

Communication Resources following an FDA Inspection

About Office of Medical Device and Radiological Health Operations (OMDRHO)
OMDRHO has 3 divisions. Your firm is located within Division 1 boundaries which covers the states of: CT, DE, IN, KY, MA, ME, MD, MI, NH, NJ, NY, OH, PA, RI, VA, VT, WV and the District of Columbia.

FDA-483 Responses

Please e-mail your inspection-related correspondence to oradevices1firmresponse@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 expedited service to stakeholders 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 Division will acknowledge receipt of your e-mail. There is no need to provide a back-up hard copy of any correspondence sent via email.

Hard copy, thumb drive, and compact disc (cd) responses are discouraged, but if that is the only way you can send a response, please use the address below:

U.S. Food and Drug Administration
Office of Medical Device and Radiological Health Operations Division 1 – East
ATTN: OMDRHO Div1 Correspondence
109 Holton Street
Winchester, MA 018900

OMDRHO Division 1 – East Contacts:

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Recall Coordinators

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Medical device recalls: Submit recall (21 CFR 806) information to oradevices1recalls@fda.hhs.gov
For general information on recalls, corrections and removals, visit:
www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/RecallsCorrectionsAndRemovals/

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/ORADevices

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>

Additional useful links:

- For general information about **OMDRHO inspections**, including your inspection report, visit: www.fda.gov/ORADevices
- 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/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities>