Partnership for Food Protection Information Technology Workgroup (PFP IT WG)

Coffee Talk with Omari Fennell

Outreach Coordinator
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The PFP IT WG recently had the pleasure of a Coffee Talk with Omari Fennell, about the ORA DX program and regulatory partner onboarding.

The ORA DX is a unified platform to securely share information between the FDA and state and local regulatory partners. The mission of the ORA DX is to streamline submission of food safety regulatory data and support timely decision making by providing access to relevant inventory, sample, and inspection information.

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.

Do regulatory partners reach out to you if they are interested in participating or do you approach them? Is participation in the ORA DX voluntary?

The answer to the first question is both! I reach out to regulatory partners to share information about the ORA DX. State partners also reach out to us via the ORA Partners Portal (ORAPP) Contact Us page and appsdesk@fda.hhs.gov.

Participation in the ORA DX is voluntary; however, it is recommended since the ORA DX will gradually become the primary means for data sharing between FDA and regulatory partners.

Give us a high-level overview of the regulatory partner onboarding process for System to System (S2S) integration with ORA DX. Are there requirements to participate in the ORA DX?

The partner onboarding process involves a series of activities, conducted by FDA and the regulatory partner. The onboarding activities begin once a regulatory partner decides to participate in any ORA DX capability and internal FDA approval is obtained. Compared to ORAPP, the onboarding process for S2S capabilities is more extensive due to various integration activities. These activities begin with kickoff tasks, followed by partner development and testing which culminates in a production roll-out. Additionally, state agencies using S2S are required to have a completed Interconnection Security Agreement (ISA), Memorandum of Understanding (MOU) and 20.88 Food and Feed agreement. The benefit for states using S2S is a time reduction in manual data entry activities along with transmitting and receiving data seamlessly between state and FDA systems.

What are the key benefits for regulatory partners using ORAPP with ORA DX?

ORAPP provides a centralized web portal where regulatory partners and FDA can submit and receive data. Inventory, inspection, and sample data sharing capabilities are available via ORAPP. Regulatory partners can access inventory capabilities to search, view, reconcile, and submit inventory data. Inspection capabilities enable partners to efficiently submit non-contracted inspection (NCI) data as part of DMR and partnership initiatives. Additionally, state lab partners can submit sample data, and state produce safety users can exchange files with the FDA.

Additionally, regulatory partners have the flexibility to participate in both S2S and ORAPP and choose their ORA DX capabilities. However, certain capabilities have prerequisites. I help potential partners figure out what will work best for them.

What are some of the challenges regulatory partners have encountered during the onboarding process, and how have they been addressed? Are some partners in a better position to participate in the ORA DX?

From my experience, the top three challenges include lack of state funding, state technical resources, and data interoperability. We have found that states often do not have the IT funding that is needed for S2S integration. To address this barrier, the FDA has provided funding to states for their IT efforts. Also, the FDA has provided funding, via cooperative agreements, to organizations such as the Association of Food and Drug Officials (AFDO) to perform the IT work on behalf of states.

State regulatory partners with funding must also have the proper IT personnel. State system configuration must be completed by the regulatory partner for S2S integration. Additionally, developers that are familiar with web services integration are needed. Some states do not

have these IT personnel in-house. Also, in certain cases, the IT department is separate from the regulatory program department.

One aspect that has required consideration and a high level of effort is determining the data interoperability between partners. There are differences in the data captured by the FDA versus states for inventory, inspection, and sample areas. Across all ORA DX systems and capabilities, the required and optional data elements that can be exchanged are clearly defined. Regulatory partners implement the necessary system and process changes to capture data required by the ORA DX.

Despite the challenges, it is encouraging to see the progress that has been made. State partners have expended significant effort to prevail and make the ORA DX successful.

What measures are in place to facilitate seamless and secure data sharing between regulatory partners and the ORA DX systems?

Users accessing ORA DX systems are always authenticated via unique credentials. Also, the FDA facilitates data exchange via S2S by providing the essential data fields, XML schema definitions, web services, and message constructs. For ORAPP, the FDA offers predefined Excel templates that include data fields, specific data requirements, and detailed mapping information to align state data fields with FDA data fields. Additionally, the FDA provides comprehensive instructions, guides, FAQs, training, example files, etc. ensuring a seamless data integration process.

How are regulatory partners trained and supported during the onboarding process and beyond?

As coordinator, I schedule ORA DX overview, technical, and 1-on-1 meetings to provide regulatory partners with the guidance that is needed as they onboard. There are also recurring group meetings with state partners who are onboarding for various capabilities. Furthermore, ORA DX Training offers free on-demand e-Learning courses and Knowledge Articles (KAs) that provide key information related to ORAPP capabilities and the ORA DX.

Have you received feedback from regulatory partners about their experience with the DX's ORAPP system?

Overall, regulatory partners have provided positive feedback on ORAPP. State partners appreciate the ease of onboarding. There is no development required by regulatory partners to utilize it. We have received kudos for the Firm Search (FS), Firm History (FH), and Inventory Reconciliation (IR) capabilities that provide essential FDA information to regulatory partners.

I look forward to continuing to enhance the ORAPP capabilities to garner more positive feedback from state users.

Highlight a success story from a regulatory partner who has effectively used the ORA DX.

There have been many successes related to the ORA DX. We've had state partners express to us that S2S has saved time for state field inspectors, which allows them to spend more time doing the inspections versus paperwork/data entry. These state inspectors no longer have to complete double data entry. Also, sample data received via the ORA DX has helped with recalling potentially harmful products. I am especially proud we have state participation now from every state. This is a wonderful achievement considering that in 2018, only 6 states were participating in the ORA DX. I am extremely grateful for the regulatory partners, ORA DX team, and other stakeholders that have supported the ORA DX Program.

Here's a great podcast about how the ORA DX is working for Maryland and Arkansas.

How can regulatory partners actively participate in the ORA DX community? How can they learn more?

Regulatory partners are encouraged to raise awareness, provide state perspectives on data sharing, and influence the program's priorities and scope. Engagement can be through various channels such as workgroups, newsletters, and regular meetings. For regulatory partners wanting to actively participate in the ORA DX, I recommend attending the PFP IT WG meeting series. The quarterly PFP IT WG newsletter is also an amazing resource to learn about what's going on with the ORA DX. Additionally, quarterly Coffee Talk articles, like this one, are beneficial.

Finally, is there something fun and interesting about yourself to share with the readers? (Hobbies, interests, vacations, pets, etc.)

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

The PFP IT WG would like to thank Omari for his promotion of the ORA DX program, and we look forward to continued collaboration with him and expanding the ORA DX program.

Contact us at appsdesk@fda.hhs.gov if you have any questions or would like additional information.