PFP IT WG NEWSLETTER

PARTNERSHIP FOR FOOD PROTECTION INFORMATION TECHNOLOGY WORKGROUP

In This Issue

Coffee Talk With Robyn Randolph

The FDA Office of Regulatory Affairs (ORA) Data Exchange (DX) team recently had the pleasure of catching up with Robyn Randolph, Senior Specialist, Food Laboratory Accreditation with the Association of Public Health Laboratories (APHL), and Project Manager with the PFP Laboratory Science Workgroup.

Robyn works with governmental human and animal food testing laboratories looking to improve their quality management systems. Read about Robyn's job and interesting perspective of the ORA DX program *on page 5*. The Coffee Talk article is also available on the *PFP website.*

ORA Data Exchange (DX) Updates

Regulatory Partner participation:

- 49 states are participating in ORA DX
- 47 states are participating in the PFP IT WG or Sample WG
- 69 partner agencies participate in the ORA Partners Portal (ORAPP)
- 24 partner agencies participate in System-to-System or Enhanced DX
- In certain cases, there is more than one partner/agency per state.
- Some partners are in the process of onboarding

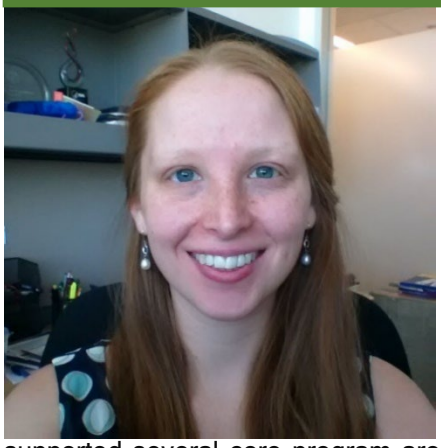
State Lab participants:

- 24 states are onboarding and participating in Sample WG
- Five state labs in CT, HI, KY, MD, and VA, are submitting multiple samples per month in production.
- AK and OH labs are currently onboarding for production
- In certain cases, there is more than one state lab participating per state

"You can never get a cup of tea large enough or a book long enough to suit me." – C. S. Lewis

Spotlight on Lauren Yeung

Laboratory Flexible Funding Model (LFFM) Technical Program Manager
Office of Regulatory Science (ORS), FDA

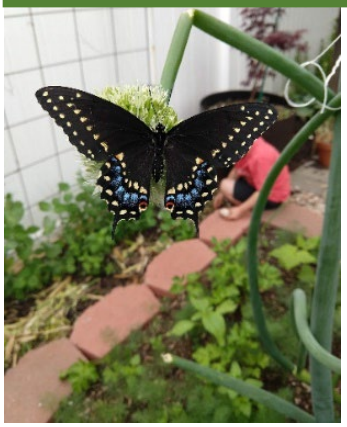


The LFFM is jointly managed by Office of Partnerships (OP) and ORS. The LFFM team provides technical support and oversight of work done under LFFM tracks. Lauren leads overall planning and coordination from a technical perspective, as well as internal and external stakeholder engagement. Lauren also supports Food Emergency Response Network (FERN) functions and currently leads the Proficiency Testing (PT) working group.

Lauren earned her B.S. in Biological Sciences from the University of Maryland College Park and is also a certified project management professional (PMP). Lauren started her FDA career in 2008 with the ORA Division of Field Science, where she supported several core program areas for the Food Emergency Response Network (FERN) National Program Office. In 2012, Lauren joined the ORA Office of Partnerships to serve as a technical lead for the Rapid Response Teams (RRT) program, developing multi-agency, multi-disciplinary teams that operate using Incident Command System (ICS) principles and a Unified Command structure to respond to human and animal food emergencies. She joined ORS to be part of the LFFM program in 2021. She is proud to have spent the last 15 years supporting integration of federal, state, and local agencies in our shared mission to protect public health.

ORA DX is a critical part of our long-term strategy for integrated data sharing between the FDA and states. Data sharing capability is essential for responding to emergency situations and supporting large scale national surveillance testing programs, like LFFM. These successful data submissions, both for FDA-collected samples and state-collected samples, are critical milestones that reflect significant progress. We greatly appreciate participating state partners who have helped pave the way for others to follow.

