

FDA'S OFFICE OF REGULATORY AFFAIRS ALIGNS FOR THE FUTURE

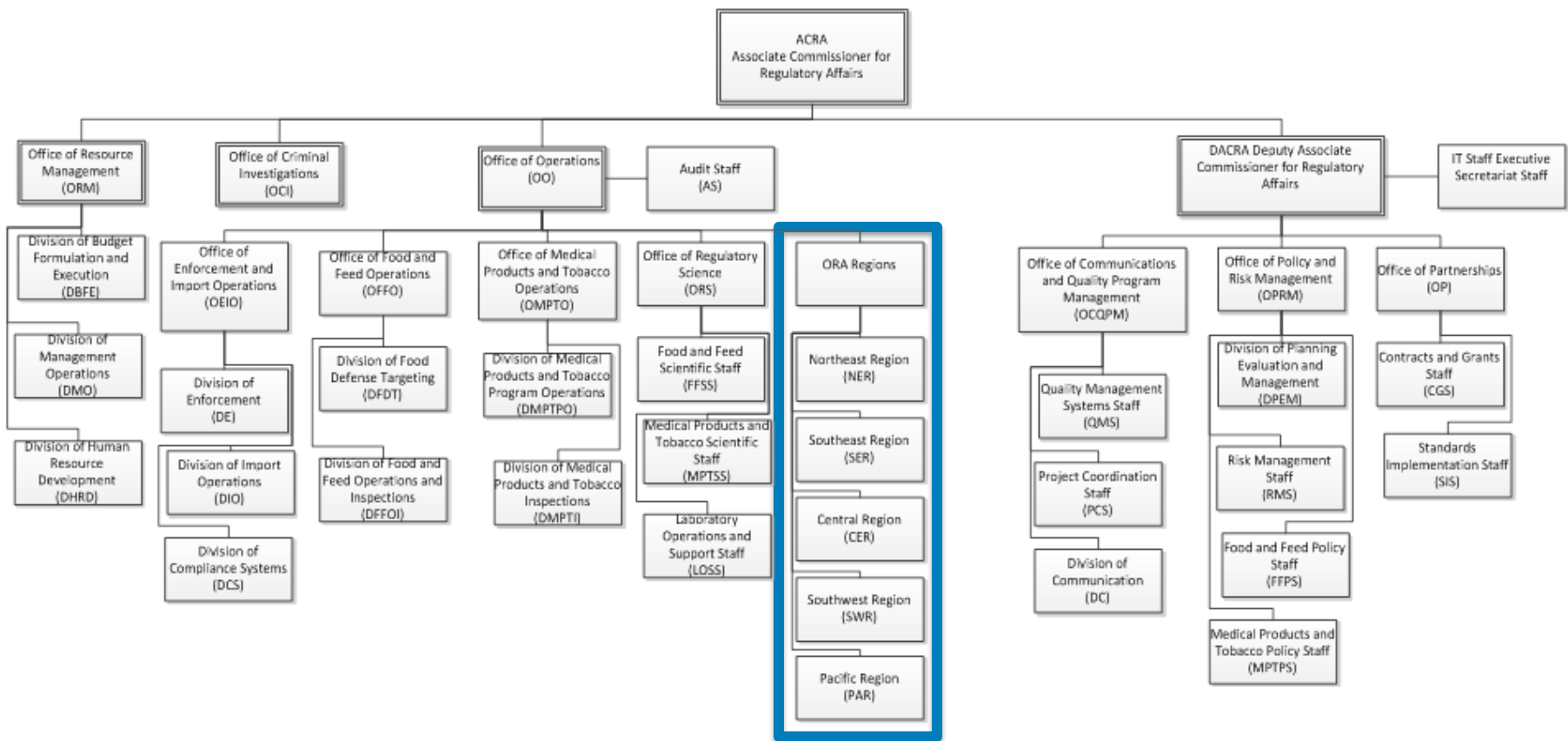
**121ST AFDO EDUCATIONAL CONFERENCE
June 19, 2017**

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

2013 FDA Program Alignment Charge

OLD

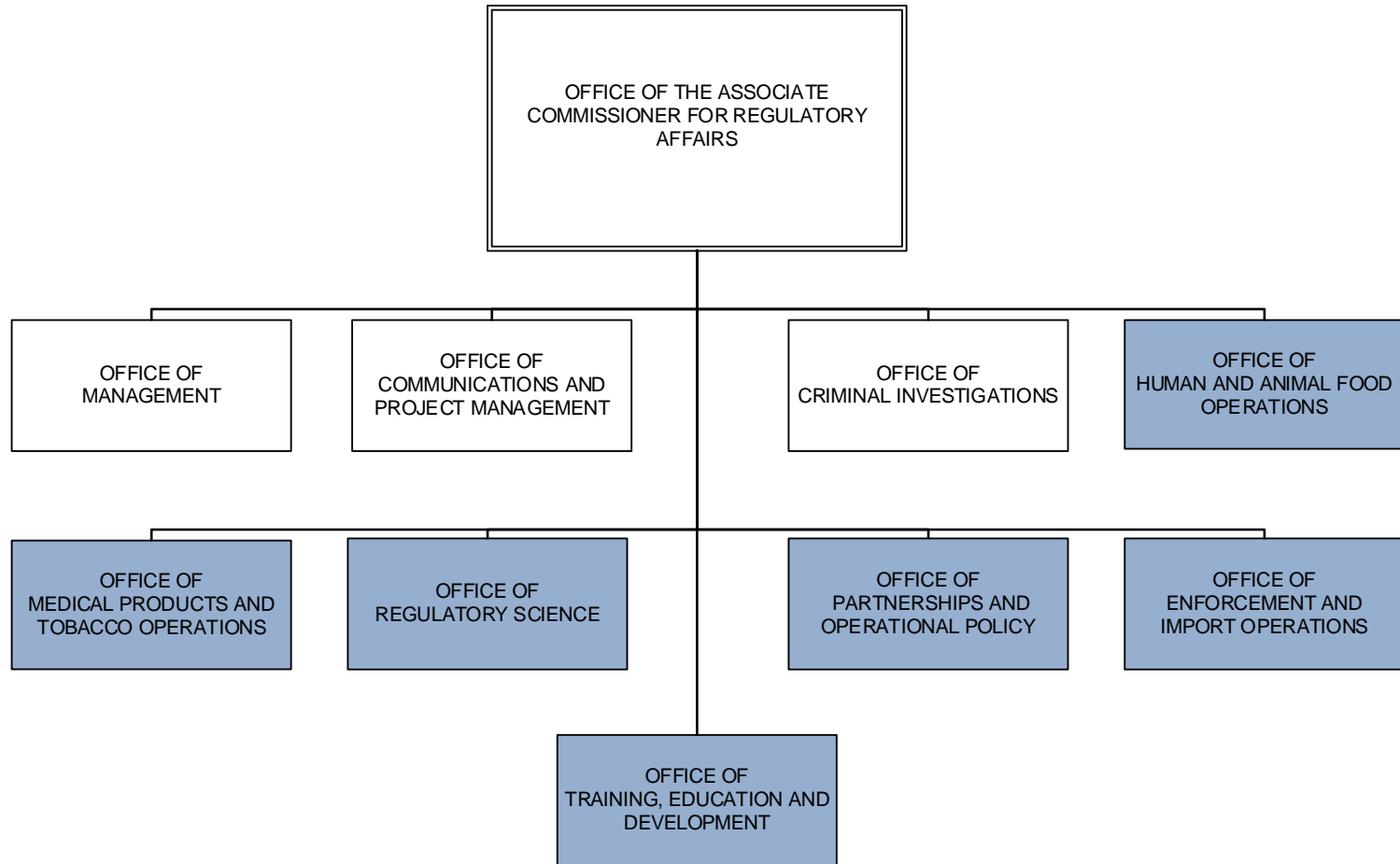
Geographically Aligned Organizational Model

