

## 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 South Division, which covers AL, AR, FL, GA, LA, MS, NC, OK, PR, SC, TN, TX, and US Virgin Islands. For information about OMDRHI, visit [www.fda.gov/OIDDevices](http://www.fda.gov/OIDDevices).

### FDA-483 Responses

Email inspection-related correspondence to [OI-DEVICES-South-Firm-Response@fda.hhs.gov](mailto:OI-DEVICES-South-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 South Division (Division 2)

For general inquiries and correspondence:

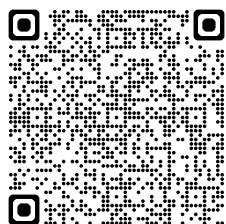
Blake Bevill, Division Director  
James Hildreth, Supervisory Senior Advisor

[Blake.Bevill@fda.hhs.gov](mailto:Blake.Bevill@fda.hhs.gov)  
[James.Hildreth@fda.hhs.gov](mailto:James.Hildreth@fda.hhs.gov)

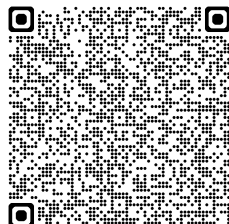
(407) 475-4734  
(404) 669-4555

#### 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](mailto: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/OIDDevices](http://www.fda.gov/OIDDevices)

#### 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

[OI-DEVICES-South-RECALLS@fda.hhs.gov](mailto:OI-DEVICES-South-RECALLS@fda.hhs.gov)



#### General Recall Information:

For details on recalls, corrections, and removals, visit:

[www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/RecallsCorrectionsAndRemovals](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/RecallsCorrectionsAndRemovals)