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

FDA Contact Information

Your firm now has new FDA contacts to correspond with regarding your medical device inspections.

Your inspections are now managed by the Office of Regulatory Affairs' Office of Medical Device and Radiological Health Operations (OMDRHO) Division 3 – West.

What is the Office of Medical Device and Radiological Health Operations (OMDRHO) Division 3 – West?

This program division solely works with medical devices, radiological health devices, and MQSA equipment. It covers the states of: AK, AR, AZ, CA, CO, HI, ID, MT, NM, NV, OK, OR, TX, UT, WA and WY.

Who do I contact following my FDA inspection?

E-mail your inspection-related correspondence to the email address listed below. A copy will be sent to the home district where your firm is located for FOI activities. Hard copy responses are discouraged, but if that is the only way you can send a response, please use the address listed below.

E-mail correspondence to ORADevices3FirmResponse@fda.hhs.gov

Office of Medical Device and Radiological Health Operations
Division 3 – West
ATTN: Program Division Director
19701 Fairchild
Irvine, CA 92612

Who do I contact about my medical device recall?

Contact the e-mail address below and a recall coordinator will contact you.

oradevices3recalls@fda.hhs.gov

Mark Chan	(408) 291-7548 ext. 1108
Paul Frazier	(214) 253-5340
Theresa Kirkham	(949) 608-4437

How do I submit my correspondence?

OMDRHO Division 3 – West prefers correspondence sent via email. E-mail submission is the preferred method due to a focus on efficiency, fiscal responsibility, and environmental awareness. The division will acknowledge receipt of your response. You do not need to mail or hand-deliver a second/back-up hardcopy response. Your response (size limit of less than 100 megabytes) may be sent via email to ORADevices3FirmResponse@fda.hhs.gov. Files larger than 100MB can be submitted as several smaller files or via hardcopy. If you are sending the response in multiple emails, please include "1 of 3", "2 of 3", etc. in the subject line of the email. Please be sure that any attachments are readily labeled and/or identified for ease of review.

What other contact information do I need to know?

The Program Division Director (PDD), OMDRHO Division 3 – West, supervises all inspections and compliance activities. Shari Shambaugh, PDD, can be reached at shari.shambaugh@fda.hhs.gov or (214) 253-5215.

The Director of Compliance Branch (DCB), OMDRHO Division 3 – West, manages FDA-483 responses and post-inspection compliance activities. Jessica Mu, DCB, can be reached at jessica.mu@fda.hhs.gov or (949) 608-4477.

The Director of Investigations Branch (DIB), OMDRHO Division 3 – West, manages all inspectional activities. Eric Anderson, DIB, can be reached at eric.anderson@fda.hhs.gov or (510) 337-6752

More Information

For general medical device, MQSA or radiological health regulatory questions, you may 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
www.fda.gov/DICE

- **For training videos and slides, visit:**
  www.fda.gov/Training/CDRHLearn

- **For general information about device registration and listing, visit:**
  www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing

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

- **For general information on mandatory reporting requirements, visit:**
  www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents