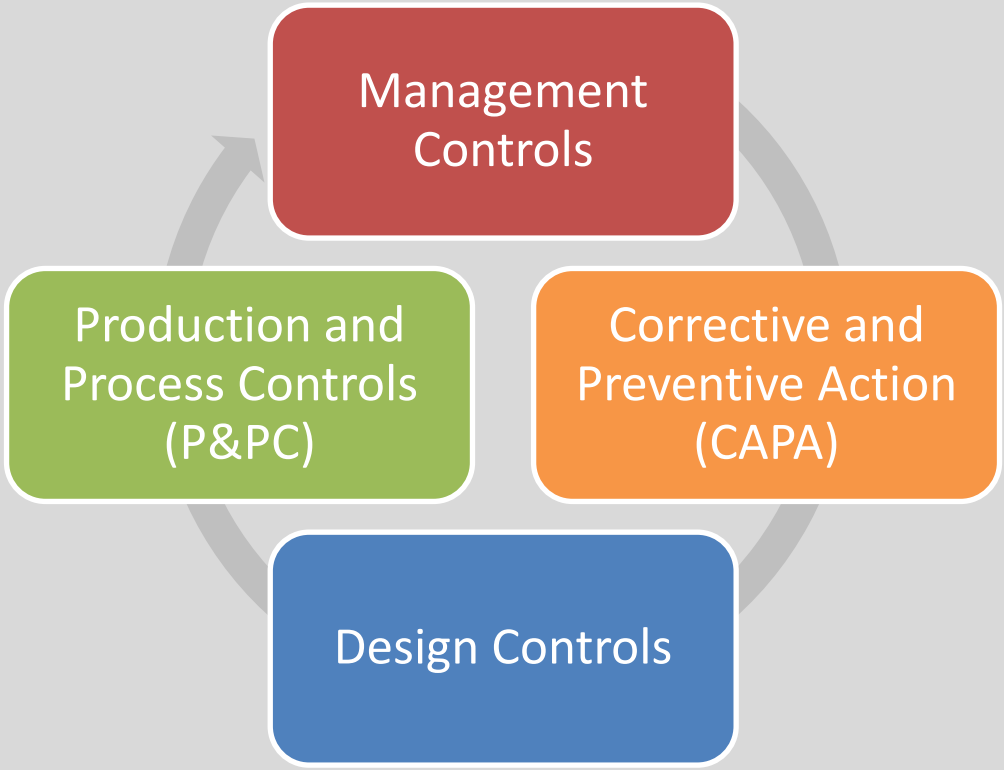
# Inspectional Approach

# Quality System Inspection Technique (QSIT)

- Released August 1999
- Systems approach
  - 4 Major Subsystems
- "Top-down" approach
  - Start with procedures (systems)



# QSIT: Four-Subsystem Approach



# QSIT Inspection Types

- **Baseline/Comprehensive Inspection**
  - Covers all 4 subsystems

  (Management, CAPA, Production & Process Controls (P&PC), and Design Controls)

- **Abbreviated Inspection**
  - Covers 2 subsystems

  (selected by Investigator: CAPA (always), P&PC or Design)

