FDA Medical Device Inspections

FDA Small Business
Regulatory Education for Industry (REdI)
Boston, MA
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U.S. Food and Drug Administration

Poll Question

If FDA calls today to schedule an inspection, what is your confidence level?

A. Ready to go!

B. Cautiously Optimistic

C. Not at all Confident

D. Not Applicable

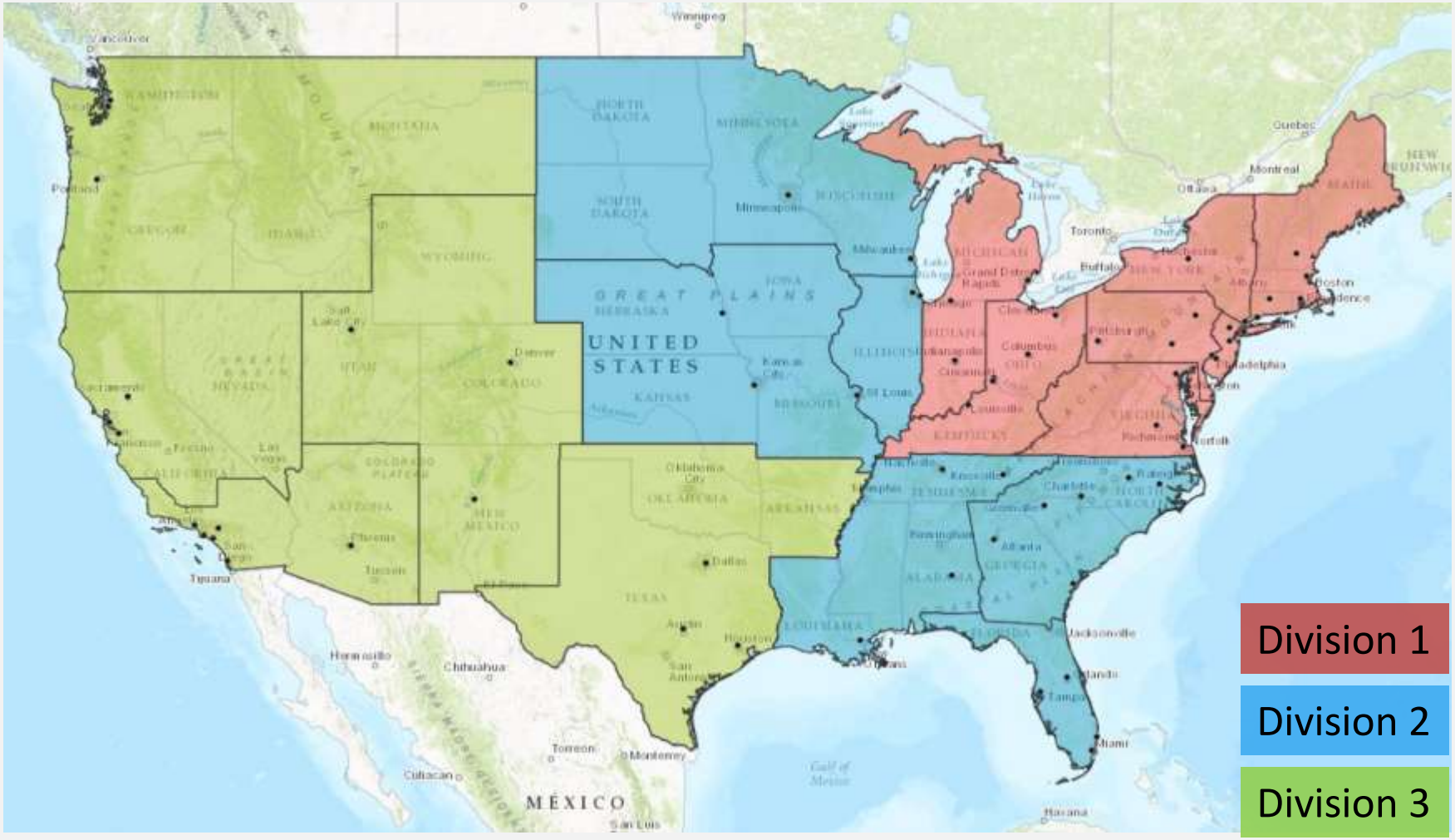
Learning Objectives

1. Describe the role of ORA Office of Medical Device and Radiological Health Operations
2. Identify how to prepare for an FDA Inspection
3. Describe expectations during the Inspection
4. Explain how to communicate with FDA after the Inspection