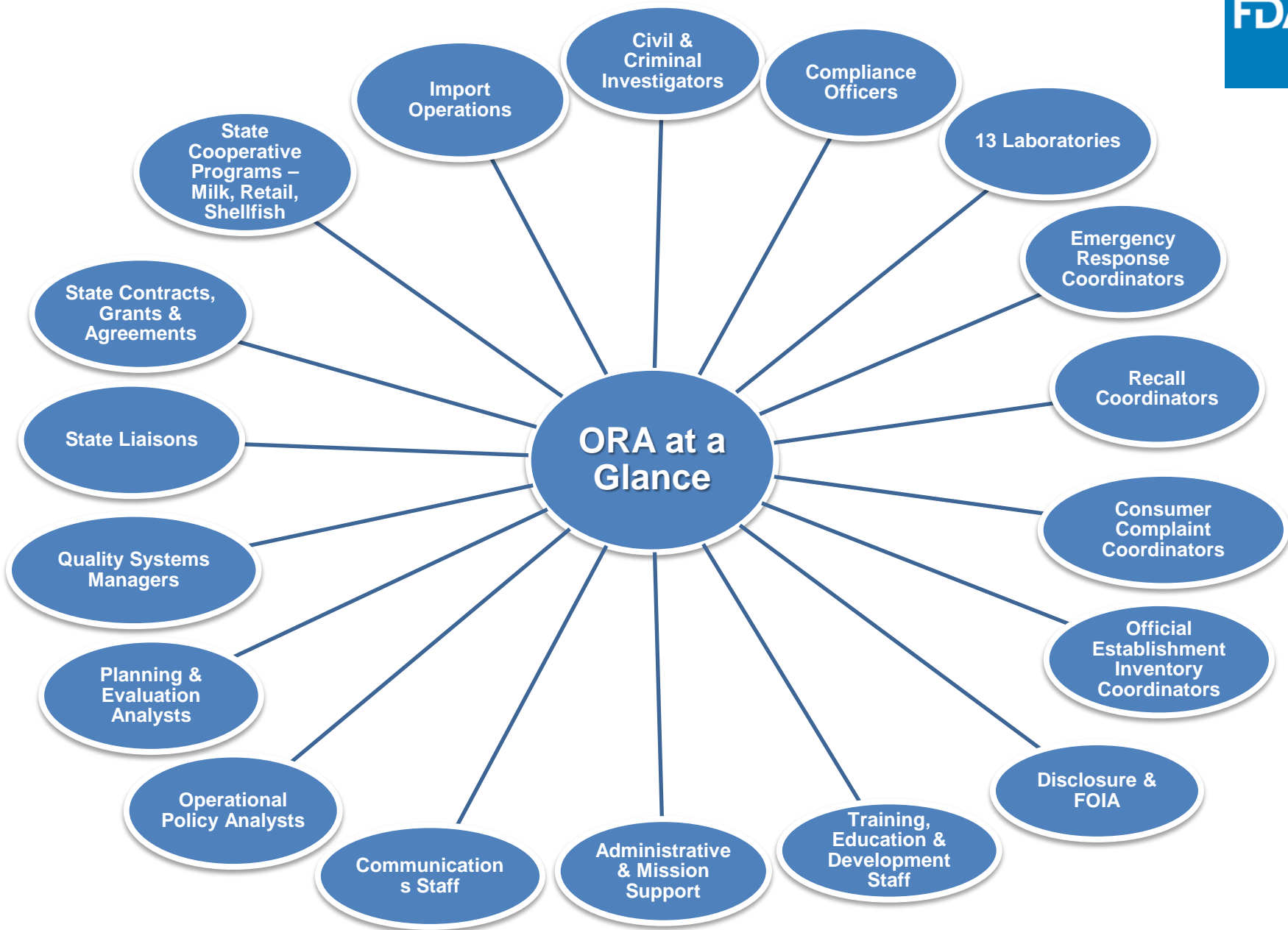


New

Program Aligned Organizational Model

FDA







Program Alignment: Key Changes

From	To
Geographic management of operations	Program management of operations, management teams based on staff: <ul style="list-style-type: none">• Bioresearch Monitoring 2 management teams• Biologics 2 management teams• Human and Animal Food 12 management teams• Medical Device and Radiological Health 3 management teams• Pharmaceutical Quality 4 management teams• Tobacco• Plus Imports as a program 5 management teams
SES Regional Food & Drug Directors	SES Program Directors
Degrees of program specialization for investigations, compliance and operational managers	Exclusive specialization in one program for investigations, compliance and operational managers
20 District Directors who manage the geographic district and all programs operations within the district	20 District Directors who manage the geographic district and only one program for operations. Plus eight new program division directors who manage program operations only – total 28 management teams
One import district and a range of import operations embedded within the 16 other districts	Five import divisions (four new import divisions) covering all borders, managing import operations nationally as a program



Program Alignment: Key Changes

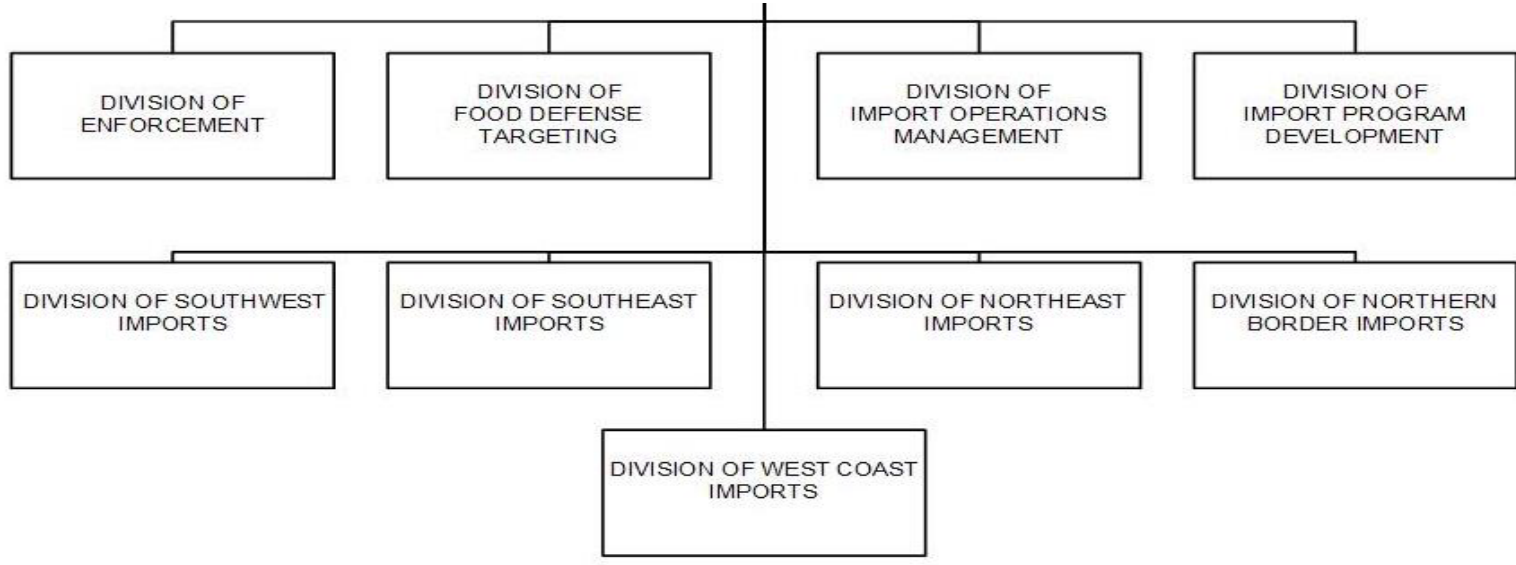
From	To
13 labs reporting into the regions	National Lab Management - 13 labs reporting into ORA's Office of Regulatory Science with three additional directors managing separate program operations
Division of Human Resource Development within the Office of Resource Management	Office of Training, Education and Development
State Cooperative Programs decentralized across five regions – shellfish, milk, retail	Office of State Cooperative Programs under the Human and Animal Food Operations, as a single national program(s)
Functions based in geography: consumer complaint coordinators, state liaisons, emergency response coordinators	Retain certain functions based in geography: consumer complaint coordinators, state liaisons, emergency response coordinators
Functions decentralized local reporting: Freedom of Information (FOI) staff, industrial hygienists (IH), and administrative staff	Staff remain embedded locally, but report into a single office: FOI staff report into Division of Information Disclosure; IHs report into the Office of Regulatory Science; administrative staff report into the Office of Management

