PARTNERSHIP FOR FOOD PROTECTION

INFORMATION TECHNOLOGY WORKGROUP NEWSLETTER

In This Issue

Coffee Talk With Omari Fennell

The PFP IT WG recently had the pleasure of catching up with Omari Fennell, Office of Regulatory Affairs (ORA) Data Exchange (DX) Outreach Coordinator for a coffee talk about the ORA DX and onboarding. Read about Omari's role, interesting perspective of the ORA DX program and onboarding process *on page 4*. The Coffee Talk article is available on the *PFP website*.

Corn is the most produced grain worldwide.

A Fond Farewell to Barbara Cassens

Farewell Barbara Cassens!

Thank you for your leadership and commitment to public health protection since joining FDA in 1990, it has been a pleasure working with you on PFP initiatives over the years. The IT WG could always count on your participation in Coffee Talks, Newsletter Spotlights, and a cute picture of Abbey the cat!

May your next chapter be full of joy and adventure.

Thank you for your service, job well done. We wish you well. Happy (December) Retirement!

"Knowledge will bring you the opportunity to make a difference." — Claire Fagin

Getting to Know the Automated Laboratory Information System (ALIS)

The **Automated Laboratory Information System (ALIS)** is a custom web-based software being developed for ORA's Office of Regulatory Science (ORS) laboratory analysts to perform daily work activities.

Sample analysis results data that have formerly been captured in the FACTS application will now be captured in ALIS. ALIS creates the ability to store more lab information than FACTS currently stores. The sample analysis data will be sent back to the FACTS Oracle database via a service called LABS Data Service (LDS).

"The ability to compile and access so much data in one spot has been tremendous." – **Dr. Paul Norris, Director, ORA, ORS**

Major Activities:

- Allows analysts to transfer and receive samples in the interface once laboratory receipt is complete.
- Captures important information needed to document scientific analysis.
- Automatically generates final analytical packages and reports.
- Submits results to desired agency systems(s) (FACTS, ORADSS, CMS, etc.)
- Tracks system and document updates/changes (audit log).

Check out this ARTICLE to learn more about ALIS and its many benefits.

A Few Words from Jack Wehr, ALIS PM

FDA tests thousands of food, drug, medical device, and other products each year at 15 regulatory labs spread across 12 locations. As such, designing and implementing an IT system to handle the wide variety and oftentimes complex analytical testing done at these locations is a monumental challenge. Only by building partnerships between the labs, contractor development teams, and FDA IT teams have we been able to make progress, delivering several major releases to over seven FDA labs.

The release of ALIS 2.0 for Microbiology labs (like those in Denver and New York) in September of 2023 ALIS now supports about 50% of regulatory samples at FDA; focused on Pesticides and Microbiology testing for Human and Animal Food. Since then, the ALIS team has continued to expand the application by adding more functionality for existing users (like supervisors and lab management) and new user groups like the Sample Evidence Specialists, who are responsible for tracking the chain-of-custody of the samples. Along the way, we have learned a lot about what works in a lab's IT system and what doesn't. Those lessons learned are being actively applied to ALIS 3.0, also called uALIS (Universal ALIS), which will further empower lab staff to customize the ALIS tool for their unique analytical subject areas. 3.0 Is still in development and is anticipated to roll-out to FDA labs in 2025.

With each release, ALIS moves closer to housing the end-to-end lifecycle of a FDA sample, transforming the business processes at the bench and ending reliance on legacy systems.

