

OFFICE OF REGULATORY AFFAIRS

OFFICE OF REGULATORY SCIENCE

Updates and Areas of Collaboration with NCTR

Sean W. Linder, Ph.D.

ORA Roles & Responsibilities

- Inspections of firms and plants producing FDA-regulated products (domestic and international)
- Investigations of consumer complaints, emergencies and criminal activity
- Enforcement of FDA regulations
- Sample collection and analysis
- Review of imported products

ORA: Presence Around the Globe

Headquarters: Maryland

International Offices:

India, China, Latin America, Europe,

Offices nationwide: >200

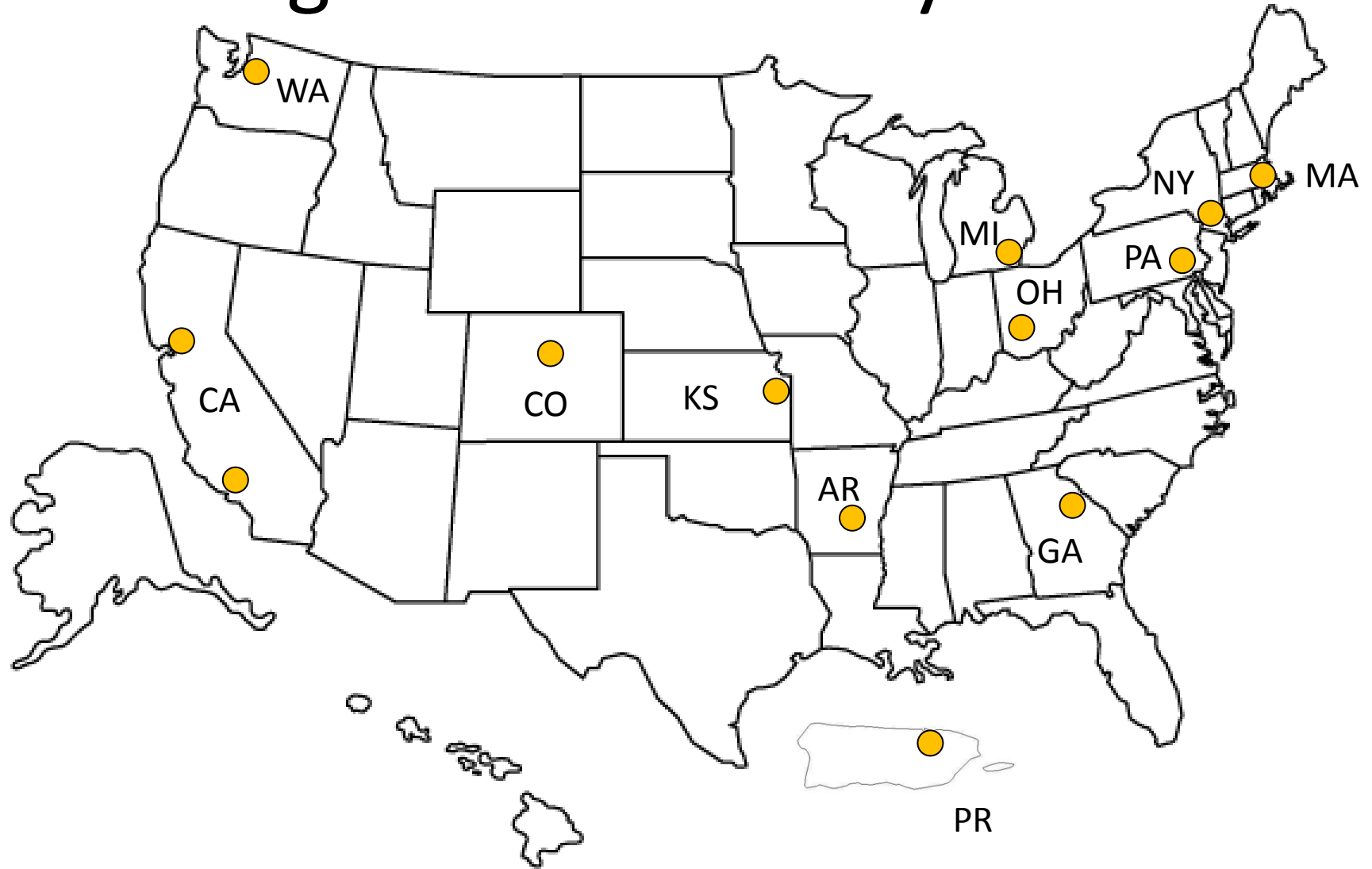
ORA Laboratories: 13

Border Screening Stations: 1

