ORA Data Exchange (DX)

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The Partnership for Food Protection (PFP) Information Technology Workgroup (IT WG) recently had an opportunity to catch-up with Jennifer Pierquet, Project Manager, Association of Food and Drug Officials (AFDO), for a *Coffee Talk - Part A* about the Office of Regulatory Affairs (ORA) DX.

Hello Jennifer, tell us about yourself and your role on the ORA DX project.

My title is Project Manager with my focus being the USAPlants and USAFoodSafety systems – the state inspectional systems that currently support 20 states that use one or both applications. The two systems encompass milk, animal food, retail, manufacturing, produce, and other inspectional programs.

Included in my oversight is working with the two vendors that currently support the existing USAPlants and USAFoodSafety systems, the current user communities, and the governing council that oversees the maintenance and support of the existing systems while

working toward a long-term plan to replace these systems with modern technology. The most exciting part of my work is to help define future needs for current and potentials users that will open the doors for additional food safety integration.

One important facet of my work is helping the current USAFoodSafety states work within the evolving parameters of the exchange of inspectional data with U.S. Food and Drug Administration (FDA) via the System-to-System (National Food Safety Data Exchange - NFSDX) of the ORA DX.

I work with the triad of stakeholders including states, current vendors, and the FDA data exchange team. My goal is to represent the states in translating what data currently is collected and what really happens in the field so that FDA and the USAFoodSafety vendor are developing to meet all needs.

What do you think are some of the benefits or advantages of participating in the ORA DX that you would like to share with the states you support at AFDO?

Really the benefits boil down to the ability to have an automated transfer of inspectional data in real time. The goal is ultimately to replace duplicative work being done at the state level. Currently, most states complete two inspection reports: 1) state inspection report; 2) FDA contract inspection report. The System-to-System replaces the need for states to login to FDA's eSAF to enter inspectional data. In lieu of manual data entry, state collected FDA information is sent from USAFoodSafety to eSAF by the click of a Submit button. The result is time savings for both the state inspector and FDA State Liaison reviewing state reports. A bonus is state inspection results are available in real time.

The DX allows for searching of FDA firms and also sharing firm information between states via State-to-State Firm Search if states permit. This search capability allows for states to look-up their state specific FDA inventory as well as search other state's firm inventory. As more products cross state lines, sharing information and issues becomes increasingly valuable for states and FDA. This sharing is critical to problems being identified and corrected quicker ultimately protecting the public.

Looking ahead, are there particular functionalities you would like to see in ORA DX for state(s) you support?

The ORA DX is being developed to be a two-way communication channel for regulatory partners and FDA. Initial functionality of the ORA DX was focused on state to FDA data sharing. Recent efforts have expanded that functionality to be more two-way-focused,

while including all stakeholders in the food safety ecosystem to include state laboratories. This would allow the FDA to provide consistent and timely communication and data to the whole state food safety community. ***Editor's Note:*** *FDA is actively working on expanding shared data sets with regulatory partners (states).*

Another project on the forefront is the Inventory Reconciliation which will look to harmonizing firm inventory data between a state and their FDA Division. The completion of this project will streamline the annual work planning process by creating a single inventory for a state and FDA Division eliminating duplicate and inactive firms.

FDA and the states are challenged to meet their own data goals while supporting each other's systems through integration due to the myriad of state technologies or lack thereof. Within FDA, this is a huge undertaking due to the breadth of internal systems currently in place. For states, understanding what FDA will require and provide in the future will be critical as a new state platform is developed.

What is your advice for states considering ORA DX System-to-System capabilities and to those that may have questions about participating in ORA DX?

At this point, this coordination relies on systems that were not developed to talk to each other. Understanding the business process of the states and the differences from state to state will be critical between the states themselves and with FDA. The transition of the USAFoodSafety states to the ORA DX System-to-System has been gradual due to the various start dates for individual state contracts and the shifting business requirements. The USAFoodSafety vendor and I are working to increase understanding by clearly defining needs and sharing them with the FDA DX team.

I would also encourage states, especially those who lack IT resources, to work with the FDA DX team to implement this data sharing connection for the common good even if they are not currently using USAFoodSafety for example. The DX is focused on the benefits of the states – ALL states – while meeting the data needs supporting FDA's responsibility. We find our coordination efforts identify state challenges working with the System-to-System data that are system diagnostic and often process questions between the states and FDA.

What data exchange issues matter most to the states you support and how can we (AFDO, states, and ORA DX) continue to work together to ensure successful data sharing?

One of the biggest issues for a state is the need to be able to provide their constituents verifiable proof of return on investment. That is a given. Investments of time and resources

are significant. State teams need to be able to confidently says that the DX is easy to use and improves efficiency while data being shared with FDA is protected.

AFDO is encouraging the formation of specific DX user groups to allow current users to share their status, discuss roadblocks, and leverage their resources separate from the PFP IT Workgroup. The reason behind specific user groups is now that the DX is in full implementation mode, targeted conversations need to take place on current and future functionality with the users who have a direct user experience. Smaller, targeted user groups will yield better and more succinct solutions to the challenges impacting their work via the DX.

Personally, my goal is to work to get valuable feedback from FDA and the states that would inform continued system growth for everyone's benefit. Often, current information sharing regulations do not support true mutual reliance and without that, working together is very difficult on both sides of the DX.

Share your insight about the ORA DX onboarding experience with the state(s) you support (e.g., the state experienced delay with development during the pandemic)?

The process is unique because of AFDO's involvement. We have ten states that are participating in the various capabilities of the DX. All the states that have a current FDA contract are aware of the benefits of the ORA DX. Our focus is to help each of these states work through whatever challenges inhibit them from participating.

There are some challenges with the onboarding paperwork – forms, legal implications. The pandemic has slowed down the signatures on both the FDA and state side, required to allow for data sharing. A more significant challenge to implementing the data exchange is the piecemeal development process which discourages states due to the desire to eliminate duplicative entry into two inspectional systems. Some examples are the need for states to send multiple Program Assignment Codes (PACs) for one inspection, updating Top Management Official (TMO), answering Intentional Adulteration (IA) questions, and sending attachments. States need the System-to-System capability to send over all the FDA contract requirements. Otherwise, states will have to login to eSAF to update the items listed above which is not the desired outcome.

Currently, the ten states are near having all data elements functional, and other non-USAFoodSafety states will hopefully benefit from AFDO's push for a complete inspectional DX. However, if FDA has delays in any development of a particular function, the states are going to be delayed in enabling a capability. This could negatively impact the desire for no

dual entry. This challenge will likely be an ongoing threat due to the changing nature of inspectional work. Both FDA and states understand this caveat and are working together to better prepare for these instances.

The PFP IT WG thanks Jennifer Pierquet and her team for their support of the ORA DX program and the PFP. We look forward to continued collaboration with AFDO on expanding the ORA DX program.

For questions or information about the ORA DX program or the PFP IT WG, contact us at NFSDX_Info@fda.hhs.gov.

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