# FDA's Office of Regulatory Affairs Aligned for the Future

Regulatory Education For Industry
May 29, 2019
Boston, MA

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Director, New England District
Director, Office of Medical Products and Radiological Health Operations Division 1

*“…Modernize and strengthen the FDA workforce to improve public health response.”*

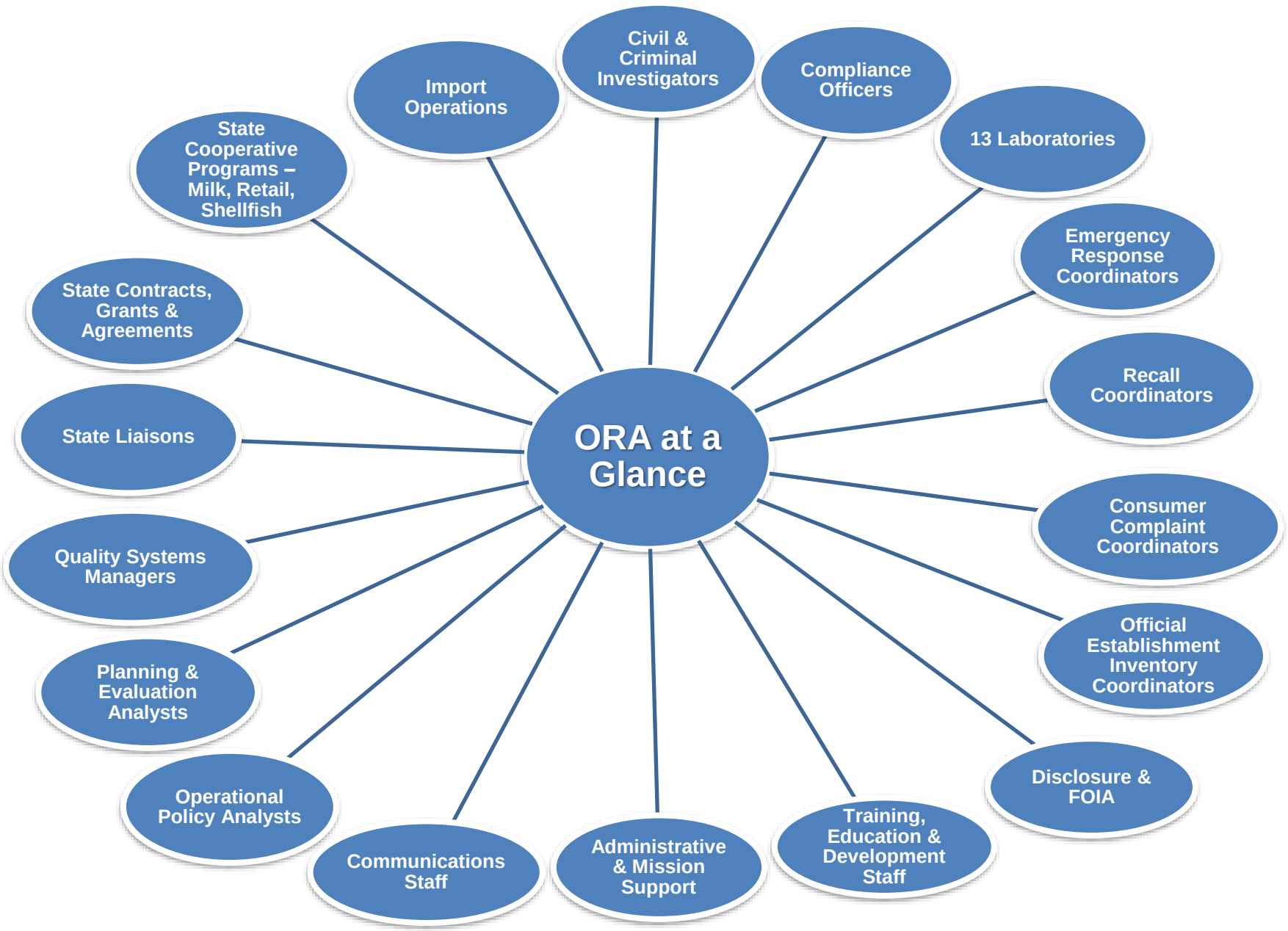
# FDA Program Alignment Charge

# Program Alignment: Key Changes

| Then | Now |
| --- | --- |
| Geographic management | Programmatic management |
| Regional Food & Drug Directors | Program Directors |
| Twenty District Directors | Twenty District Directors ***plus*** eight new program division directors |
| Degrees of program specialization | Exclusive specialization in one program for investigators, compliance officers and operational managers. |