Total ORA Investigators: ~1800

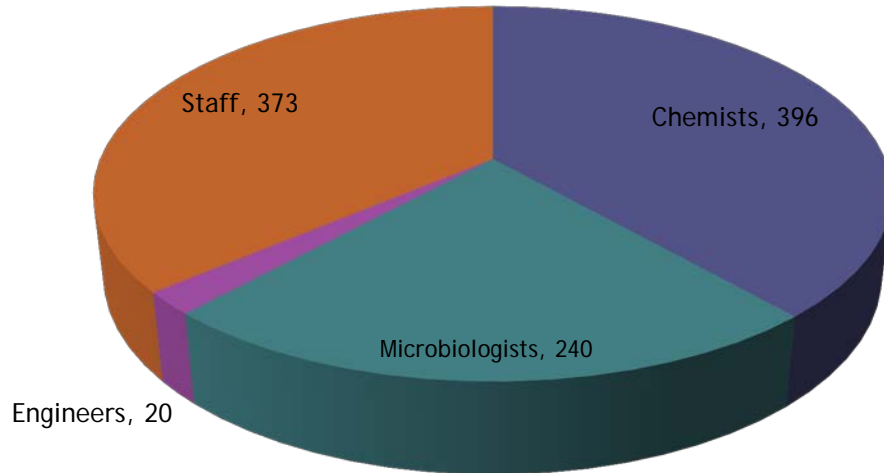
Total ORA Analysts: ~ 900 (including support staff)

Existing ORA Laboratory Locations



ORA Lab Employee Demographics

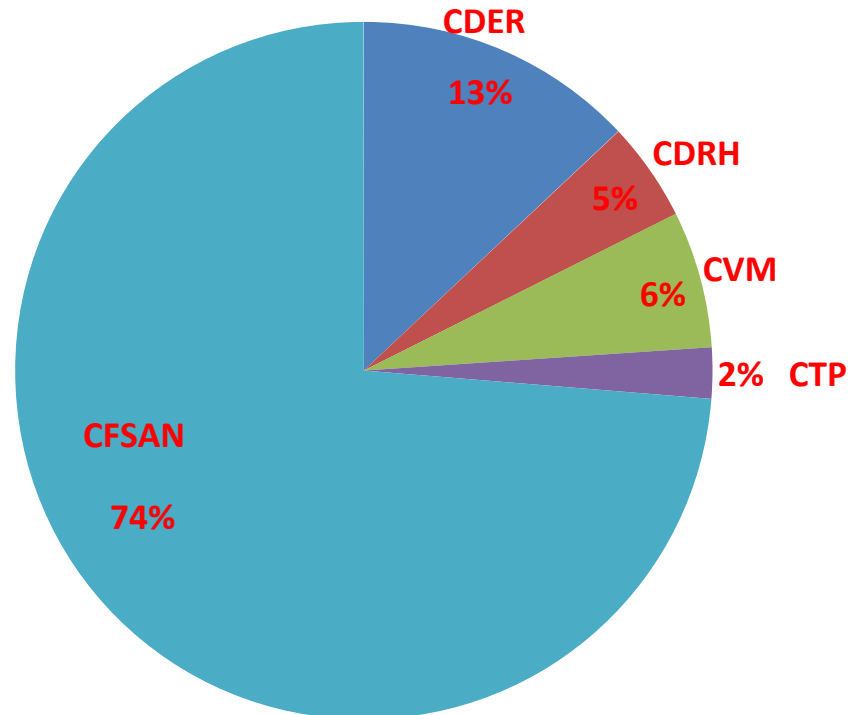
ORA Lab Employees by Scientific Discipline, as of 12/21/15



Lab	FY16 Personnel On-Board
ARL	96
DEN	80
DET	27
FCC	75
KAN	63
NRL	130
PHI	22
PRL-NW	79
PRL-SW	97
SAN	56
SJN	26
SRL	159
WEAC	71
HQ-ORS	48

*Staff category includes all non-analytical personnel within the labs, such as lab director, branch director, supervisors, quality system manager, industrial hygienist, sample custodian, administrative staff, etc.