More About Lauren



Butterfly hanging out in Lauren's Garden.

amount of dill every year specifically to attract black swallowtail butterfly caterpillars. Her family loves holiday decorations and may or may not have recently acquired a large plastic skeleton that spent weeks being moved throughout the house daily to surprise the kids, in what one could described as a creepy Halloween version of an elf on the shelf.

Welcome Kirsten Hirneisen

The PFP IT WG welcomes Kirsten Hirneisen, PhD. as the New PFP Laboratory Sciences Co-Chair!

Kirsten is a Microbiologist working with the external laboratories group in the US FDA Office of Regulatory Affairs, Office of Regulatory Science, Office of Human and Animal Foods Laboratory Operations, Human and Animal Food Scientific Staff. Before this role she was a microbiology analyst in the FDA Pacific Southwest Food and Feed Laboratory in Irvine, CA. She has been a member of the PFP Lab Science Workgroup for the past year, becoming familiar with the group's members, Strategic Plan objectives and activities, and past accomplishments. She became the PFP Lab Sciences WG co-chair in October 2022, to replace Don Burr as he retired.

Kirsten works closely with many of the workgroup members through the FDA Laboratory Flexible Funding Model (LFFM) cooperative agreement and is very excited to engage more with the human and animal food laboratory community through the PFP Lab Sciences workgroup.

Welcome aboard, Kirsten!

"Rainy days should be spent at home with a cup of tea and a good book." – Bill Watterson

ORA DX TechTalk Podcast

On October 12, 2022, the fourth installment of FDA's podcast series on technology and food safety focuses on efforts to streamline and enhance data sharing between FDA and its regulatory partners at the state and local levels.

Entitled "**Data Exchange in the New Era of Smarter Food Safety**," this podcast explores the platform created by FDA's Office of Regulatory Affairs (ORA) to securely share information between the agency and its regulatory partners at the state and local levels.

Clockwise from top left, Jennifer Pierquet; Kristen Lozinak; Phillip Fruechting; Frank Yiannas; Barbara Cassens; Omari Fennell.

In this fourth podcast, **Frank Yiannas**, FDA Deputy Commissioner of Food Policy and Response, **Barbara Cassens**, Director of FDA's Office of Partnerships, and **Omari Fennell**, ORA DX Outreach Coordinator, lead a discussion with experts, **Jennifer Pierquet** Association of Food and Drug Officials (AFDO); **Kristen Lozinak** (Maryland Department of Health); and **Phillip Fruechting** (Arkansas Department of Health) on subjects that include how FDA, state, and local regulators use the ORA Data Exchange to advance public health, including compliance measures and outbreak response, the technology involved in increasing the efficiency of electronic data exchange, how consumers and the food industry benefit, and what's on the horizon in FDA's New Era of Smarter Food Safety. Listen to the full episode HERE.

Drinking tea can boost your immune system, fight off inflammation, and even ward off cancer and heart disease.

Health Benefits of Tea

"Tea is one of the main stays of civilization in this country." – George Orwell

Coffee Talk with Robyn Randolph

Senior Specialist, Food Laboratory Accreditation
Association of Public Health Laboratories (APHL)
Project Manager, PFP Laboratory Science Workgroup

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Hello, Robyn! Tell us about yourself, your job role, and your involvement with the ORA DX program.

In my role as Senior Specialist in APHL's Food Safety program, I work to support Human and Animal Food (HAF) laboratories across the country in a variety of ways; including improving data defensibility, assisting in the development of best practices and quality-related resources, and supporting laboratories involved in the various Laboratory Flexible Funding Model (LFFM) tracks. I also serve as staff liaison to APHL's HAF Committee, and project manager for the PFP Laboratory Science Workgroup. Through both groups, I have been working with FDA and the PFP IT WG to support laboratories involved in the ORA DX program.

Based on your role as Senior Specialist for APHL, PM for the PFP Lab Science WG, and DX stakeholder, share your thoughts on some of the benefits for state labs looking to participate with the ORA DX.

I think that the ORA DX program is a fantastic opportunity for increased sharing and collaboration between food safety regulatory partners in real time. The multitude of ways to share data through the DX platform (Office of Regulatory Affairs Partners Portal (ORAPP), Enhanced DX Client, or System-to-System), allows states to determine the best way to work with the system, based on their unique needs/situations. For laboratories going the System-to-System route, time spent on upfront system integration development and testing is decreased and frees analysts from hours of manual data entry.

What challenges has APHL heard from laboratories participating in ORA DX?

