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

U.S. Food and Drug Administration
Office of Inspections and Investigations (OII)
Office of Medical Devices and Radiological Health Inspectorate
Midwest (Division 4)
www.fda.gov

OMDRHI Post-Inspection Resources

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

OMDRHI operates through four domestic divisions. Your firm falls under our Midwest Division, which covers IA, IL, IN, KS, MI, MN, MO, MT, ND, NE, OH, SD, WI, and WY. For information about OMDRHI, visit www.fda.gov/OIIDevices.

FDA-483 Responses

Email inspection-related correspondence to OII-DEVICES-Midwest-Firm-Response@fda.hhs.gov. Include your company name and FEI number (from form FDA-483) in both the email subject line and cover letter/attachments.

Submission Instructions: Submit as a single PDF with bookmarks identifying contents, memos, and attachments for efficient review. If exceeding 100MB, use multiple bookmarked PDFs. Label all attachments clearly and avoid submitting multiple folders with individual files as this delays processing. The agency will acknowledge email receipt.

Contacts for OMDRHI Midwest Division (Division 4)

For general inquiries and correspondence: OII-OMDRHI-Inspectorate-MIDWEST-Director@fda.hhs.gov

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

Submit recall (21 CFR 806) information to

OII-DEVICES-Midwest-RECALLS@fda.hhs.gov

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