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 (OMDRHI)
Northeast (Division 3)
www.fda.gov

Communication Resources following an FDA Inspection

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

OMDRHI has four divisions. Your firm is located within our Northeast Division which covers the states of: CT, DE, KY, MA, MD, ME, NH, NJ, NY, PA, RI, VA, VT, WV, and the District of Columbia. You can learn more about OMDRHI @www.fda.gov/OIIDevices

FDA-483 Responses

Please e-mail your inspection-related correspondence to OII-Devices-NORTHEAST-Firm-Response@fda.hhs.gov Include your company's name and FEI number found on the form FDA-483 in the subject of the email, and on the cover letter or attachments. We prefer e-mail correspondence for efficiency, fiscal responsibility, and environmental awareness. Be sure that any attachments are readily labeled and/or identified for ease of review and submitted as a single pdf file, with bookmarks to easily identify table of contents, memos, attachments, etc. If a single pdf file exceeds the 100MB size limit, please submit multiple pdf files, with bookmarks, as appropriate. Do not provide multiple folders that contain individual files as this will delay the processing of your response. The agency will acknowledge receipt of your e-mail. Please do not send a back-up hard copy of any correspondence. If hard copy, thumb drive, or compact disc (cd) are the only way you can send a response, please email Joseph.Matrisciano@fda.hhs.gov to obtain a mailing address.

Contacts for OMDRHI Northeast (Division 3)

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Final Rule: Revised FDA regulation effective in 2026

On February 2, 2026, the *Quality Management System Regulation* (QMSR) will go into effect. On the effective date, FDA device inspections will review a manufacturer's compliance with this revised regulation. Links to the final rule and the Frequently Asked Questions can be found on OMDRHO's webpage www.fda.gov/OIIDevices

On 02/02/2024 the agency published Quality Management System Regulation: Final Rule. Read the rule. For more information read the Frequently Asked Questions FDA.

If you have questions about the QMSR, contact the Center for Devices and Radiological Health's (CDRH) Division of Industry and Consumer Education (DICE).

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

Medical Device Recalls

Submit recall (21 CFR 806) information to

OII-Medical-Device-Recalls-NORTHEAST@fda.hhs.gov

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

Additional useful links:

- For general information about **OMDRHI inspections**, including your inspection report, visit **What We Do: Inspections** at www.fda.gov/OIIDevices
- For general information about **device registration and listing**, visit: https://www.fda.gov/medical-devices/how-study-and-market-your-device/device- registration-and-listing
- For general information on **mandatory reporting requirements**, visit: https://www.fda.gov/Mandatory-Reporting-Requirements-Manufacturers-Importers-and-Device-User-Facilities