# Knowledge Check

**Which quality subsystem is always covered during every FDA Inspection?**

a) Management Controls

b) Purchasing Controls

c) CAPA

d) Production and Process Controls

# Expectations During the Inspection

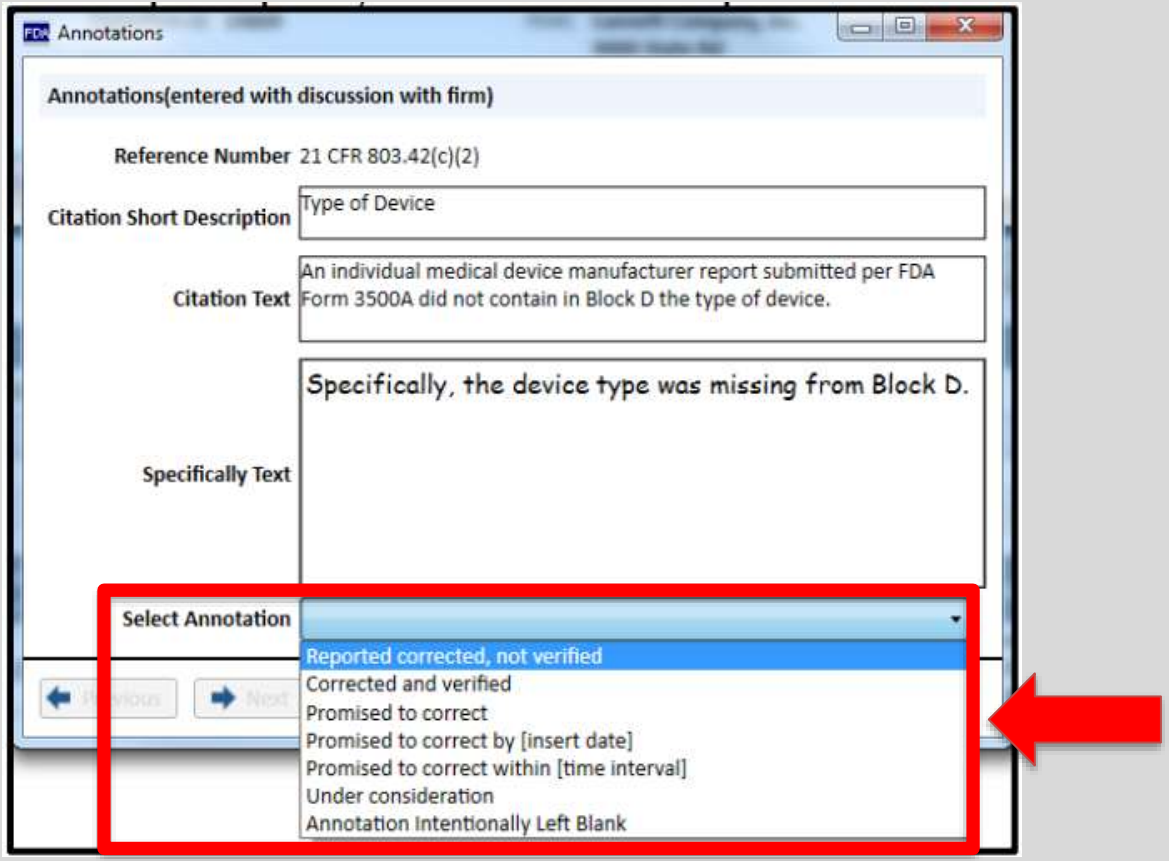
## Transparency and Cooperation

- Communicate concerns during the Inspection
- Provide daily updates
- Timely access to records and personnel
- Be truthful and forthcoming
- If you don’t understand the question, ask.
- If you do not know the answer, be upfront

# Inspection Close-Out Meeting

1. Summarize Inspection/coverage and findings
2. Issue FDA 483 if Objectionable Conditions were observed. Some items excluded from 483 (510k, labeling)
   - Discuss FDA's annotation process; Devices only
   - Issue FDA 483 to top Management present
   - Encourage written response to the FDA 483 within 15 business days

# Example: Annotations



# Form FDA 483

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 300 River Place, Suite 5900<br>Detroit, MI 48207<br>(313) 393-8100 Fax: (313) 393-8139 | [redacted]<br>FEI NUMBER<br>[redacted] |
| NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED<br>[redacted] | |
| FIRM NAME<br>[redacted] | STREET ADDRESS<br>[redacted] |
| CITY, STATE, ZIP CODE, COUNTRY<br>[redacted] | TYPE ESTABLISHMENT INSPECTED<br>Medical Device |

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

*The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.*

**DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:**

**OBSERVATION 1**

# Post Inspectional Activity

# Inspection Classification

- Investigator writes Establishment Inspection Report (EIR)
- Supervisor endorses Report, recommends classification:
  - NAI (No Action Indicated)
  - VAI (Voluntary Action Indicated)
  - OAI (Official Action Indicated)

# Firm's 483 Response

- Responding to the form FDA-483 is voluntary
- Firm's response reviewed by Compliance
- If response is adequate, classification will be VAI
- If response is not adequate, Official Action may be indicated

# Official Action may consist of:

- Regulatory Meeting(s)
- Warning Letter
- Untitled Letter
- Seizure
- Injunction
- Civil money penalties
- Prosecution
- Foreign Firm: Import Alert/Detention

# Obtaining the Inspection Report

- Copy of EIR is sent to NAI or VAI firms
- Per: Field Management Directive FMD 145
- For OAI classification
  - Copy of EIR not sent until all inspection activities are considered completed/closed

# Summary

- ORA's Office of Medical Device and Radiological Health Operations plays a major role in establishment inspections, investigations, collecting samples for analysis, and monitoring recalls
- When preparing for an FDA Inspection, make sure you know all of the relevant regulations
- CAPA is covered during each inspection
- Various activities, including responding to FDA, take place after an inspection is completed

# Resources

| Slide Number | Cited Resource | URL |
|---|---|---|
| 10 | Quality System Regulation 21 CFR 820 | www.ecfr.gov/cgi-bin/text-idx?SID=e219afd4e5b35168f184f1410bc5e67d&mc=true&node=pt21.8.820&rgn=div5 |
| 11 | Unique Device Identifier | www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system |
| 21 | Quality System Inspection Technique (QSIT) | www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-guides/quality-systems |

# Questions




FDA U.S. FOOD & DRUG ADMINISTRATION