U.S. FOOD & DRUG ADMINISTRATION
Office of Regulatory Affairs

U.S. Food and Drug Administration
Office of Regulatory Affairs
Office of Medical Device and Radiological Health Operations (OMDRHO) Division 3 – West
19701 Fairchild
Irvine, CA 92612
Telephone: (949) 608-2900 www.fda.gov

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 3 boundaries which covers the states of: AK, AR, AZ, CA, CO, HI, ID, MT, NM, NV, OK, OR, TX, UT, WA and WY.

FDA-483 Responses

Please e-mail your inspection-related correspondence to oradevices3firmresponse@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 3 – West
ATTN: Program Division Director
19701 Fairchild
Irvine, CA 92612

OMDRHO Division 3 – West Contacts:

Shari Shambaugh, Program Division Director (PDD) manages all inspections and compliance activities.	Shari.Shambaugh@fda.hhs.gov (214) 253-5215
Trang Cox, Director of Investigations Branch (DIB) manages all inspectional activities.	Trang.Cox@fda.hhs.gov (404) 273-9231
Jessica Mu, Director of Compliance Branch (DCB) manages FDA-483 responses and post-inspection compliance activities.	Jessica.Mu@fda.hhs.gov (949) 608-4477
Recall Coordinators	Mark Chan (408) 291-7548 ext. 1108 Paul Frazier (214) 253-5340 Theresa Kirkham (949) 608-4437

Medical device recalls: Submit recall (21 CFR 806) information to oradevices3recalls@fda.hhs.gov

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

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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/ORADevices

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> 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