"I was gratified to be able to answer promptly, and I did. I said I didn't know." — Mark Twain

PFP IT WG and ORA Data Exchange (DX) Then & Now

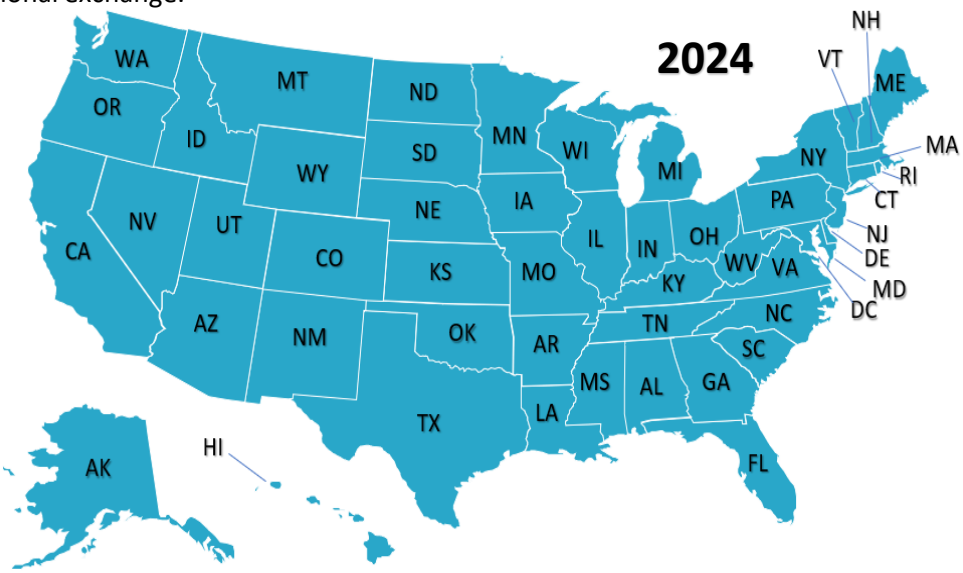
Established in 2012, **PARTNERSHIP FOR FOOD PROTECTION (PFP) INFORMATION TECHNOLOGY (IT) WORK GROUP** meetings were designed as a way to engage with various local, state, and federal agencies working toward the protection of public health, providing a collective IT vision and approach for sustainable uniform electronic data exchange with Integrated Food Safety System (IFSS) partners. Participation offers the opportunity to learn about the System-to-System (S2S) initiative, and accomplishments in a bi-directional exchange.

All 50 States Participating in ORA DX!

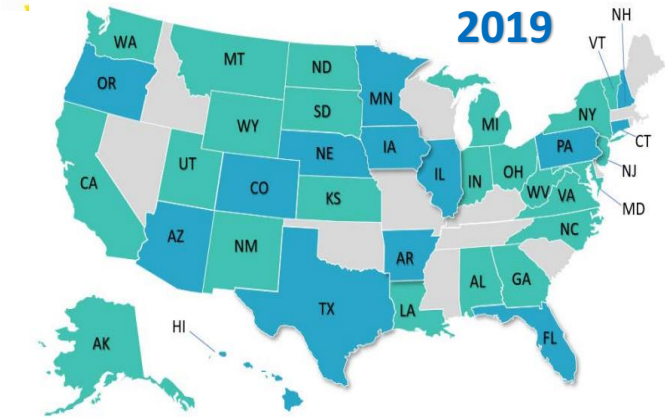
47
States participating in PFP IT WG or Sample WG

75
Partner agencies participating in ORAPP

23
Partner agencies participating in S2S or Enhanced DX Client



- In certain cases, there is more than one partner/agency per state
- Some partners are in the process of onboarding



13
States were Participating in ORA DX

33
States were participating in the PFP IT WG

Check out the **FIRST ISSUE** of the PFP IT WG Newsletter to see how far we've come!

We are thrilled to announce that the **OFFICE OF REGULATORY AFFAIRS (ORA) DATA EXCHANGE (DX) HAS SUCCESSFULLY ACHIEVED PARTICIPATION IN ALL 50 STATES!** This milestone marks a significant achievement in our ongoing efforts to enhance regulatory collaboration and data sharing across the nation. The commitment and hard work of everyone involved have been instrumental in reaching this goal, and we look forward to the continued growth and success of ORA DX as it fosters greater transparency and efficiency in our regulatory processes. ***Thank you to everyone involved in helping to reach this goal!***

"I did then what I knew how to do. Now that I know better, I do better." — Maya Angelou