# ORA FY 2018

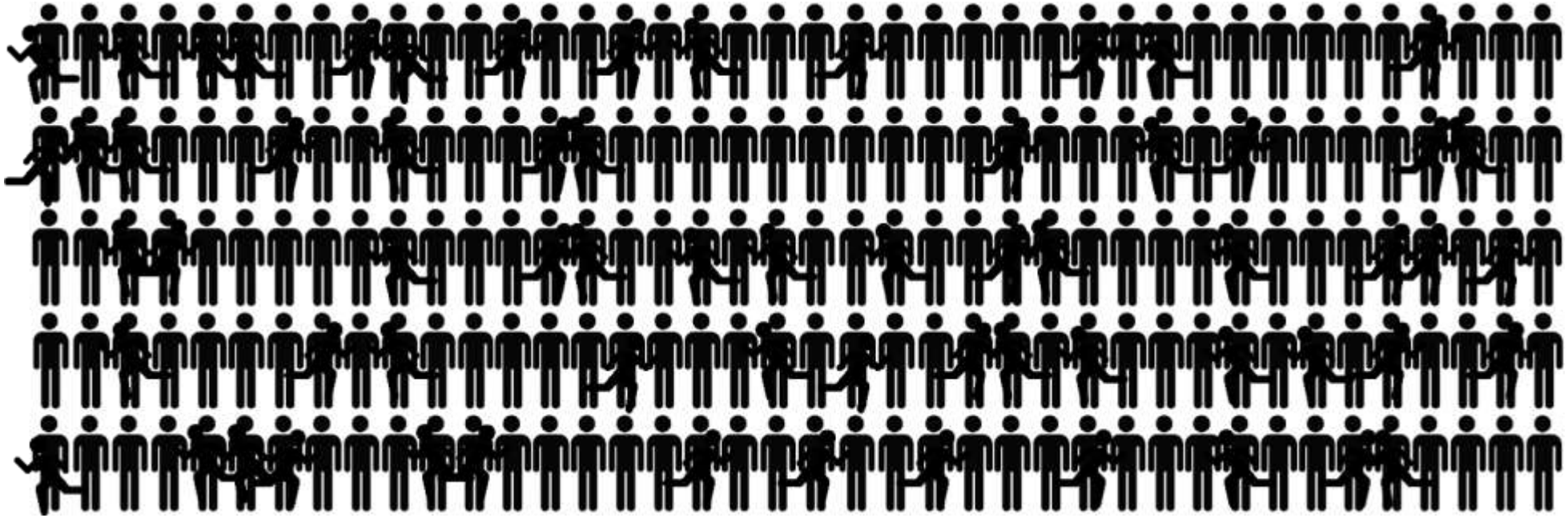
## *FACTS*


ORA at a Glance
Civil & Criminal Investigators
Compliance Officers
13 Laboratories
Emergency Response Coordinators
Recall Coordinators
Consumer Complaint Coordinators
Official Establishment Inventory Coordinators
Disclosure & FOIA
Training, Education & Development Staff
Administrative & Mission Support
Communications Staff
Operational Policy Analysts
Planning & Evaluation Analysts
Quality Systems Managers
State Liaisons
State Contracts, Grants & Agreements
State Cooperative Programs – Milk, Retail, Shellfish
Import Operations