Office of Enforcement and Import Operations

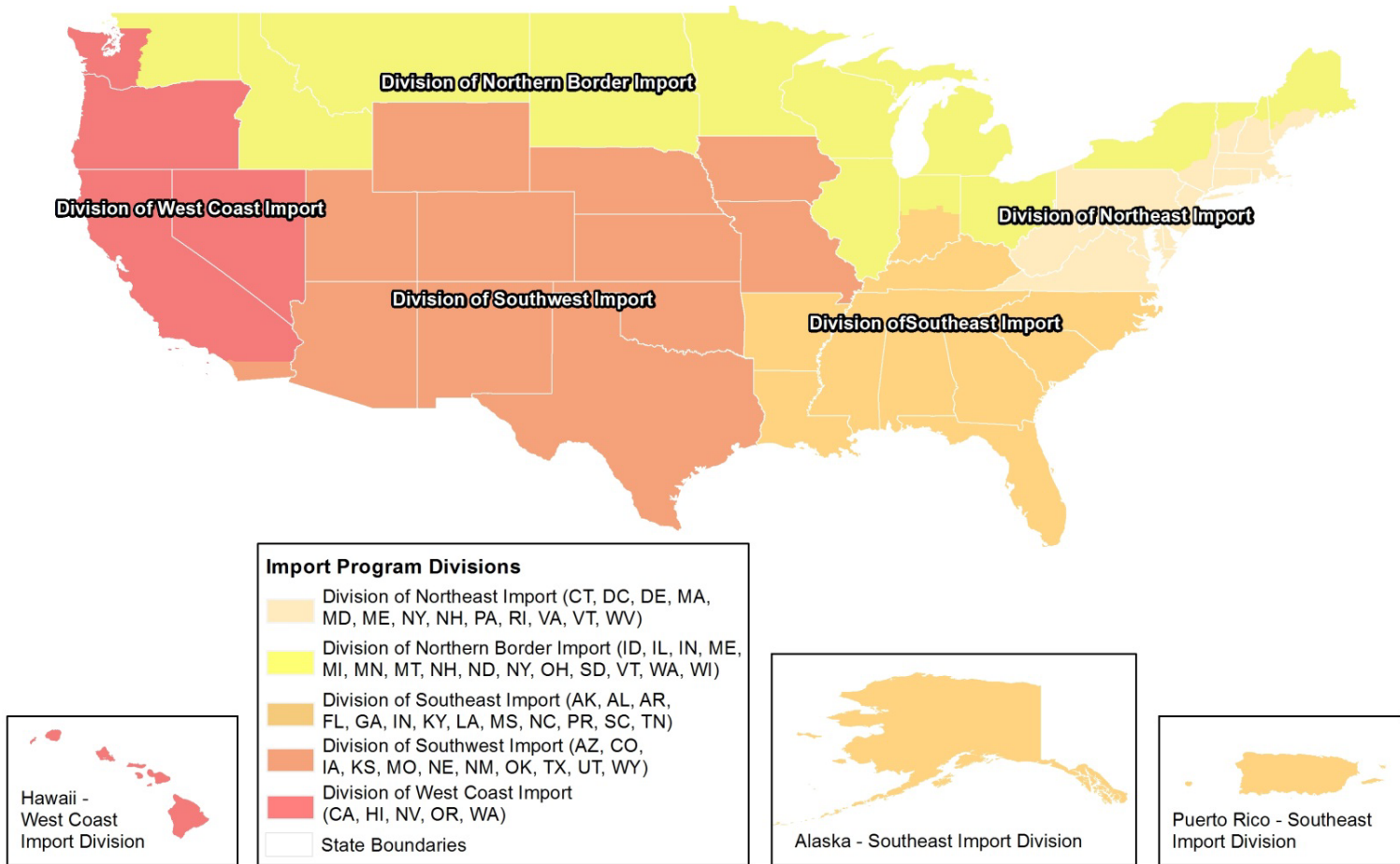
OFFICE OF ENFORCEMENT AND IMPORT OPERATIONS



Doug Stearn, JD
 Director, Office of
 Enforcement and Import
 Operations



Office of Enforcement and Import Operations



Office of Enforcement and Import Operations

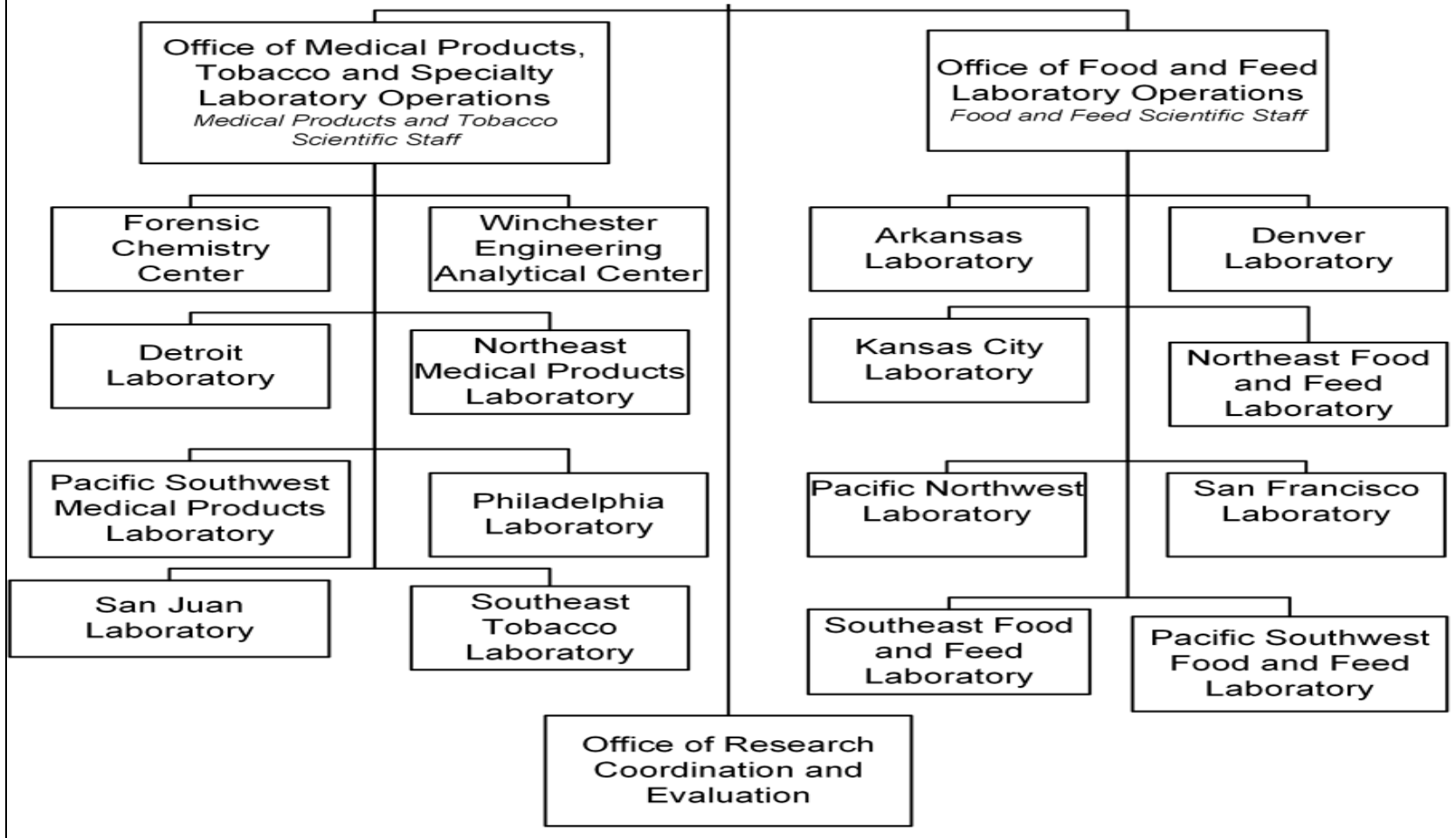


Office/Division	Title	Name
OEIO	Director	Doug Stearn
OEIO	Deputy Director	Armando Zamora
Division of Enforcement	Director	Scott MacIntire
Division of Food Defense Targeting	Director	Angel Suarez
Division of Import Operations Management	Director	Detail TBA
Division of Import Program Development	Director	John Verbeten
Division of Southwest Imports	Director	Todd Cato
Division of Southeast Imports	Director	Ruth Dixon
Division of Northeast Imports	Director	Anna Alexander (acting)
Division of Northern Border Imports	Director	Sandy Sylvester (acting)
Division of West Coast Imports	Director	Dan Solis (acting)