Coffee Talk with Omari Fennell

Outreach Coordinator
Office of Regulatory Affairs (ORA) Data Exchange (DX)
U.S. Food and Drug Administration (FDA)

Continued from page 1

Hello, Omari! Tell us about yourself, and your role and responsibilities as Outreach Coordinator with the Office of Regulatory Affairs (ORA) Data Exchange (DX) Program. For the past seven years, I have been part of the ORA DX program. In my role as the Outreach Coordinator, I support state regulatory partner outreach, onboarding, and other related activities. I oversee building awareness and interest in the DX program, support regulatory partners with deciding on the capabilities that are a best fit, and assist users with obtaining ORA DX access.

What is the ORA DX and how does participation benefit a regulatory partner? The ORA DX exists to enable more efficient food safety data sharing between the FDA and regulatory partners so that collaboratively we can contribute to a safer national food supply. Participation offers several benefits to regulatory partners, including increasing secure bidirectional data exchange and ensuring that critical information is shared efficiently. This seamless exchange of data reduces the need for dual data entry, significantly saving time and resources for regulatory partners.

Additionally, the ORA DX enhances collaboration by supporting key acts, workgroups, and initiatives such as the Food Safety Modernization Act (FSMA), Integrated Food Safety System (IFSS), New Era of Smarter Food Safety, Domestic Mutual Reliance (DMR), and the Partnership for Food Protection Information Technology Workgroup (PFP IT WG). By improving the speed of information sharing, the ORA DX ensures that relevant parties have access to contextual information needed to conduct regulatory activities. Additionally, increased data standardization offered by ORA DX enables interoperability amongst disparate systems.

Global production of grains surpasses 2.5 billion tons

Did you Know?

When not at work, **Omari** enjoys exploring emerging technologies, listening to a good audiobook, assisting with a local food insecurity program, and spending time with his two kids and wife. They recently had a wonderful family vacation at American Dream in New Jersey, New York, and Rehoboth Beach.

Omari and his lovely family: Kendrick (son), Jocelyn (wife), and Kiersten (daughter).

The PFP IT WG would like to thank Omari for his support of the ORA DX program. For more on Omari's insight, continue reading the rest of the conversation ***on the PFP site****!*

The PFP IT WG would like to know what YOU think! Please share your thoughts about the PFP IT WG newsletter, and if there are any areas of interest you'd like to see featured. Please share your thoughts via an email to PFP-IT-WG-Info@fda.hhs.gov.

"An investment in knowledge always pays the best interest." — Benjamin Franklin

ORA DX Frequently Asked Questions (FAQs)

Question: What is the ORA DX program and ORA DX Systems?
Answer: The ORA DX program enables electronic information sharing between regulatory partners and the U.S. Food and Drug Administration. The ORA DX program supports the Food Safety Modernization Act (FSMA), national Integrated Food Safety System (IFSS), Partnership for Food Protection (PFP), Domestic Mutual Reliance (DMR), and more for a safer food supply.

The ORA DX systems include two IT systems to support secure data exchange of inventory, inspection, and sample data: ORAPP and System-to-System (S2S). The ORAPP is a web portal. The S2S is a set of web services and uses the technical components such as XML, Java, and Soap Web Services. The ORA DX systems also include the Enhanced DX Client which supports the submission of sample data (i.e., collection, receipt, and analysis data) to FDA.

The ORA DX One Pager provides a quick overview of the ORA DX program and the About Page on the ORAPP provides additional information about the current ORA DX capabilities and the recent releases.

Question: How does a regulatory partner sign-up for an ORA DX capability?
Answer: Regulatory partners should contact the ORA Apps Desk via the Contact Us page on ORAPP or contact the FDA state liaison or field management to indicate participation interest. In certain instances, the FDA reaches out to the regulatory partner based on various FDA initiatives and ORA DX outreach. Every participation request is reviewed and approved by the FDA.