# ORA FY 2018

## 4,550

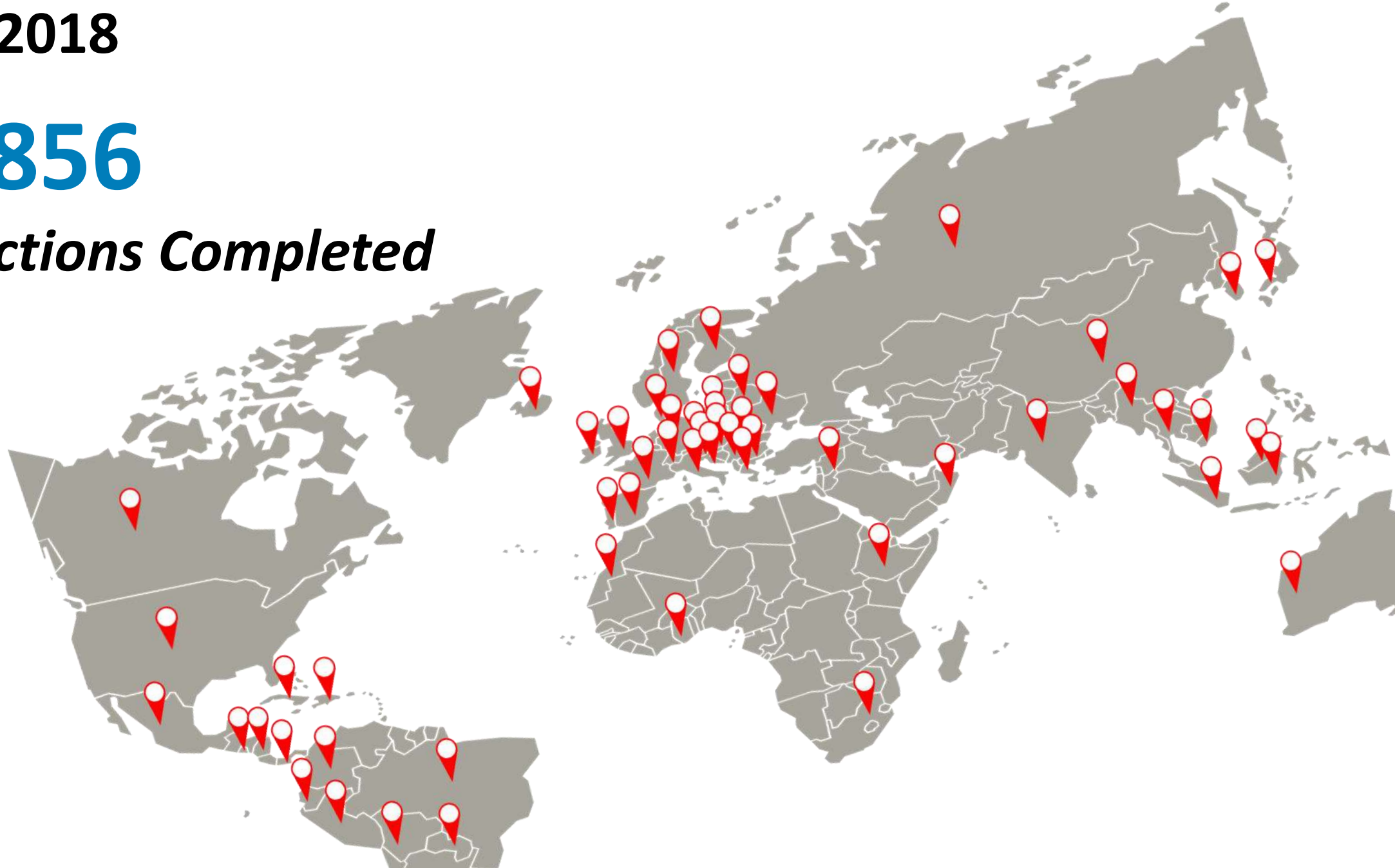
***Employees***



# ORA FY 2018

## 38,856

***Inspections Completed***



# ORA FY 2018

## 43,099

***Samples Analyzed***


# ORA FY 2018

## 14,285

***Warning Letters Issued***

# ORA FY 2018

## 7,562

***Products Recalled***