APHL has been working closely with HAF Committee members and others participating in ORA DX to help identify challenges and communicate them with FDA partners. The common challenges for laboratories, which includes Firm Establishment Identifier (FEI) numbers and lot size data fields, boil down to identifying the critical data that FDA needs to be submitted in ORA DX versus what information would be "nice to know" if eventual traceback is needed. Laboratories are submitting data for hundreds of samples, and the time commitment for both laboratories and state regulatory partners to collect and upload the metadata can be a huge hinderance. Many laboratories are suffering burnout and understaffing, and this time commitment can be untenable. I think it is important to find that balance between what data is critical for timely follow-up and what would be nice to know for trending or risk assessment.

The laboratories have also expressed gratitude towards the ORA DX team for their willingness to listen to the states, hear their concerns, and work towards solutions that benefit both parties as well as protect public health.

The PFP IT WG thanks Robyn Randolph for her support of the ORA DX program and the PFP. For more on Robyn's insight and ways state lab(s) can improve their ORA DX onboarding experience, continue reading the rest of the conversation, *here*!

Next PFP IT WG Meeting: February 27, 2023

Holiday Food Safety

Many people do not realize that food safety is the most important ingredient in preparing food for the holidays.

Cookies are a holiday favorite – and this season is a good time to remember that ready-to-cook foods of all kinds, including raw, packaged cookie dough, need to be cooked. Eating these kinds of foods right out of the package, without cooking them, could make you sick from bacteria. Cooking them according to the package directions before you eat them kills bacteria that could make you sick.

Watch FDAs Holiday Food Safety Video to learn how to store, prepare, and serve food safely.

"But indeed, I would rather have nothing but tea." – Agatha Christie

ORA Data Exchange (DX) Frequently Asked Questions

Resources and Useful Information

- PFP Website and Twitter
- PFP IT WG Page
- PFP Strategic Plan
- ORA Partners Portal Homepage
- AFDO Newsletters
- Presentations at MFRPA Conferences
- Contact Us at AppsDesk@fda.hhs.gov

Question: Does a regulatory partner have to sign formal agreements to participate in the ORA DX program?

Answer: Yes. The Food and Feed 20.88 agreement is required to participate in the ORA DX program. Additionally, a Memorandum of Understanding (MOU) and Interconnection Security Agreement (ISA) are required to participate in the System-to-System, along with a Non-Disclosure Agreement (NDA) for uploading attachments.

Question: How does participation in the ORA DX program help a regulatory partner?

Answer: Participation in the ORA DX program provides the regulatory partner with improved information sharing capabilities with FDA. At a minimum, it eliminates dual data entry in the state's system and FDA's system and any challenges associated with the related data updates. ORAPP is envisioned to be the centralized and comprehensive portal for all electronic data exchange between the regulatory partner and FDA. Additional FDA data that will benefit the regulatory partner may be made available to partners in the future.

Question: How does a regulatory partner sign-up for an ORA DX capability?

Answer: A regulatory partner can email the ORA Apps Desk at appsdesk@fda.hhs.gov or contact the FDA state liaison or field management to indicate participation interest. In certain instances, FDA reaches out to the regulatory partner based on various FDA initiatives and ORA DX outreach. Every participation request is reviewed and approved by FDA.

For additional ORA DX FAQs *read more...*

Information Corner

Contact us at APPSDesk@fda.hhs.gov

ORA DX Training Highlights

The PFP IT WG is excited to announce the arrival of ORA DX e-Learning! Training is now available on the new ORAPP Training page! After successfully logging in to ORAPP, access the e-Learning tab of the Training page to view the following courses:

- ORA DX Program Overview (10 minutes)
- ORA DX Onboarding (6 minutes)
- ORA Partners Portal (ORAPP) Overview (6 minutes)
- ORA DX Firm Search and Firm History (10 minutes)
- ORA DX Non-Contracted Inspection (NCI) Overview (10 minutes)
- ORA DX Non-Contracted Inspection (NCI) Submission (10 minutes)
- ORA DX Non-Contracted Inspection (NCI) Errors, Correction, and Resubmission (8 minutes)

e-Learning courses for the various ORA DX capabilities are in development and will be available soon! Check out the ORAPP Training page regularly to view the latest e-Learning courses and upcoming instructor-led courses.

To register for upcoming courses, or to find out more information on ORA DX e-Learning, please contact us at APPSdesk@fda.hhs.gov.

"But indeed, I would rather have nothing but tea." – Jane Austen