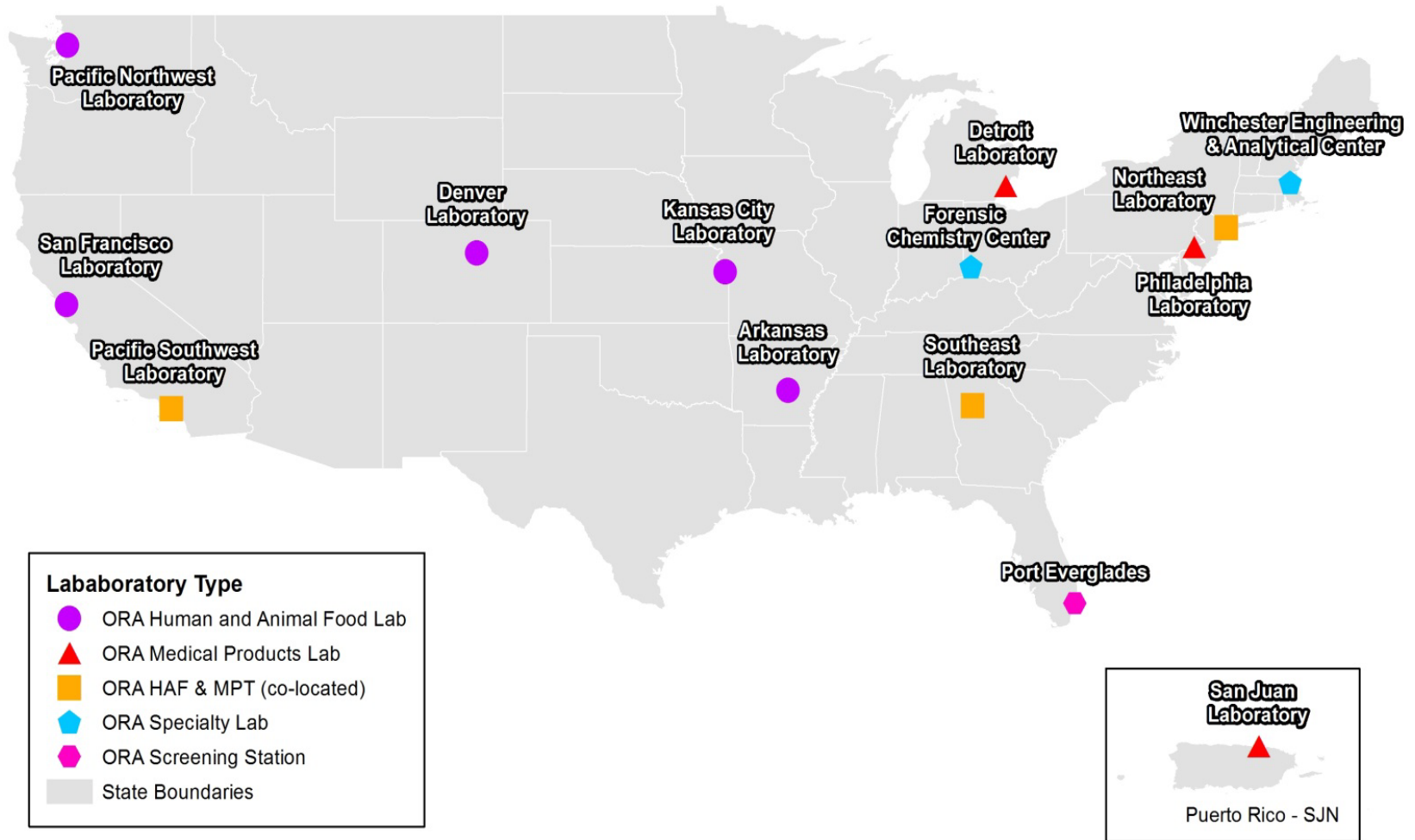
Office of Regulatory Science



Paul Norris, DVM, MPA
Director, Office of
Regulatory Science



Office of Regulatory Science





Office of Regulatory Science

Office/Division	Title	Name
Immediate Office	Director	Paul Norris, DVM, MPA
Immediate Office	Senior Science Advisor	Sean Linder, PhD
Immediate Office /Automated Laboratory Management Staff	Staff Director	Mivoyel JeanPaul
Immediate Office/Safety and Risk Management Staff	Staff Director	Sufian AlKhalidi, PhD (acting)
Office of Medical Products, Tobacco and Specialty Laboratory Operations	Associate Director	Debra Barnes, PhD
Office of Food and Feed Laboratory Operations	Associate Director	Dan Rice, DrPH (acting)
Office of Research Coordination and Evaluation	Associate Director	Selen Stromgren, PhD (acting)

Office of Regulatory Science Laboratory Directors



Laboratory	Title	Name
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PHARMACEUTICAL LABS

Detroit Laboratory	Laboratory Director	Sheryl Duquet (acting)
Philadelphia Laboratory	Laboratory Director	Hector Espinet (acting)
San Juan Laboratory	Laboratory Director	Marisol Faberlle
Northeast Medical Products Laboratory	Drug Program Director	TBD
Pacific Southwest Medical Products Laboratory	Drug Program Director	TBD

SPECIALTY LABS

Forensic Chemistry Center	Laboratory Director	Duane Satzger, PhD
Winchester Engineering Analytical Center	Laboratory Director	Brian Baker
Southeast Tobacco Laboratory	Tobacco Program Director	TBD

Office of Regulatory Science Laboratory Directors



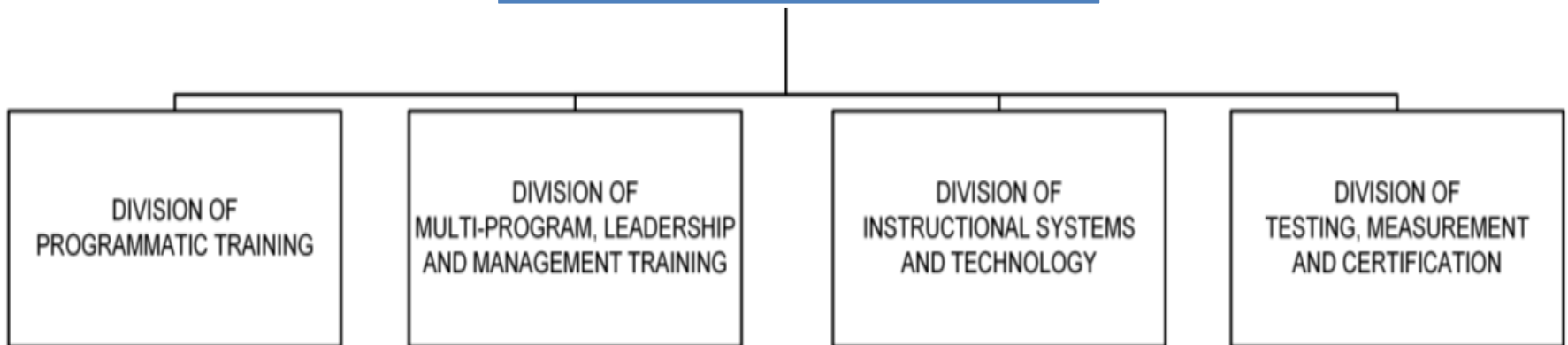
Office/Division	Title	Name
HUMAN AND ANIMAL FOOD LABS		
Arkansas Laboratory	Laboratory Director	Michael Wichman, PhD
Denver Laboratory	Laboratory Director	Mark Madson
Kansas City Laboratory	Laboratory Director	Aref El-Demerdash, PhD
Northeast Food and Feed Laboratory	Laboratory Director	John Leazer, PhD
Pacific Northwest Laboratory	HAF Program Director	Lisa Newberry, PhD (acting)
Pacific Southwest Food and Feed Laboratory	Laboratory Director	William Martin, PhD
San Francisco Laboratory	Laboratory Director	Tom Sidebottom
Southeast Food and Feed Laboratory	Laboratory Director	Khalil Kerdahi

Office of Training, Education and Development

OFFICE OF TRAINING, EDUCATION AND DEVELOPMENT



Patricia Alcock,
Director Office of
Training, Education, and
Development



Office of Training, Education and Development



Office/Division	Title	Name
OTED Immediate Office	Office Director	Patricia Alcock
OTED Immediate Office	Deputy Director	Loney Nunemaker
OTED Immediate Office	Deputy Director	Thomas Hughes
OTED Immediate Office	Administrative, Logistics, and Finance Staff Director	Shanell Owens
Division of Programmatic Training	Division Director	John Stoll (acting)
Division of Multi-Program, Leadership and Management Training	Division Director	Monica Caphart (acting)
Division of Instructional Systems and Technology	Division Director	Lee Vogtman (acting)
Division of Testing, Measurement and Certification	Division Director	William Farmer (acting)

Office of Partnerships and Operational Policy

Office of Partnerships



Barbara Cassens
Acting
Associate Commissioner
for Partnerships and Policy

No Photo
Available

Alan Tart
Acting Director,
Office of Partnerships

DIVISION OF
PARTNERSHIP
INVESTMENTS AND
AGREEMENTS

DIVISION OF
INTEGRATION

DIVISION OF
STANDARDS
IMPLEMENTATION

Office of Partnerships

Office/Division	Title	Name
OP Immediate Office	Office Director	Alan Tart (acting)
OP Immediate Office/Partnership Services Group	Acting Supervisor	Matthew Avis (acting)
OP Division of Integration	Division Director	Detail TBA
OP Division of Standards Implementation	Division Director	Timothy Weigner (acting)
OP Division of Partnership Investments and Agreements	Division Director	Abram Brown III (acting)