# ORA FY 2018

**317**
***Arrests***

**215**
***Convictions***

# ORA FY 2018

## $2,182,317,876

***Paid Fines & Restitution***

## $114,163,550

***Forfeited & Seized Assets***

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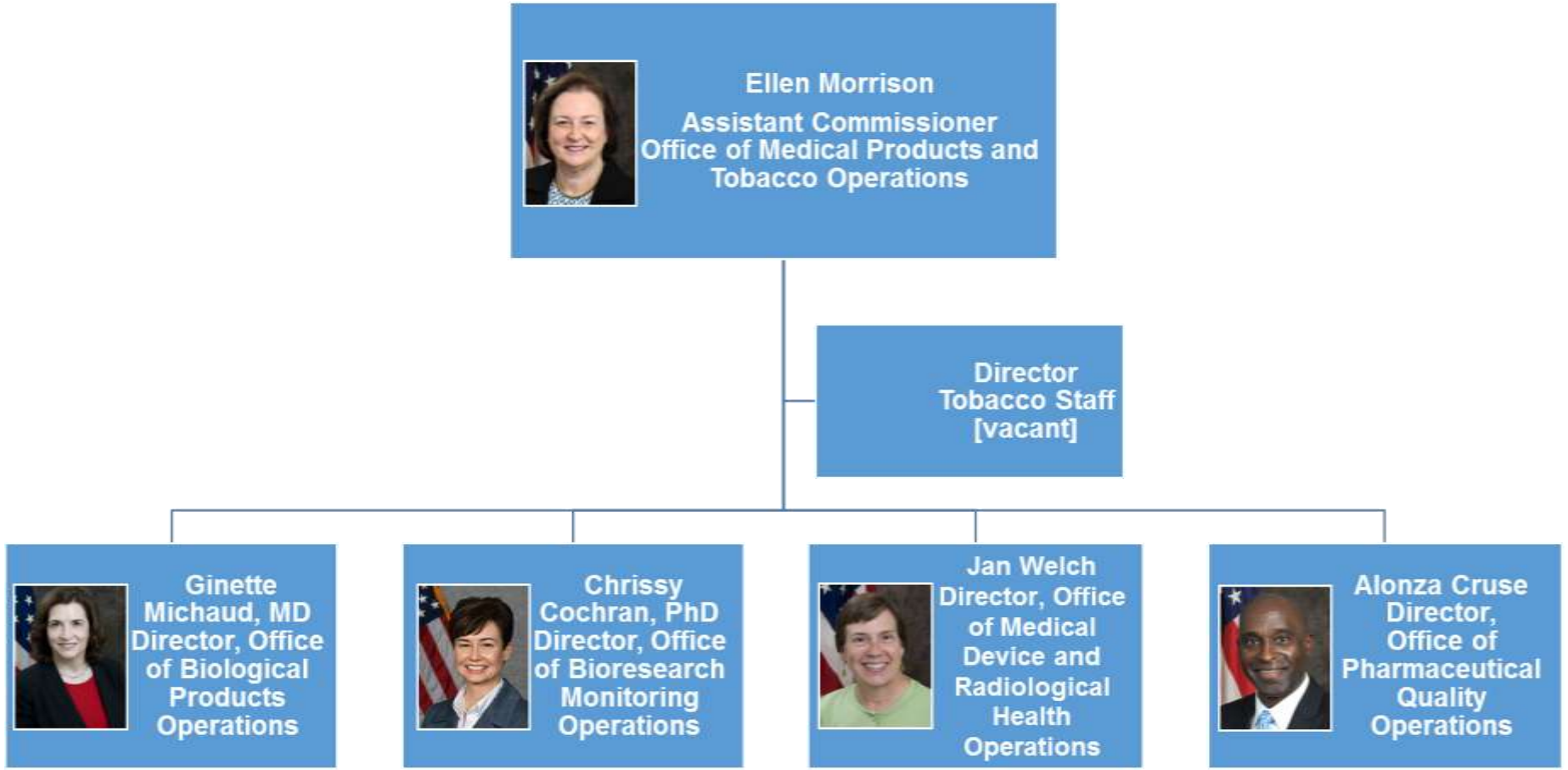
## $2,296,481,426

