Office of Medical Devices and Radiological Health

OMPTO/ORA/FDA

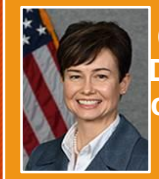
Office of Medical Products and Tobacco Operations

Ellen Morrison

Assistant Commissioner
Office of Medical Products and Tobacco Operations

Director
Tobacco Staff
[vacant]

Ginette Michaud, MD
Director, Office of Biological Products Operations



Chrissy Cochran, PhD
Director, Office of Bioresearch Monitoring Operations

Jan Welch
Director, Office of Medical Device and Radiological Health Operations

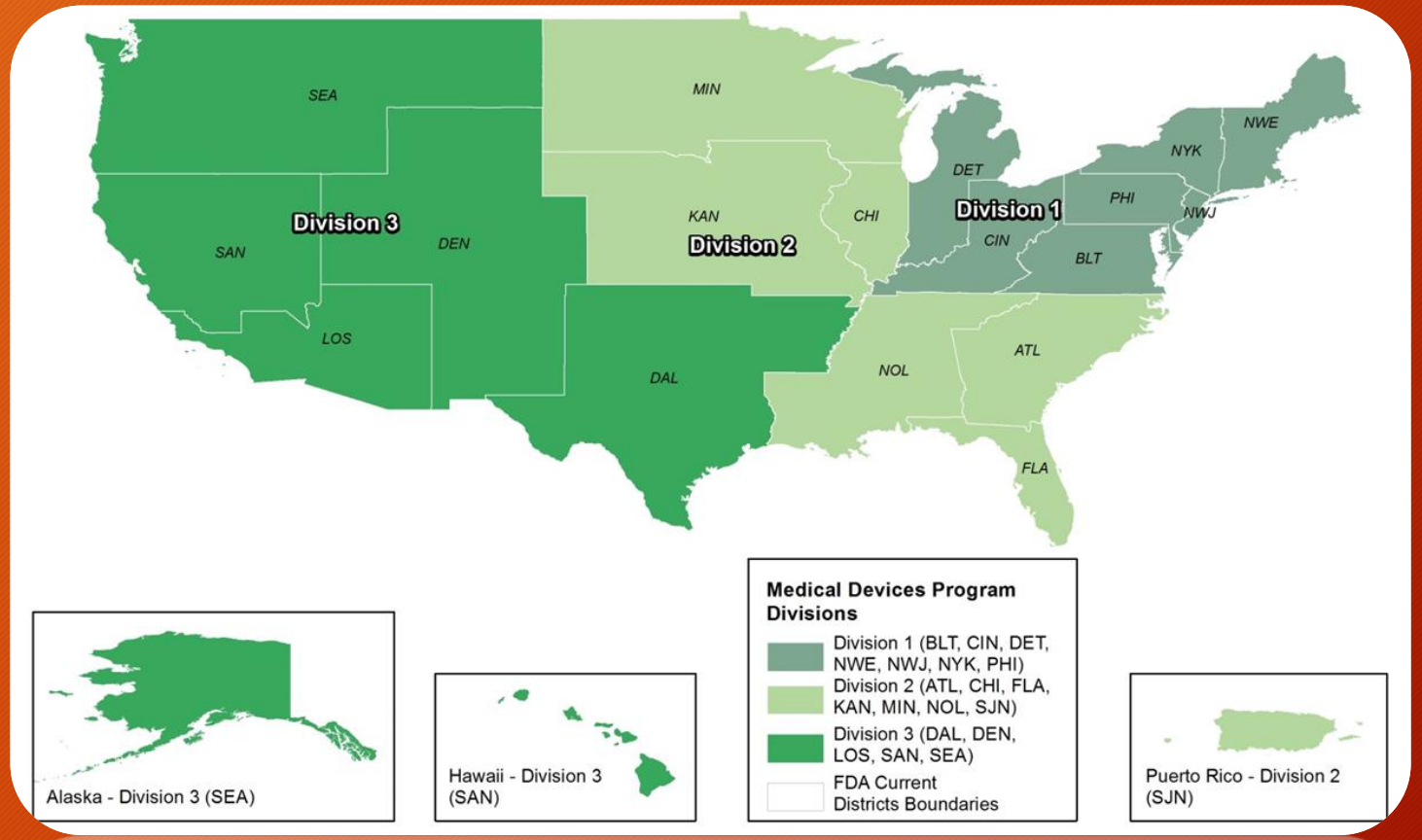
Alonza Cruse
Director, Office of Pharmaceutical Quality Operations

Office of Medical Devices and Radiological Health

Office of Medical Devices 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 (Acting)
OMDRHO/Foreign Medical Devices and Radiological Health Inspection Staff	Staff Director	Dorothy Lee