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 Biological Products Operations

OFFICE OF MEDICAL PRODUCTS AND TOBACCO OPERATIONS
 OFFICE OF BIOLOGICAL PRODUCTS OPERATIONS

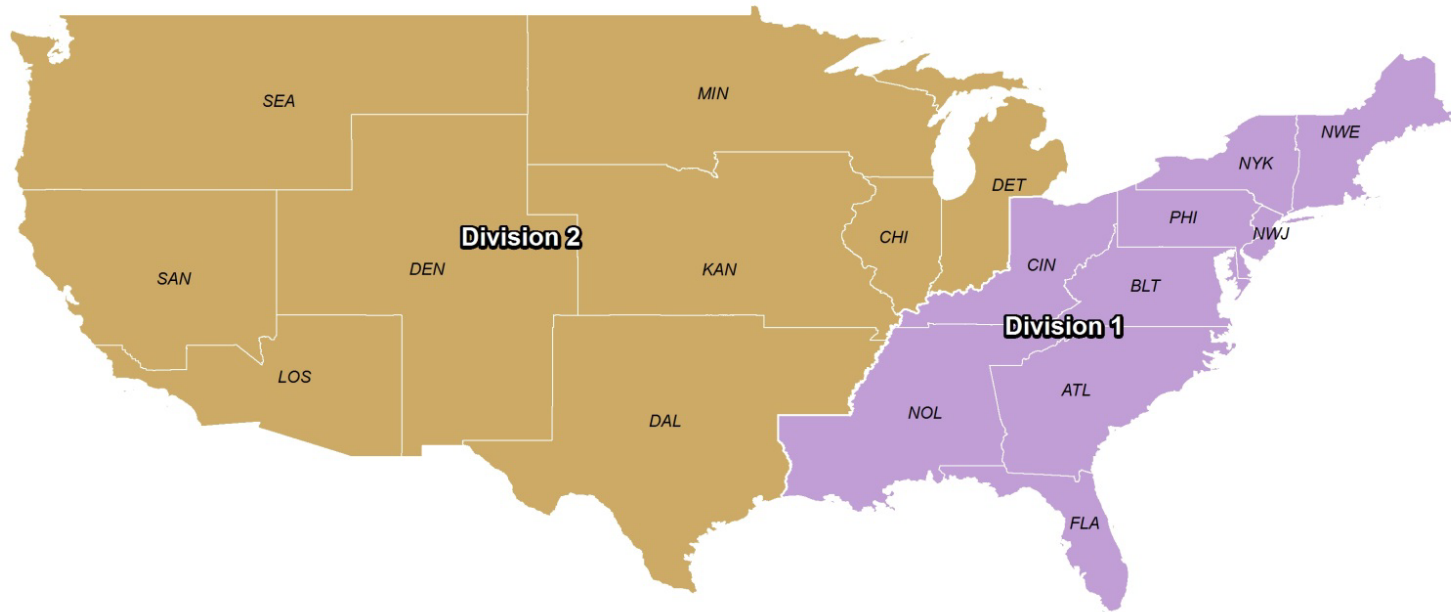


Ginette Michaud, MD
 Director, Office of
 Biological Products
 Operations

DIVISION OF
 BIOLOGICAL PRODUCTS
 OPERATIONS I

DIVISION OF
 BIOLOGICAL PRODUCTS
 OPERATIONS II

Office of Biological Products Operations



Biologics Program Divisions

- Division 1 (ATL, BLT, CIN, FLA, NOL, NWE, NWJ, NYK, PHI, SJJ)
- Division 2 (DAL, DEN, DET, KAN, CHI, LOS, MIN, SAN, SEA)
- FDA Current District Boundaries