# ORA Program Divisions

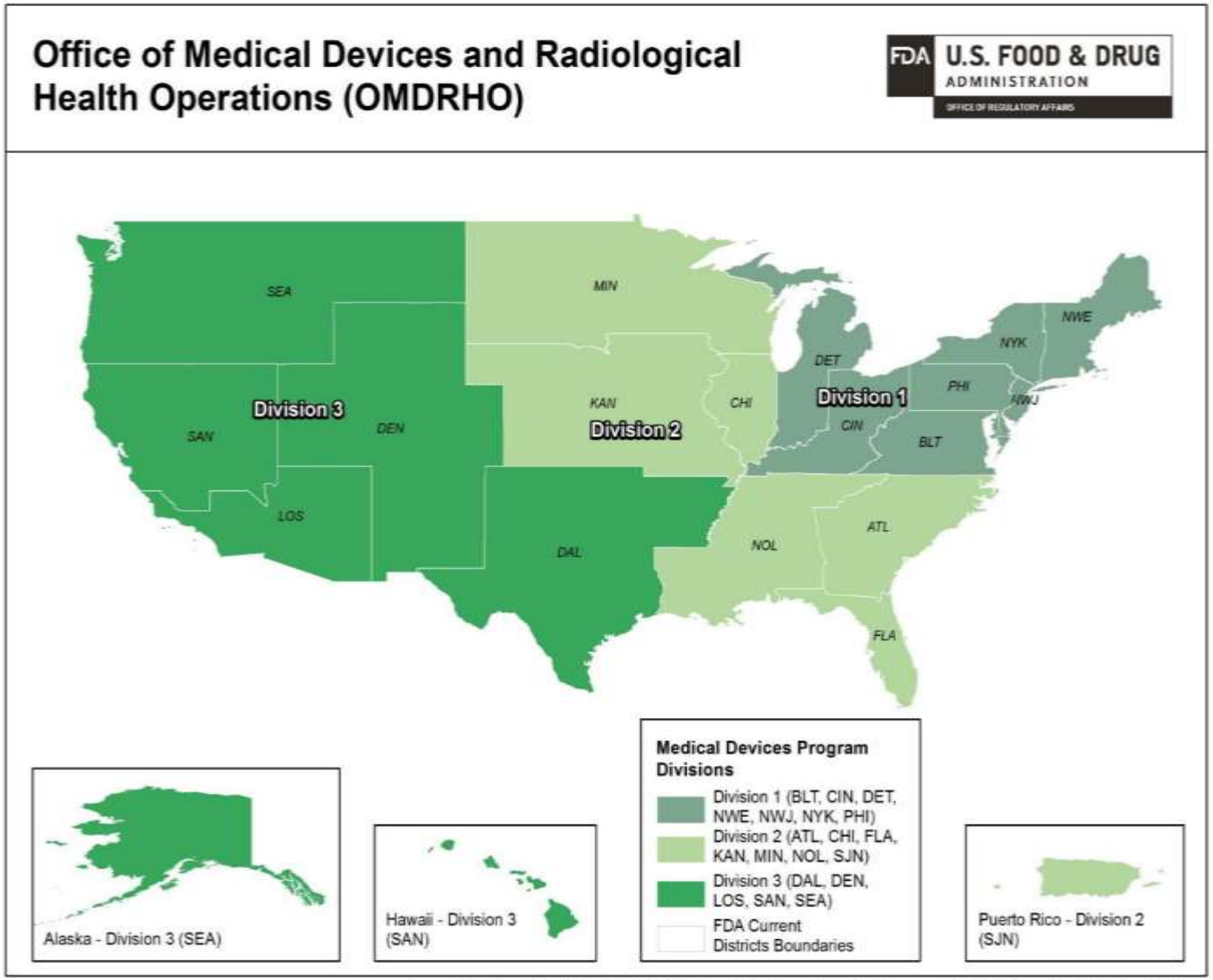
- **Office of Bioresearch Monitoring Operations (OBIMO)**
- **Office of Biological Products Operations (OBPO)**
- **Office of Medical Device and Radiological Health Operations (OMDRHO)**
- **Office of Pharmaceutical Quality Operations (OPQO)**
- **Office of Human and Animal Food Operations (OHAFO)**
- **Office of Enforcement and Import Operations (OEIO)**
- **Tobacco Operations Program**

