U.S. FOOD & DRUG ADMINISTRATION
Office of Inspections and Investigations

**U.S. Food and Drug Administration**
**Center for Devices and Radiological Health**
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# OMDRHI Foreign Post-Inspection Resources

## About the Office of Medical Devices and Radiological Health Inspectorate (OMDRHI)

OMDRHI's Foreign Operations Branch manages the inspection of foreign facilities utilizing both dedicated foreign inspection staff as well as staff who also conduct inspections within the US. For information about OMDRHI, visit www.fda.gov/OIIDevices.

## FDA-483 Responses

Email FDA-483 responses to **CDRHEnforcement@fda.hhs.gov**. Include your company name and FEI number (from Form FDA-483) in both the email subject line and cover letter/attachments.

**Subject Line Format**: "Firm name, FEI#: [number], FDA-483 response dated MM/DD/YYYY"

**Submission Instructions:**

- Submit as PDF files with clear numbering (e.g., 1FDA-483 response, 2Documents, 3Documents)
- Maximum 10 PDF files per submission
- Total file size cannot exceed 100MB; if exceeding 100MB, use compression or multiple emails
- Provide English translations for all non-English documentation
- Avoid special characters (@, #, %, etc.) in file names
- Include original signed response letter and supporting documentation

The agency will acknowledge email receipt. If files cannot be opened, paper copies may be requested.

## Post-Inspection Contacts

**For general inquiries and correspondence**: CDRHEnforcement@fda.hhs.gov
*Note: CDRH operates in Eastern Standard/Eastern Daylight Time Zone*

### Quality Management System Regulation (QMSR)

The Quality Management System Regulation (QMSR) became effective February 2, 2026. FDA device inspections now review a manufacturer's compliance with this revised regulation. The inspection process follows Compliance Program, CP 7382.850: Inspection of Medical Device Manufacturers.

*Compliance Program CP 7382.850: Inspection of Medical Device Manufacturers*

*QMSR Frequently Asked Questions*

**Questions about QMSR:** Contact the Center for Devices and Radiological Health's (CDRH) Division of Industry and Consumer Education (DICE).

Email: DICE@fda.hhs.gov
Phone: 1(800) 638-2041 or (301) 796-7100
Website: https://www.fda.gov/DICE

### Additional Resources

**OMDRHI Inspections:** For information about inspections, including your inspection report, visit *What We Do: Inspections* at www.fda.gov/OIIDevices

**Device Registration and Listing:**
https://www.fda.gov/medical-devices/how-study- and-market-your-device/device-registration-and- listing

**Mandatory Reporting Requirements:**
https://www.fda.gov/Mandatory-Reporting-Requirements-Manufacturers-Importers-and-Device-User-Facilities

### Medical Device Recalls

Contact your FDA Division Recall Coordinator (DRC). Foreign manufacturers and importers should contact the DRC where their US agent is located.

**Recall Coordinator Information**:
www.fda.gov/safety/industry-guidance-recalls/oii-recall-coordinators (Product Type: "Medical Device")

**General Recall Information:** For details on recalls, corrections, and removals, visit: www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/RecallsCorrectionsAndRemovals