Resources and Useful Information

Contact Us via ORAPP

PFP Strategic Plan

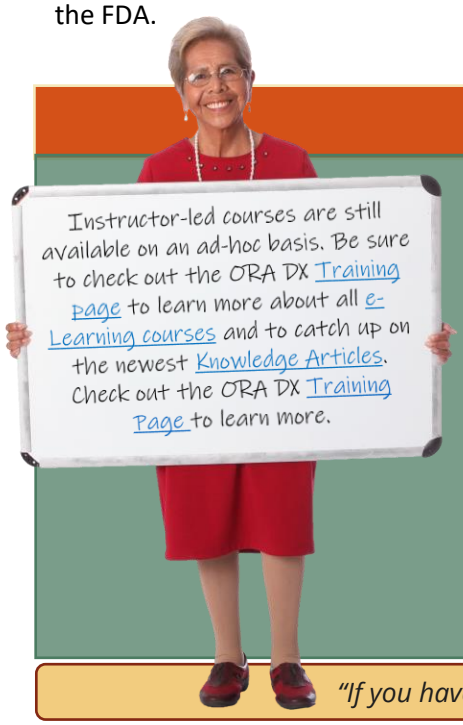
PFP IT WG Page

PFP Website

ORA Partners Portal (ORAPP)

The FAQs for the ORA DX program may be updated with every ORA DX release. For additional ORA DX FAQs read more . . .

ORA DX Training: We're Here For YOU!



The ORA DX Training Team has developed two *NEW* Knowledge Articles (KAs) with updates to several KAs and e-Learning courses, to add to the list of growing training resources!

New KAs:
- Sample Collections, Errors & Corrections
- Sample Receipt & Analysis Errors & Corrections

Updated KAs:
- ORAPP Multi-File Submission for Sample Collections
- ORAPP Multi-File Submission for Sample Receipt and Analysis

Updated e-Learning Courses:
- Non-Contracted Inspections (NCI) Overview
- Non-Contracted Inspections (NCI) Submission
- Non-Contracted Inspections (NCI) Submission Errors & Resubmission

"If you have knowledge, let others light their candles in it." — Margaret Fuller

Announcement: FDA Reorganization

FDA's Reorganization Approved for Establishing Unified Human Foods Program, New Model for Field Operations and Other Modernization Efforts

The U.S. Food and Drug Administration (FDA) reached a significant milestone with approval of its reorganization involving the creation of a unified Human Foods Program (HFP), adoption of a new model for its field operations, and other significant modernization efforts. The **reorganization implementation is currently targeted for Oct. 1, 2024**, notably enhancing the agency's ability to oversee and protect the human food supply and other products the FDA regulates.

The reorganization will enable the FDA to be more efficient, nimble and prepared for the ever-changing and complex industries we regulate, new food and medical product technologies, as well as the impacts of globalization, climate change and other factors that require the agency to quickly adapt.

The reorganization establishes the HFP by realigning the functions of the Center for Food Safety and Applied Nutrition, the Office of Food Policy and Response, as well as key functions from the Office of Regulatory Affairs (ORA) under one program.

Additionally, the restructuring of ORA will enable our field operations unit to focus on inspections, Investigations, and imports as its core mission. The FDA is changing the name of ORA to the Office of Inspections and Investigations (OII) to better convey the organization's role as the frontline of the FDA, which provides real time insights and science-based evidence necessary to ensure the safety and quality of products Americans depend on.

Access the FULL ARTICLE to learn more about the reorganization with implementation set to begin on October 1st.

Getting to know the PFP IT WG

The Partnership for Food Protection (PFP) is a group of dedicated professionals from Federal, State, and Local governments with roles in protecting the food supply and public health. PFP is the structure used to coordinate representatives with expertise in food, feed, epidemiology, laboratory, animal health, environment, and public health to develop and implement an Integrated Food Safety System, (IFSS).

The goal of the ***PFP IT WG*** is to provide a collaborative information technology (IT) vision and approach for sustainable, uniform electronic data exchange for national Integrated Food Safety System (IFSS) partners.

Access the FULL ARTICLE to learn more about safe food handling & preparation.

"A fool can know. The point is to understand." — Albert Einstein