Distribution of ORA's Lab Work by Center



- Compliance testing
- Surveillance testing
- For-cause sample testing (outbreaks, adverse events, customer complaints)

ORA Labs Program Work

Work plan – Annual map for allocation of ORA resources (inspectional, collections, analytical testing) to different areas of concern

ORA utilizes analytical capabilities in areas of chemistry, microbiology, radiochemistry, and engineering to perform the designated program work

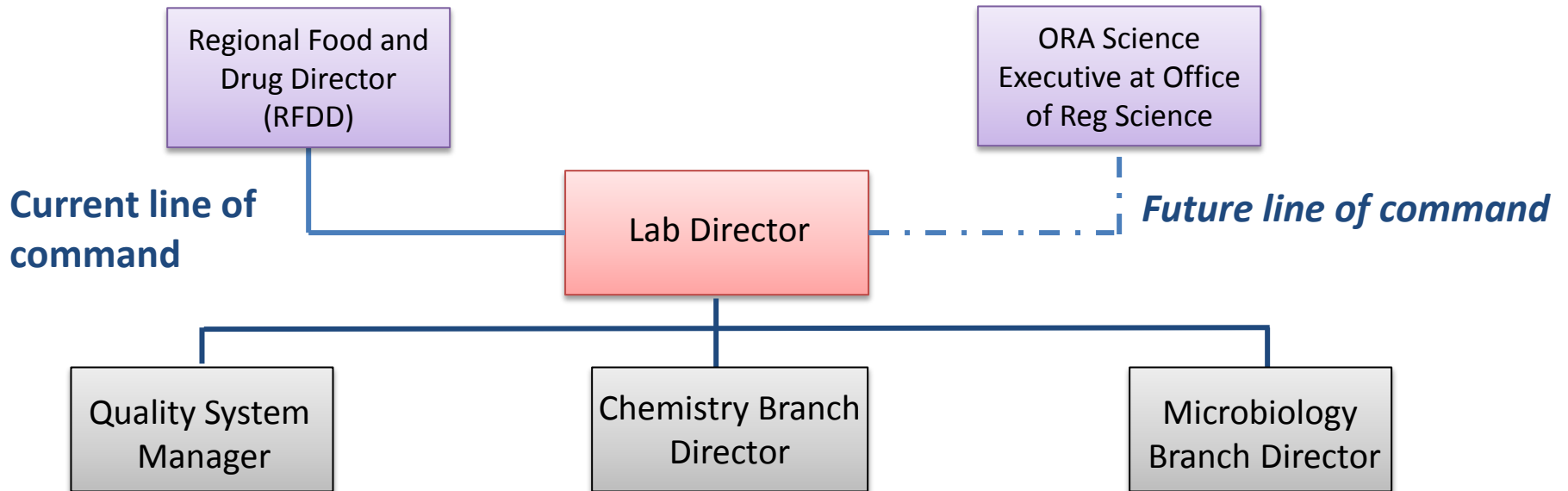
ORA supports the various Centers in the following areas of testing:

Product	Areas of Testing/Analytical Activities Performed by ORA
Foods & Feeds	Pesticides, dioxins, mycotoxins, chemotherapeutics, color additives, toxic metals, filth, select radioisotopes
Pharmaceutical Products	Active pharmaceutical ingredient testing, dissolution testing
Devices/Radiation Products/Rad Safety	Risk-identified medical devices and radiation emitting products, field exam guideline and device field test kit/tool development, safety
Tobacco Products	Flavor compounds in cigarettes, contaminants testing, substantial equivalence
Nanotechnology	Method development and research activities
All products	Private lab package reviews
	Analysts-on-inspections

ORA Laboratory Reorganization

- Support Program Alignment & Laboratory Optimization
- Elevate Science within Organization (*Office of Research Coordination and Evaluation*)
- Streamline Communications, Resource Management, Decision Processes
- Add Support Functions
- Commodity Specific Laboratories
- Centrally Managed Safety and Risk Assessment
- Expected Implementation during FY2017

Local Structure of an ORA Laboratory



Current ORA/NCTR Collaborations

- Nanotechnology (NCTR/ORA Nanotechnology Core Facility & associated projects)
- Pattern recognition techniques (support of filth program)
- Quantitation of antibiotics in fecal matter (support NCTR research activities in the Division of Microbiology)

Potential Areas of ORA/NCTR Collaboration

- Bioinformatics (whole genome sequencing)
- Technical support with advanced technologies (NMR, etc.)
- Repository of analytical methods
- Roster of available expertise during emergency situations

