

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 West Division, which covers AK, AZ, CA, CO, HI, ID, NM, NV, OR, UT, and WA. For information about OMDRHI, visit www.fda.gov/OIIDevices.

FDA-483 Responses

Email inspection-related correspondence to OII-DEVICES-West-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 West Division (Division 1)

For general inquiries and correspondence:

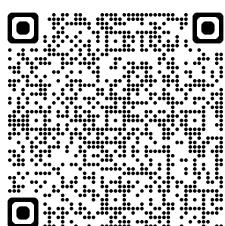
Shari Shambaugh, Division Director
Trang Cox, Supervisory Senior Advisor

Shari.Shambaugh@fda.hhs.gov
Trang.Cox@fda.hhs.gov

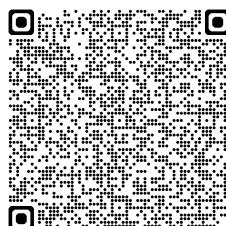
(214) 253-5215
(404) 669-4540

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-West-RECALLS@fda.hhs.gov



General Recall Information:

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