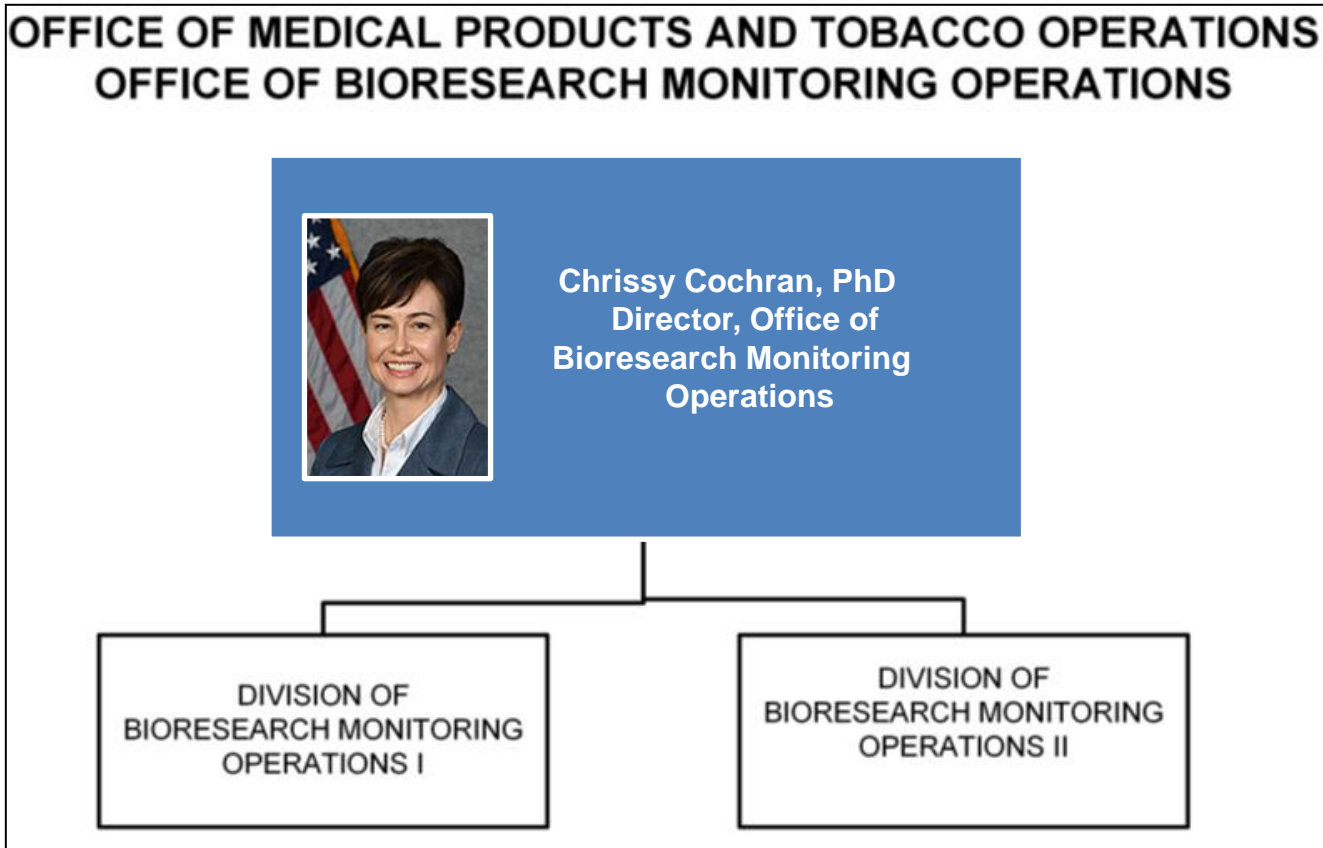


Office of Biological Products Operations

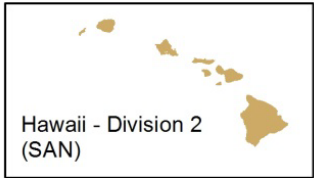
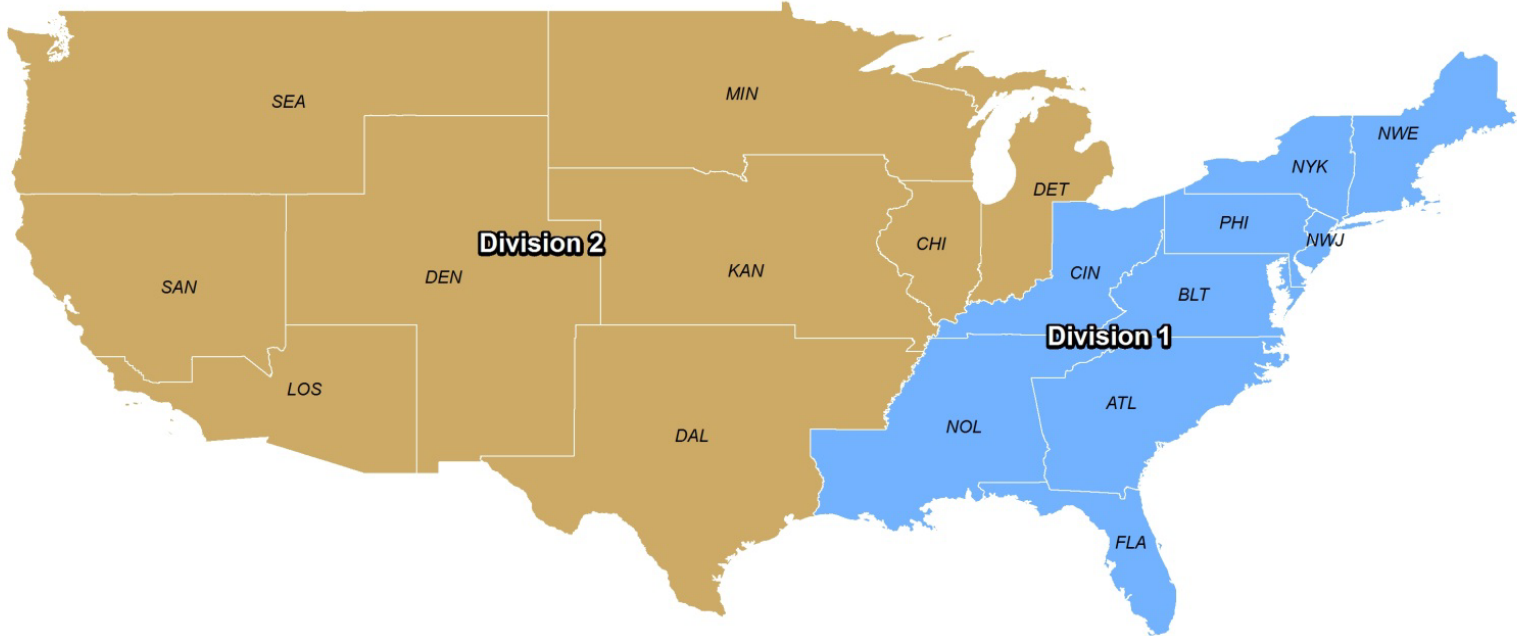


Office/Division	Title	Name
OBPO Immediate Office	Director	Ginette Michaud
Biological Products Operations Staff (includes national/program experts, PTO, QSM)	Deputy Director	Susan Turcovski (acting)
OBPO Division I	District Director/Program Division Director	Elizabeth Waltrip (acting)
OBPO Division II	Program Division Director	Karlton Watson (acting)
Team Biologics Staff	SCSO	Colleen Hoyt

Office of Bioresearch Monitoring Operations



Office of Bioresearch Monitoring Operations



BIMO Program Divisions

- Division 1 (ATL, BLT, CIN, FLA, NOL, NWE, NWJ, NYK, PHI, SJA)
- Division 2 (DAL, DEN, DET, KAN, CHI, LOS, MIN, SAN, SEA)
- FDA Current District Boundaries





Office of Bioresearch Monitoring Operations

Office/Division	Title	Name
OBIMO Immediate Office	Director	Chrissy Cochran, PhD
OBIMO Immediate Office	Deputy Director	David Glasgow (acting)
OBIMO Division I	District Director/Program Division Director	Anne Johnson
OBIMO Division II	Program Division Director	Thomas Berry, PharmD (acting)

Office of Medical Device and Radiological Health Operations

**OFFICE OF MEDICAL PRODUCTS AND TOBACCO OPERATIONS
OFFICE OF MEDICAL DEVICES AND RADIOLOGICAL HEALTH OPERATIONS**



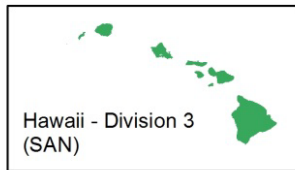
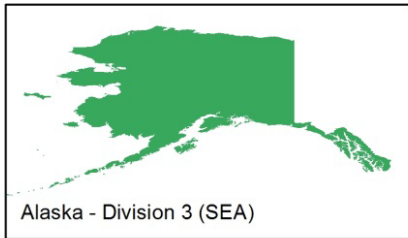
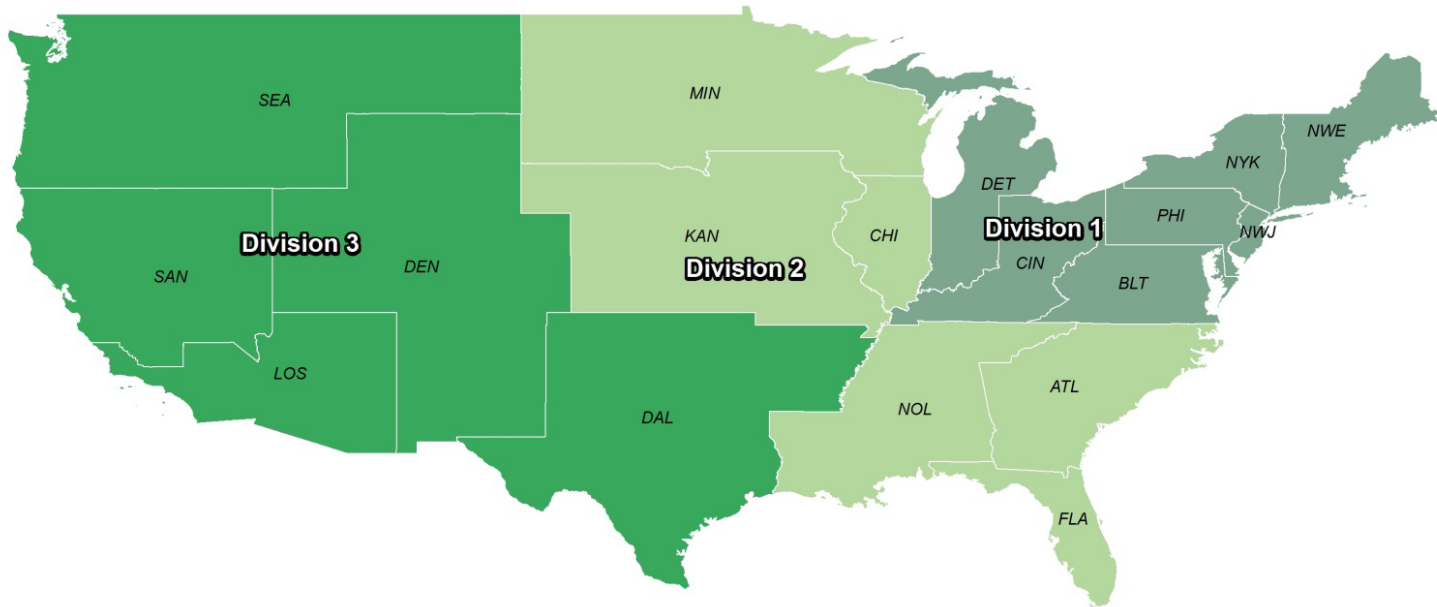
Jan Welch
Director, Office of
Medical Device
and Radiological Health

DIVISION OF
MEDICAL DEVICES AND
RADIOLOGICAL HEALTH
OPERATIONS I

DIVISION OF
MEDICAL DEVICES AND
RADIOLOGICAL HEALTH
OPERATIONS II

DIVISION OF
MEDICAL DEVICES AND
RADIOLOGICAL HEALTH
OPERATIONS III

Office of Medical Device and Radiological Health Operations



Medical Devices Program Divisions

- Division 1 (BLT, CIN, DET, NWE, NWJ, NYK, PHI)
- Division 2 (ATL, CHI, FLA, KAN, MIN, NOL, SJA)
- Division 3 (DAL, DEN, LOS, SAN, SEA)
- FDA Current Districts Boundaries



Office of Medical Device and Radiological Health Operations

Office/Division/Staff	Title	Name
OMDRHO Immediate Office	Director	Jan Welch
OMDRHO Immediate Office	Deputy Director	Anne Reid
OMDRHO Division I	District Director/Program Division Director	Joseph S. Matrisciano Jr.
OMDRHO Division II	Program Division Director	Blake Bevill (acting)
OMDRHO Division III	Program Division Director	Shari Shambaugh (acting)
OMDRHO Foreign Medical Devices and Radiological Health Inspection Staff	Staff Director	Dorothy Lee