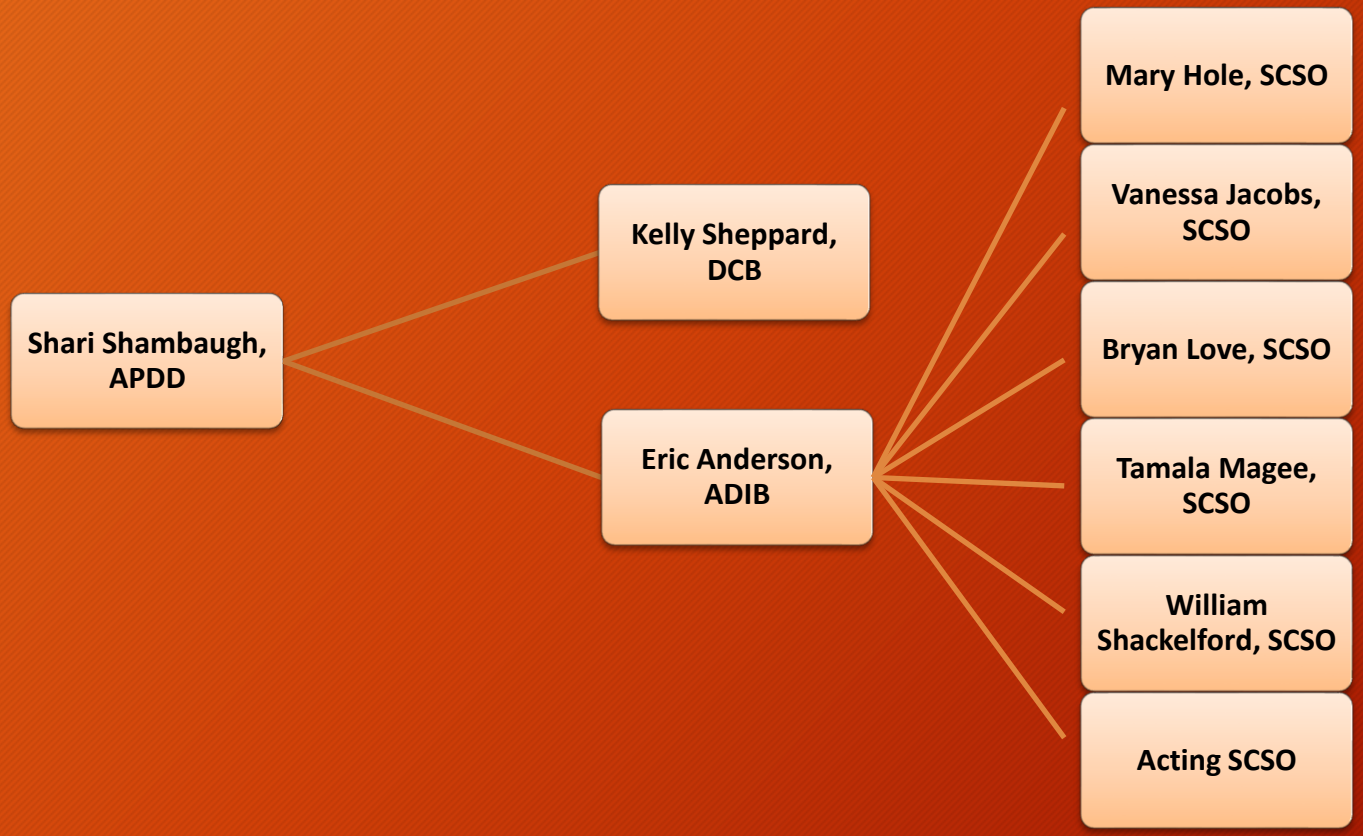
Office of Medical Devices and Radiological Health – Division 3/W



Office of Medical Devices and Radiological Health – Division 3/W

Office	Title	Name	Coverage
OMDRHO Division III	Program Division Director	Shari Shambaugh (Acting)	LOS/DAL/DEN/SAN/SEA
OMDRHO Division III	Compliance Branch Director	Kelly Sheppard	LOS/DAL/DEN/SAN/SEA
OMDRHO Division III	Investigations Branch Director	Eric Anderson (Acting)	LOS/DAL/DEN/SAN/SEA

Office of Medical Devices and Radiological Health – Division 3/W Management



Office of Medical Devices and Radiological Health – Division 3/W

- Known as Division 3 or the West Division
- Sixteen states, three time zones
- Five former district medical device programs
- Investigative, compliance, support staff and management personnel widely distributed throughout the division
- Work centrally planned and monitored

What's Next

- Complete the structural changes
- Continue to advance operational change (e.g.)
  - Updated training programs & subspecialties
  - Revamp work planning
  - National operations SOPs
- Continuous Improvement

Inspectional Handouts

U.S. FOOD & DRUG

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 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 NSIRA 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 FDI 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

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.

Nadine Alonso [407] 475-4717
Meredith Andrews [407] 475-4722
Marie Pina [904] 845-6139

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 . 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.

Resources and Contacts

www.FDA.gov/ORA

- ORA Organization Charts and Boundary Maps
- Fact Sheets
  - ORA's New Structure
  - Operational Offices
- Investigations Operations Manual
  - Headquarters, District/Division Contact Information

ORA Contacts

- State and local inquiries
  - District Director/Program Division Directors
  - State Liaison
- General Inquiries
  - engageORA@fda.hhs.gov