Office of Regulatory Affairs (ORA) Data Exchange (DX)

Coffee Talk with David Kamal

Lab IT Program Manager
Division of Enforcement System Solutions (DESS)
Office of Information Systems and Management (OISM)
Office of Regulatory Affairs (ORA)
Food and Drug Administration (FDA)

The Partnership for Food Protection (PFP) Information Technology Workgroup (IT WG) recently had an opportunity to catch-up with David Kamal, for a Coffee Talk about the ORA DX.

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

I am the Lab IT Program Manager, and my role involves providing high-level oversight, establishing requirements, and defining the roadmap for all lab IT activities. I am the co-lead for program management of the sample domain within ORA DX for state labs' submissions. I also manage emerging lab systems and legacy lab modules. My background with legacy IT systems helps me to ensure the continued collaboration with the ORA DX program. My goal is to share guidance and build a feasible solution for the FDA labs and state labs.

In your role as a Lab IT Program Manager, what do you think are some of the advantages of state labs participating in the ORA DX?

I believe the main advantage for the state labs participating in the ORA DX is having the ability to exchange laboratory sample results data rapidly and securely for analysis of foods and/or food-related environmental samples collected by federal, state, or local agencies. Should there be a large-scale outbreak, national event, or even a planned assignment where FDA needs surge capacity from state laboratories to analyze FDA-collected samples, this capability is essential to rapidly and securely integrating the state analytical data with the FDA collection report, making the complete sample record accessible in the legacy Field Compliance Tracking System (FACTS). Laboratories with both analytical capability and ORA DX capability will be go-to laboratories due to the logistical ease in reporting analytical results to FDA. ORA DX also allows for states to share state-collected and state-analyzed sample data with FDA.

The primary driver for submission of state-collected, state-analyzed data through ORA DX will be the Laboratory Flexible Funding Model (LFFM) Product Testing Tracks. This acts as a force multiplier to provide FDA with access to a vastly expanded number of high-quality sample collection and analytical results, for use in risk assessment, data modeling, predictive analytics, etc. Moving to ORA DX will be a process improvement for LFFM reporting. This improvement will allow FDA Center and ORA Compliance and Investigations staff to rapidly access the sample analysis results and review the outcomes in FACTS, and through the ORADSS data warehouse reporting tool. Whereas prior to moving to ORA DX, they waited for quarterly compiled spreadsheets that lacked key fields (like FEI, PAC, and Product Code) allowing the state data and FDA data to be successfully integrated and analyzed as a whole.

Looking ahead, are there any ORA DX systems enhancements being considered to improve user experience for ORA DX sample capabilities?

The July 2022 ORA DX release focused on resolving significant user challenges. The release lets users do the following in the ORA DX:

- Conduct FDA firm search across states
- Report multiple sample analyses results for one sample

There are additional improvements planned for the upcoming fiscal year (FY23) to improve user experience:

- Implement multiple Problem Area Flags and Program Assignment Codes (multi-PAFs/PACs) processing for the same state lab sample number via a spreadsheet for sample collections
- Display upload status for the same state lab sample number with multi-PAF/PAC combinations
- Upload multiple FDA sample numbers in a single Excel file for sample receipts and analysis
- Support processing multiple Excel files in one transaction
- Enhance sample data sharing to enable state labs to update state sample collection via ORA DX

How does FDA collaborate with state labs to determine sample data sharing enhancements for future ORA DX releases or to streamline sample data submission?

FDA actively engages state labs to review planned data sharing features or capabilities, as well as solicit feedback regarding ORA DX enhancements prioritization. Upon approval, the features become part of the upcoming sample data sharing enhancements.

The future ORA DX program vision is to increase FDA collaboration with states. This will support active bidirectional activities and listening sessions for increased state input into the ORA DX roadmap including user support, priorities, and potentially reducing the complexity and number of required data elements for sample submissions.

Please share your insight about the ORA DX onboarding experience with the state lab(s) from the ORA DX systems perspective?

The state labs establish and lead their own ORA DX onboarding timeline. The ORA DX teams support the state labs during the onboarding process. Once complete, labs can practice submitting real-world data in the ORA DX Pre-Production environment. The ORA's Office of Regularity Science (ORS) reviews the submissions, provides feedback regarding the data quality, and shares any additional tips and tricks for data entry before allowing the state labs to submit data in the ORA DX Production environment.

How can state lab(s) improve their ORA DX onboarding experience?

Most of the state labs work closely with their Laboratory Information Management System (LIMS) contractor to review the "Sample Integration Guide" and perform data mapping exercises for ORA DX onboarding. Having both the laboratory expertise and IT skills ensures a smooth onboarding experience. I share the following tips for the labs:

- **Network** with other state labs as many either have the same LIMS software and/or LIMS vendors
- **Pool knowledge** to collectively work through the onboarding process
- **Participate** in Sample Data Sharing – IT Implementation and the PFP IT Workgroup meeting series
- **Volunteer** in User Acceptance Testing (UAT) for an upcoming ORA DX release to receive a preview of the upcoming release and have the opportunity to practice their DX skills

The PFP IT WG would like to thank David Kamal for his support of the ORA DX program and the PFP. We look forward to continued collaboration with David and expanding the ORA DX program. For questions or information about the ORA DX or the PFP IT WG, contact us at appsdesk@fda.hhs.gov.