FDA Organization for Regulation of Medical Devices and Radiological Health

Center for Devices and Radiological Health (CDRH)	ORA Office of Medical Device and Radiological Health Ops (OMDRHO)
• Responsibilities include: – Premarket review – Postmarket surveillance – Policymaking and guidance development – Public communication and education	• Responsible for medical device field activities: – Establishment inspections – Investigations – Collect samples for analysis – Monitor recalls

Office of Medical Device and Radiological Health Ops
OMDRHO



Primary Medical Device Regulation

- **Quality System Regulation (QSR):** 21 CFR 820
  - Also known as Current Good Manufacturing Regulation (CGMP)

- **Preamble to 21 CFR 820**
  - **1996**
  - **industry comments**
  - **FDA responses**

Other Regulations covered on Inspections

- **21 CFR 803:** Medical Device Reporting
- **21 CFR 806:** Corrections and Removals
- **21 CFR 807:** Registration and Listing
- **21 CFR 801:** Labeling
  - Unique Device Identifier – UDI
  - Phasing in 2014-2022

Other Regulations covered as Applicable

- **21 CFR 821:** Medical Device Tracking
- **21 CFR 11:** Electronic Records; Electronic Signatures
- **21 CFR 1000-1050:** Electronic Product Radiation Control (EPRC)
- **21 CFR 4:** cGMPs for Combination Products

Keys to Inspection Preparation

- Establish Quality System:
  - Define, Document and Implement
- Train your staff
- Keep good records
- Report recalls and adverse events
- Audit your Quality System regularly:
  - Internal Audits

Prior to the Inspection:
Investigator

- Review Previous Inspection Report
- Previous Observations and FDA 483 responses
- Registration and listings
- 510(k)s and PMAs
- MDRs and recalls
- Relevant standards

Inspection Pre-announcement

- **Purpose:** Facilitate the inspection
- Domestic Inspection minimum five days in advance:
  - Set date/time/working hours
  - Inspection type/nature/records
  - May request procedures
- Foreign Inspections are planned further in advance due to country clearance requirements

Start of the Inspection

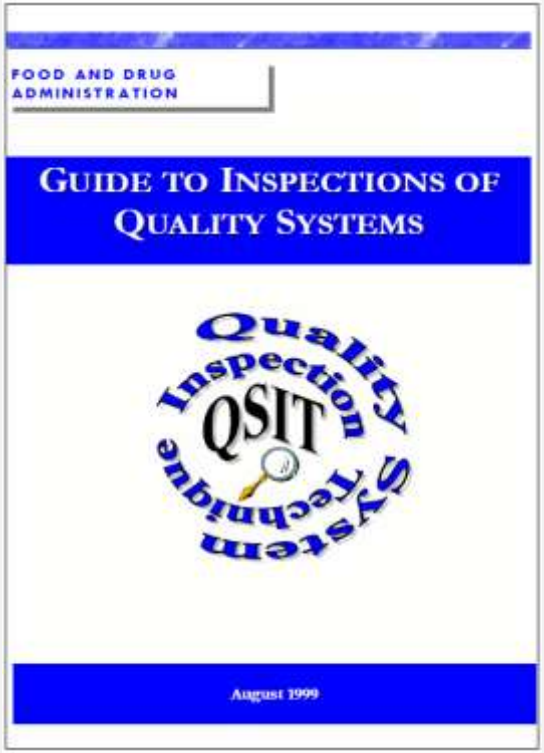
1. Identify top Management Official on site
2. Present credentials
3. Issue an FDA 482, *Notice of Inspection*
4. Conduct an opening meeting
5. Perform a facility walkthrough