# Office of Medical Products and Tobacco Operations



# Office of Medical Device and Radiological Health Operations

# Program Alignment – post 5/15/17



# Office of Medical Device and Radiological Health

## Immediate Office

| Office | Title | Name |
|---|---|---|
| **OMDRHO** | Director | Jan Welch |
| **OMDRHO** | Deputy Director | Anne Reid |
| **OMDRHO** | Special Assistant | Kristina Donohue |
| **OMDRHO** | QMS Manager | Lynne Dwyer |
| **OMDRHO** | Training Officer | Monica Forrest |
| **OMDRHO/Medical Device and Radiological Health Staff Operations** | Staff Director | Rhonda Mecl |
| **OMDRHO/Foreign Medical Devices and Radiological Health Inspection Staff** | Staff Director | Dorothy Lee |

# Office of Medical Device and Radiological Health

## Division I

| Office | Title | Name | Coverage |
|---|---|---|---|
| **OMDRHO Division I** | Program Division Director/District Director | Joseph S. Matrisciano Jr | NWE/BLT/CIN/DET/ NWJ/NYK/PHI |
| **OMDRHO Division I** | Compliance Branch Director | Gina Brackett | NWE/BLT/CIN/DET/ NWJ/NYK/PHI |
| **OMDRHO Division I** | Investigations Branch Director | Arduino Frankovic | NWE/BLT/CIN/DET/ NWJ/NYK/PHI |
| **OMDRHO Division I** | Recall Coordinators | Melinda Ruiz<br>Cynthia Aycock<br>Andrew Lang | NWE/BLT/CIN/DET/ NWJ/NYK/PHI |

# Office of Medical Device and Radiological Health

## Division II

| Office | Title | Name | Coverage |
|---|---|---|---|
| **OMDRHO Division II** | Program Division Director | Blake Bevill | FLA/ATL/CHI/KAN/ MIN/NOL/SJN |
| **OMDRHO Division II** | Compliance Branch Director | Melissa Michurski | FLA/ATL/CHI/KAN/ MIN/NOL/SJN |
| **OMDRHO Division II** | Investigations Branch Director | Kathleen Sinninger | FLA/ATL/CHI/KAN/ MIN/NOL/SJN |
| **OMDRHO Division II** | Recall Coordinators | Neisa Alonso<br>Meredith Andress<br>Marie Fink | FLA/ATL/CHI/KAN/ MIN/NOL/SJN |

# Office of Medical Device and Radiological Health

## Division III

| Office | Title | Name | Coverage |
|---|---|---|---|
| **OMDRHO Division III** | Program Division Director | Shari Shambaugh | LOS/DAL/DEN/SAN/SEA |
| **OMDRHO Division III** | Compliance Branch Director | Vacant | LOS/DAL/DEN/SAN/SEA |
| **OMDRHO Division III** | Investigations Branch Director | Eric Anderson | LOS/DAL/DEN/SAN/SEA |
| **OMDRHO Division III** | Recall Coordinator | Theresa Kirkham | LOS/DAL/DEN/SAN/SEA |

# New Contact Information

- Inspection FAQ Handout
- On The Web:
  https://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ContactORA/ucm604350.htm#OMDRHO

U.S. FOOD & DRUG ADMINISTRATION

## FAQs on FDA Medical Device Inspections

Inspections of medical devices are managed by FDA's Office of Regulatory Affairs (ORA), Office of Medical Device and Radiological Health Operations (OMDRHO) Division 1 – East.

This division oversees only medical device inspections within 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.

### How do I submit my correspondence?

- E-mails to oradevices1firmresponse@fda.hhs.gov are best (limit to 100 MB per message); acknowledgement of receipt is automatic.
- To expedite review, clearly label attachments and submit documents in a single pdf file; include bookmarks that identify table of contents, memos, attachments, etc. If your pdf file exceeds 100MB, submit multiple pdf files (include bookmarks). Do not provide multiple folders that contain individual files as this will delay a response. Do not provide a back-up hard copy of any correspondence sent via e-mail, thumb drive, or CD format. Contact the FDA Administrative Officer (781-587-7451 or donna.dismukes@fda.hhs.gov) with questions.

### whom do I follow-up after the inspection?

- Send inspection-related correspondence to oradevices1firmresponse@fda.hhs.gov.