Office of Pharmaceutical Quality Operations

OFFICE OF MEDICAL PRODUCTS AND TOBACCO OPERATIONS
OFFICE OF PHARMACEUTICAL QUALITY OPERATIONS



Alonza Cruse
Director, Office of
Pharmaceutical Quality
Operations

DIVISION OF
PHARMACEUTICAL
QUALITY OPERATIONS I

DIVISION OF
PHARMACEUTICAL
QUALITY OPERATIONS II

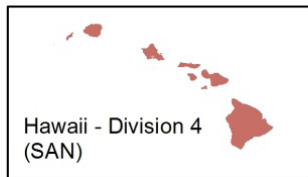
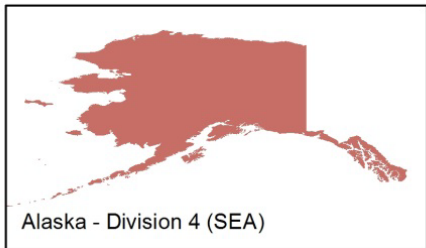
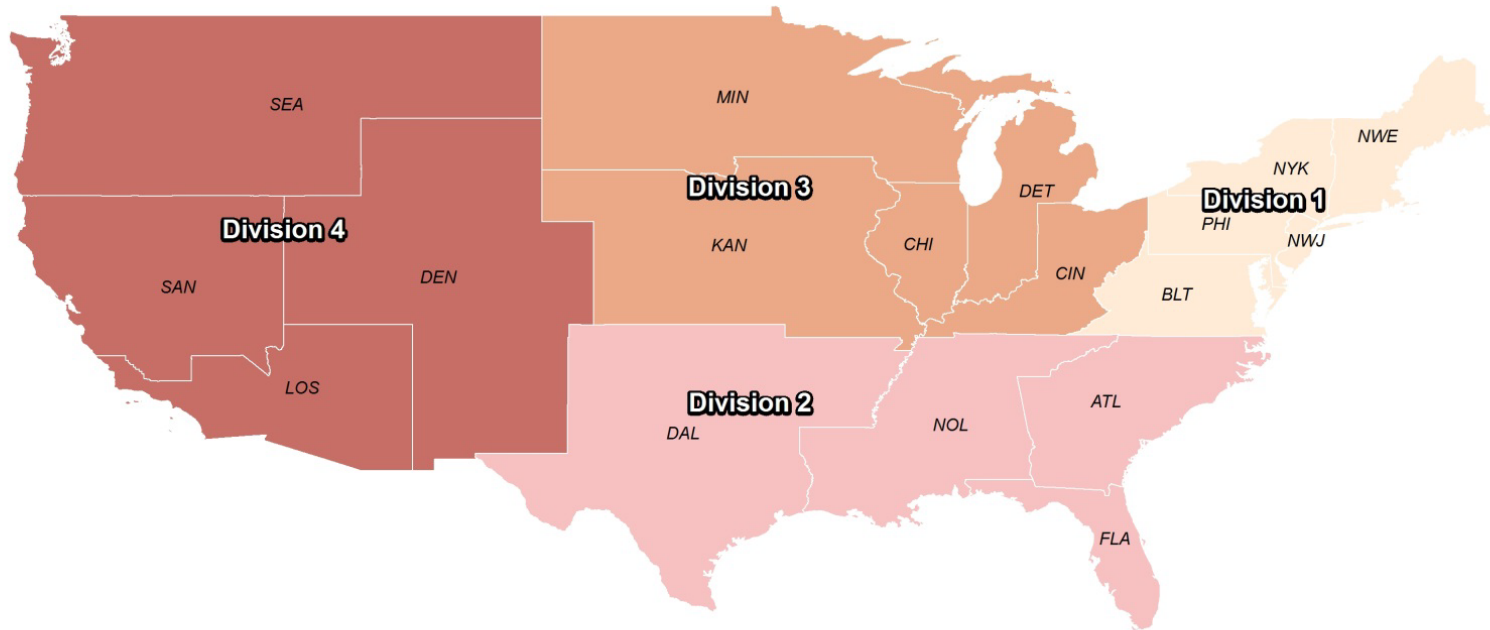
DIVISION OF
PHARMACEUTICAL
QUALITY OPERATIONS III

DIVISION OF
PHARMACEUTICAL
QUALITY OPERATIONS IV

DIVISION OF
PHARMACEUTICAL
QUALITY PROGRAMS

DIVISION OF
FOREIGN
PHARMACEUTICAL
QUALITY INSPECTIONS

Office of Pharmaceutical Quality Operations



Pharmaceutical Quality Program Divisions

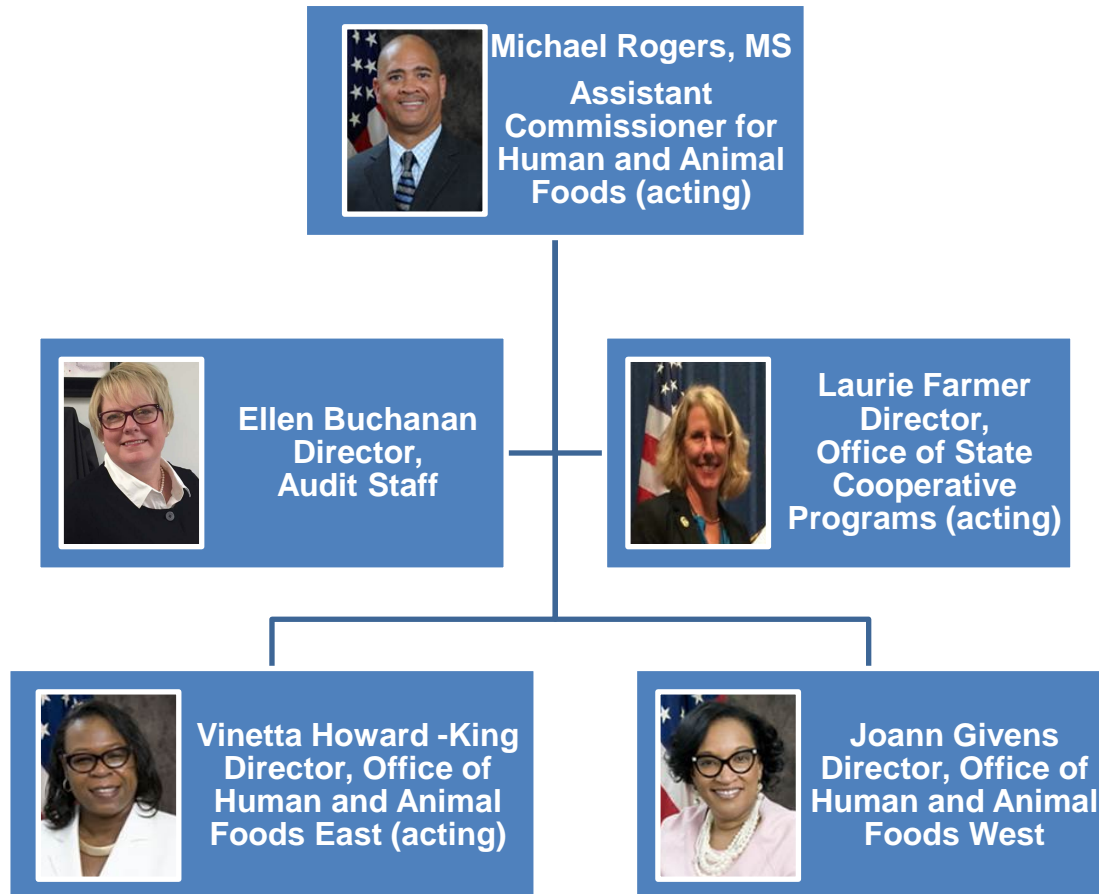
- Division 1 (BLT, NWE, NWJ, NYK, PHI)
- Division 2 (ATL, DAL, FLA, NOL, SJA)
- Division 3 (CIN, CHI, DET, KAN, MIN)
- Division 4 (DEN, LOS, SAN, SEA)
- FDA Current Districts Boundaries