FDA Medical Device Inspection Procedures

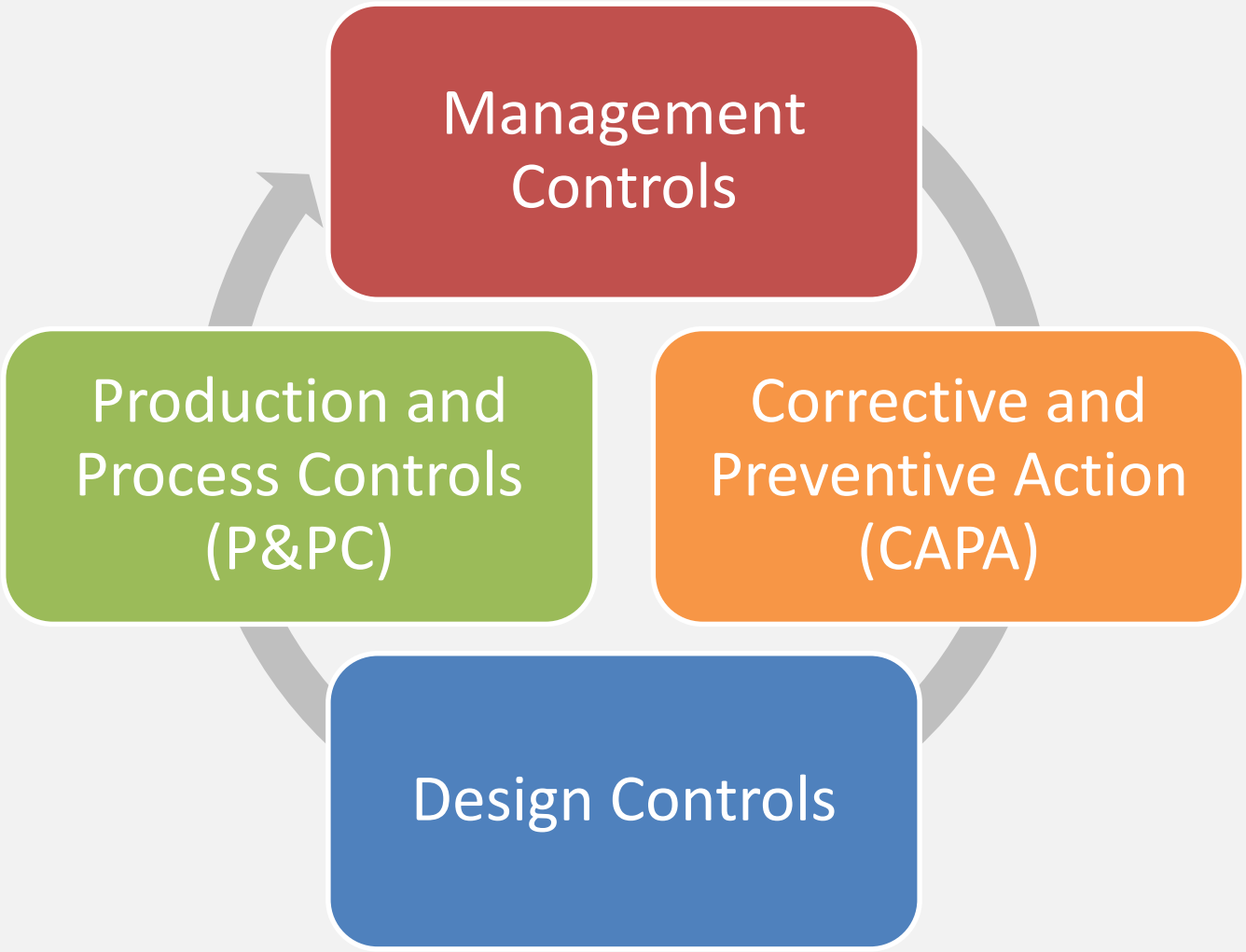
- Quality System Inspection Technique (QSIT)
- Compliance Program 7382.845: Inspection of Medical Device Manufacturers
- Investigations Operations Manual (IOM)

Quality System Inspection Technique (QSIT)

- Introduced in 1999
- "Top-down" approach
  - Start with procedures (systems)
  - Examine records
- 3-6 days is estimate for a Routine QSIT Inspection