U.S. Food and Drug Administration
Office of Medical Device and Radiological Health Operations Division 1 – East
TTN: OMDRHO Div1 Correspondence
e Montvale Avenue
eham, MA 02180

### act about a device recall?

vices1recalls@fda.hhs.gov.



www.fda.gov

U.S. Food and Drug Administration
Office of Regulatory Affairs
Office of Medical Device and Radiological Health Operations (OMDRHO) Division 1 – East
One Montvale Avenue
Stoneham, MA 02180
Telephone: (781) 587-7500
www.fda.gov

# New 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 1 – East.

## What is the Office of Medical Device and Radiological Health Operations (OMDRHO) Division 1 – East?

This Program Division solely works with medical devices. It 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.

## How do I submit my FDA-483 Response following my inspection?

E-mail your inspection-related correspondence to the email address listed below. Please include your company's FEI number, if known, in the subject of the email, and on the cover letter or documentation. Hard copy responses are discouraged, but if that is the only way you can send a response, please use the address listed below. Thumb drive or compact disc (cd) may be sent to the address below.

We prefer e-mail correspondence due to efficiency, fiscal responsibility, expedited service to stakeholders and environmental awareness. The Division will acknowledge receipt of your e-mail (size limit 100 megabytes) to ORADevices1FirmResponse@fda.hhs.gov.

Please be sure that any attachments are readily labeled and/or identified for ease of review to include the FEI number. Documentation should be 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. Please do not provide multiple folders that contain individual files as this will delay the processing of your response. There is no need to provide a back-up hard copy of any correspondence sent via email or provided in thumb drive or cd format.

**E-mail correspondence to** oradevices1firmresponse@fda.hhs.gov

U.S. Food and Drug Administration
Office of Medical Device and Radiological Health Operations Division 1 – East
ATTN: OMDRHO Div1 Correspondence
One Montvale Avenue
Stoneham, MA 02180

## Who do I contact about my medical device recall?

**Contact e-mail address** oradevices1recalls@fda.hhs.gov

## What other contact information do I need to know?

The Program Division Director (PDD), OMDRHO Division 1 – East manages all inspections and compliance activities. Joseph Matrisciano, DD/PDD may be reached at joseph.matrisciano@fda.hhs.gov or by phone at (781) 587-7490.

The Director of Compliance Branch (DCB), OMDRHO Division 1 – East manages FDA-483 responses and post-inspection compliance activities. Gina Brackett, DCB, can be reached at Gina.Brackett@fda.hhs.gov or by phone at (513) 679-2700.

The Director of Investigations Branch (DIB), OMDRHO Division 1 – East, manages all inspectional activities. Arduino Frankovic, DIB, may be reached at arduino.frankovic@fda.hhs.gov or by phone at (718) 662-5664.

## Why are you changing my FDA contacts?

In May 2017, as part of a broader agency initiative called program alignment, the U.S. Food and Drug Administration's (FDA) Office of Regulatory Affairs (ORA) implemented a program-based management structure that aligns staff by FDA-regulated product. This organizational approach replaces a management structure based on geographic regions. The changes within ORA are being made as part of the agency's Program Alignment strategy to modernize and strengthen the FDA's workforce and improve our public health response.
For more information on program alignment, visit:
https://www.fda.gov/aboutfda/centersoffices/officeofglobalregulatoryoperationsandpolicy/ora/ucm549087.htm

## More Information

For general medical device regulatory questions, you may contact the Center for Devices and Radiological Health's (CDRH) Division of Industry and Consumer Assistance (DICE)

**E-mail:** DICE@fda.hhs.gov
**Phone:** 1(800) 638-2041 or (301) 796-7100
https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ContactDivisionofIndustryandConsumerEducation/default.htm

- **For training videos and slides, visit:**
  https://www.fda.gov/Training/CDRHLearn/
- **For general information about device registration and listing, visit:**
  https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053185.htm
- **For general information on recalls, corrections and removals, visit:**
  https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/RecallsCorrectionsAndRemovals/default.htm
- **For general information on mandatory reporting requirements, visit:**
  https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/

# Program Alignment: ORA Contacts

- Visit **www.fda.gov/ora**

  ↳Click on “View ORA Contacts”

    ↳Click “ORA Contacts”

# Thank You!