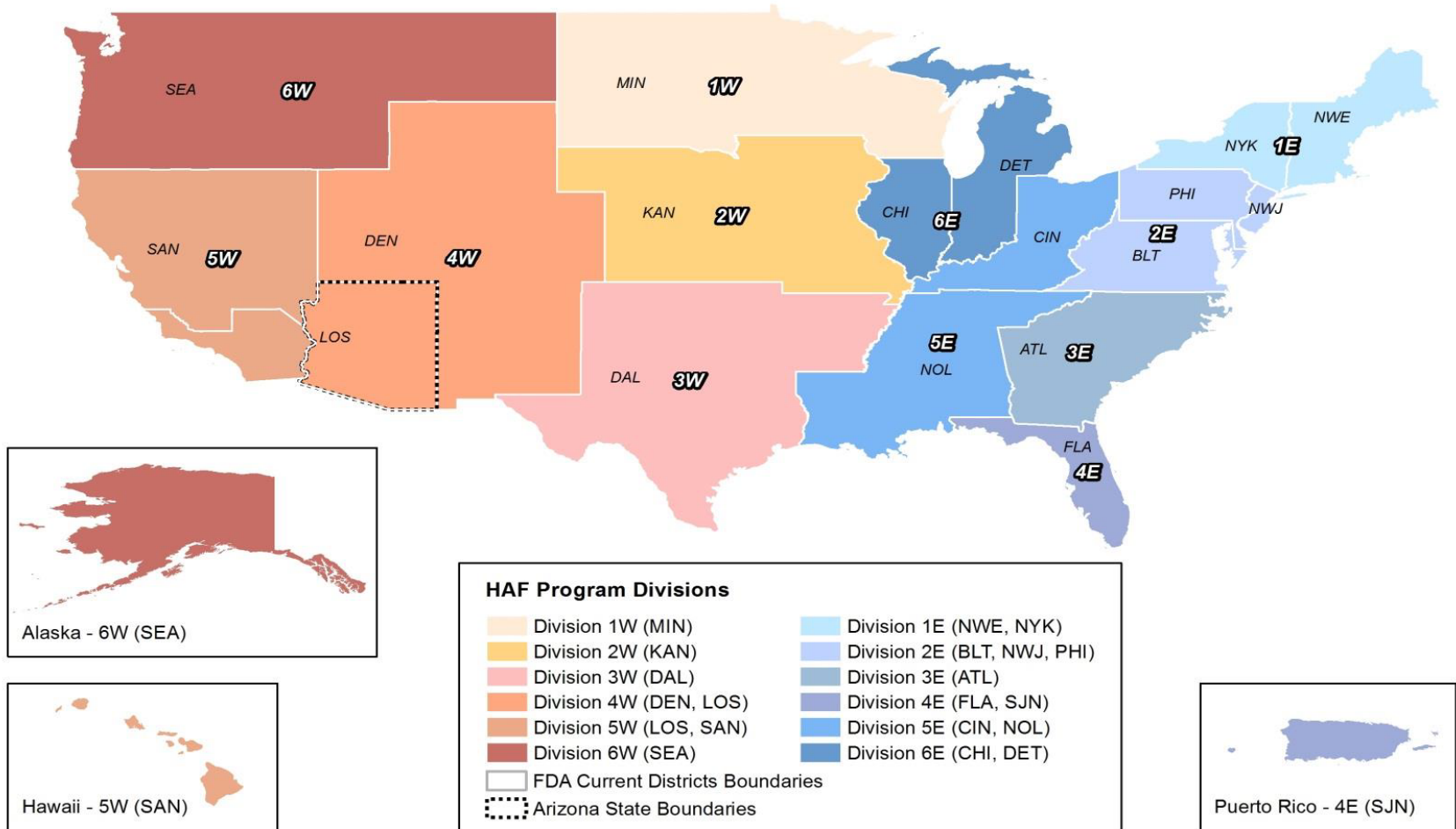
Office of Pharmaceutical Quality Operations

Office/Division	Title	Name
OPQO Immediate Office	Director	Alonza Cruse
OPQO Immediate Office	Deputy Director	Nancy Rolli (acting)
OPQO Division I	District Director/Program Division Director	Diana Amador Toro
OPQO Division II	Program Division Director	Monica Maxwell (acting)
OPQO Division III	District Director/Program Division Director	Art Czabaniuk
OPQO Division IV	District Director/Program Division Director	Steven Porter
OPQO Division of Pharmaceutical Quality Programs	Division Director	Ann Marie Montemurro

Office of Human and Animal Food Operations



Office of Human and Animal Food Operations





Office of Human and Animal Food Operations

Office/Division	Title	Name
OHAFO Immediate Office	Assistant Commissioner	Michael Rogers (acting)
OHAFO Audit Staff	Staff Director	Ellen Buchanan
Office of State Cooperative Programs	Director	Laurie Farmer (acting)
OHAFO East	Director	Vinetta Howard-King (acting)
OHAFO East	Deputy Director	Charles Becoat
OHAFO West	Director	Joann Givens
OHAFO West	Deputy Director	Glenn Bass

Office of Human and Animal Food Operations - EAST

Office/Division	Title	Name
OHAFO Division East I	District Director/Program Division Director	Ron Pace
OHAFO Division East II	District Director/Program Division Director	Evelyn Bonnin
OHAFO Division East III	District Director/Program Division Director	Ingrid Zambrana
OHAFO Division East IV	District Director/Program Division Director	Maridalia Torres Irizarry
OHAFO Division East V	District Director/Program Division Director	Steven Barber
OHAFO Division East VI	District Director/Program Division Director	Bill Weissinger
OHAFO Division of Foreign Human and Animal Food Operations	Division Director	Linda Chasey (acting)

Office of Human and Animal Food Operations - WEST



Office/Division	Title	Name
OHAFO Division West I	District Director/Program Division Director	Mick Dutcher
OHAFO Division West II	District Director/Program Division Director	Cheryl Bigham
OHAFO Division West III	District Director/Program Division Director	Edmundo Garcia
OHAFO Division West IV	District Director/Program Division Director	LaTonya Mitchell
OHAFO Division West V	District Director/Program Division Director	Darlene Almogela (acting)
OHAFO Division West VI	District Director/Program Division Director	Miriam Burbach
OHAFO West Division of Domestic Human and Animal Food Operations	Division Director	Eric Pittman (acting)

ORA Ombudsman



Jessica Zeller, JD, MA
Ombudsman

- Informally and impartially addresses concerns, complaints, and disputes between ORA and external parties:
 - Industry
 - Federal, state, territory, and tribal government entities
 - Public
- Contact:
 - 513-679-2777 or 240-535-6021
 - ORAmbudsman@fda.hhs.gov

PUBLIC HEALTH PARTNERSHIPS:

Enhancing ORA operations by serving as an objective, neutral resource to improve communication channels, resolve disputes, and foster positive relationships with internal and external stakeholders.

What's Next?

- Complete the first phase – realignment
- Continue to invest in ORA's culture and values
- Advance the next phase – operational change

Advancing Operational Change

Medical Products and Tobacco

- Continue implementation of new authorities
- Enhance the use of Geographic Information System tool
- Advance research subject protection and data reliability
- Continue Data Integrity training
- Develop regulatory program standards for quality improvements
- Implement new inspection protocols in drug manufacturing facilities
- Measure and describe the public health impact of our work

Human and Animal Food

- Continue implementation of FSMA
- Enhance the use of Geographic Information System tool
- Promote Program Standardization
- Streamline Inspections
- Increase risk-based targeting of foreign firms for inspections
- Enhance engagement of all regulatory partners
- Measure and describe the public health impact of our work

Office of Regulatory Affairs Executive Advisory Council

Melinda K. Plaisier, MSW

Associate Commissioner for Regulatory Affairs

Ellen F. Morrison

Assistant Commissioner for Medical Products and Tobacco Operations

Michael C. Rogers, MS

Acting Assistant Commissioner for Human and Animal Food Operations

Barbara Cassens

Acting Assistant Commissioner for Partnerships and Policy

Erika Anderson, JD, MPA

Senior Advisor to the ACRA

Glenda Barfell, MS

Director, Office of Management

Chrissy J. Cochran, PhD

Director, Office of Bioresearch Monitoring Operations

Alonza Cruse

Director, Office of Pharmaceutical Quality Operations

L'Tonya Davis, MPM

Director, Office of Communications and Project Management

CAPT Laura Draski

Acting Director, Office of Strategic Planning and Operational Policy

Joann M. Givens

Director, Office of Human and Animal Food Operations - West

Catherine Hermsen

Acting Director, Office of Criminal Investigations

Vinetta Howard-King

Acting Director, Office of Human and Animal Food Operations – East

Kara Lynch

Transition Manager

Ginette Y. Michaud, MD

Director, Office of Biological Products Operations

Paul E. Norris, DVM, MPA

Director, Office of Regulatory Science

Doug W. Stearn, JD

Director, Office of Enforcement and Import Operations

Alan Tart

Acting Director, Office of Partnerships

Jan Welch

Director, Office of Medical Device and Radiological Health Operations

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
- Partnerships
 - OP-ORA@fda.hhs.gov



Thank You!