QSIT: Four-Subsystem Approach



Expectations During the Inspection

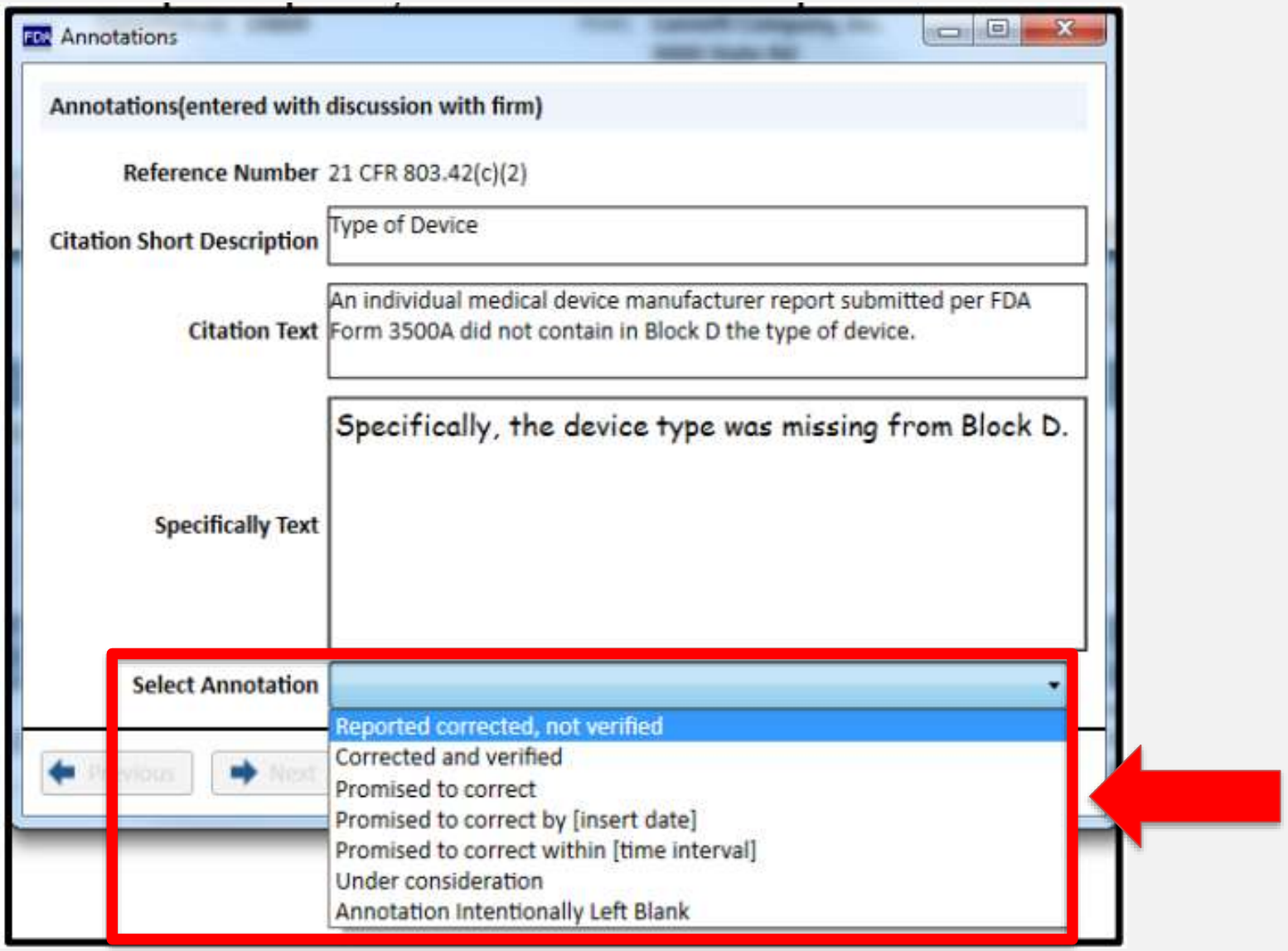
Transparency and Cooperation

- Communicate our concerns as we see them
- Provide daily briefings
- Timely access to records and personnel
- Be truthful and forthcoming

Inspection Close-Out Meeting

1. Review Inspection Results
2. Issue FDA 483 If Objectionable Conditions Were Observed
   - Offer FDA 483 annotation process
   - Print and Issue 483 to top management
   - Encourage written FDA 483 response within 15 business days

Annotations



FDA 483

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER
300 River Place, Suite 5900
Detroit, MI 48207
(313) 393-8100 Fax: (313) 393-8139

DATE(S) OF INSPECTION
[redacted]

FEI NUMBER
[redacted]

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
[redacted]

FIRM NAME
[redacted]

STREET ADDRESS
[redacted]

CITY, STATE, ZIP CODE, COUNTRY
[redacted]

TYPE ESTABLISHMENT INSPECTED
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

Inspection Classification

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

Firm's 483 Response

- If FDA 483 was issued, Firm's Response will be reviewed
- FDA will provide Non-binding Feedback upon request
- If Response is adequate classification will be VAI and a VAI letter will be sent to the firm
- If Response is not adequate Official Action may still be indicated

Official Action may consist of:

- Regulatory Meeting
- Warning Letter
- Seizure
- Injunction
- Civil money penalties
- Prosecution
- Foreign Firm: Import Alert/Detention without Physical Examination

Obtaining the Inspection Report

- Copy of EIR is sent to firm within 30 business days of NAI or VAI classification.
- Field Management Directive FMD 145

- Please Note: For OAI classification
  - Copy of EIR not sent until case closed

Summary

1. Learned about the role of ORA Office of Medical Device and Radiological Health Operations
2. Described how to prepare for an FDA Inspection
3. Identified the expectations during the Inspection
4. Reviewed how to communicate with FDA after the Inspection

Questions

Your Call to Action

- **Be prepared for your next FDA inspection**
  - Understand your regulatory obligations
  - Perform thorough, meaningful quality audits
- **Let's communicate and cooperate to promote more efficient inspections**
  - Less burden on manufacturers
  - Better use of FDA resources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