

FDA EXTERNAL FACT SHEET

About the Office of Medical Device and Radiological Health Operations

A specialized office to help protect and promote the safety and quality of medical devices and radiation-emitting products.

The Office of Medical Device and Radiological Health Operations (OMDRHO), a program within the Office of Medical Products and Tobacco Operations in the Office of Regulatory Affairs (ORA), provides advice and counsel to ORA and FDA leaders regarding medical device and radiological health program operations, including emergency response activities. OMDRHO collaborates with the agency's Center for Devices and Radiological Health (CDRH) on all FDA-regulated medical devices and radiation-emitting products.

OMDRHO coordinates, directs and assists with medical device and radiological health inspectional activities, including conducting inspections of medical devices and radiation-emitting products, as well as providing technical assistance regarding medical devices and radiological health inspectional operations. ORA and CDRH partner to develop annual work plans and strategic priorities for inspections, compliance, analysis, and import operations as part of FDA's implementation of the, [Medical Device User Fee and Modernization Act](#).

[Jan Welch](#) directs OMDRHO's day-to-day operations and coordination with CDRH. The office structure includes the Foreign Medical Device and Radiological Health Inspection Staff, Medical Device and Radiological Health Operations Staff, and Divisions of Medical Device and Radiological Health Operations I, II, and III, with responsibility for oversight of staff conducting inspections, managing compliance activities, recalls, and partnerships.

ORA's Program Division Directors, formerly District Directors, are the most senior FDA official in their geographic area and continue to be the point of contact for local staff, public and industry. FDA's local coordination with federal, state, local, tribal, and territorial regulatory and public health agency officials will continue to be managed by district state liaisons. Contact OMDRHO at engageORA@fda.hhs.gov.

For more information visit:

- [Office of Regulatory Affairs](#)
- [Center for Devices and Radiological Health](#)

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, and products that give off electronic radiation, and for regulating tobacco products.