

Remote Regulatory Assessments (RRA) for Medical Device Facilities

FDA Small Business Regulatory Education for Industry (REdI)

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Brittani Franklin

Consumer Safety Officer

Division II

Office of Medical Devices and Radiological Health Operations

Office of Regulatory Affairs

U.S. Food and Drug Administration

Would you like to know how FDA assessed facilities during the COVID-19 Pandemic?



**If your
answer is
YES, stay
tuned...**

- FDA adapted operations for oversight of regulated products during COVID-19
- **One of the tools utilized are Remote Regulatory Assessments (RRAs)**

Learning Objectives

- Describe a remote regulatory assessment
- Identify FDA's jurisdiction to conduct an RRA
- Review the process of conducting an RRA
- List RRA benefits and additional resources

What is a Remote Regulatory Assessment ?

- Examination of an FDA-regulated establishment and their records
- Evaluates compliance with laws and regulations administered by FDA
- Conducted remotely

Purpose of Remote Regulatory Assessments

Assesses and verifies information submitted

- Pending premarket applications/licenses
- Compliance follow-up activities
- Regulatory enforcement action adherence

Types of Remote Record Review Activities

1

Remote Interactive
Evaluations

2

Remote Regulatory
Reviews

3

**Remote Regulatory
Assessments
(medical devices)**

FDA's Jurisdiction to Conduct an RRA

Jurisdiction to Conduct an RRA

- **Section 805(d)** of the Federal Food, Drug, and Cosmetic (FD&C) Act
 - Foreign Supplier Verification Program (Food Importers)
 - Statutorily authorized

Jurisdiction to Conduct an RRA

- **Section 704(a)(4)** of the Federal Food, Drug, and Cosmetic (FD&C) Act
 - Requests for records or other information for pharmaceutical drug products
 - Statutorily authorized

Jurisdiction to Conduct an RRA

Medical Device RRAs:

- Section **704(a)(1)** of the Federal Food, Drug, and Cosmetic (FD&C) Act
- Tool used in conjunction with FDA's authority to conduct inspections
- Voluntary

Why Conduct an RRA?

If FDA cannot physically conduct an inspection, an RRA may be conducted

- Travel restrictions
- Pre-inspection planning
- Time crunch

Knowledge Check

Are Medical Device RRAs considered
statutory or voluntary?

Remote Regulatory Assessment Process

Conducting an RRA

1. Request to conduct a remote regulatory assessment

- FDA staff will contact establishment's Point of Contact
- Initial request/invitation will be sent
- Establishment agrees/disagrees to participate

Conducting an RRA

2. Obtain agreement to participate in RRA

- Arrange virtual meetings and schedule interviews
- Establish a secure remote connection
- Provide RRA Handout
- No issuance of FDA Form 482- 'Notice of Inspection'

Conducting an RRA

3. Request records or other information

- Review standard operating procedures
- Review quality documents/records
- Identify and review source/raw data
- Review processes and/or electronic systems

Conducting an RRA

4. Use File Transfer Systems

- Emails (acceptable during RRAs)
- Box.com
- Electronic Submission Gateway (Web Trader)

Conducting an RRA

5. Review requested records and other information

- Determine compliance with cGMPs
- Identify if corrective actions have been mitigated
- Provide updates to observations and outstanding issues

cGMP = current good manufacturing practice

Conducting an RRA

6. Finalize the RRA

- Schedule closeout meeting
- Discuss results of record review with management
- No FDA Form 483, 'Observation List' will be issued

Conducting an RRA

7. Complete After Assessment Activities

- Write narrative report of assessment
- Determine final action or outcome
- Make redacted report available for public disclosure

RRA Benefits and Resources

Benefits of RRAs

- Allows establishment to correct quality issues outside inspectional framework
- Potentially decreases future inspection time
- Evaluates adherence to regulatory enforcement actions

Benefits of RRAs

- May assist with assessing pending premarket applications
- Can support the agency's oversight on a firm's compliance
- Helps determine prioritization of inspections/follow up activities

Benefits of RRAs

Continuing to protect the public health by assuring the safety, effectiveness, and security of medical devices and radiation-emitting products

RRA Resources

- OMPTO RRA Fact Sheet
 - www.fda.gov/media/150036/download
- OMDRHO Foreign Remote Regulatory Assessment Handout
 - www.fda.gov/media/152916/download
- Remote Regulatory Assessment Draft Guidance is being developed

Knowledge Check

Which FDA Forms will be issued during a voluntary RRA?

- A. Notice of Inspection (FDA Form 482)
- B. List of Observations (FDA Form 483)
- C. Both A and B
- D. None of the Above

Summary

- Medical Device remote regulatory assessments are voluntary
- FDA 482/483 Forms are NOT issued during a remote regulatory assessment
- A benefit of an RRA is FDA oversight without physical presence

Questions

