ORA Data Exchange (ORA DX)

Erin Woodom-Coleman
Branch Chief of the Laboratory, Medical Products, and Innovation Branch
FDA's Office of Partnerships (OP)
Office of Regulatory Affairs (ORA)
U.S. Food and Drug Administration (FDA)

The Partnership for Food Protection (PFP) Information Technology Workgroup (IT WG) recently had the opportunity to catch-up with Erin Woodom-Coleman, Branch Chief of the Laboratory, Medical Products, and Innovation Branch in FDA's Office of Partnerships, ORA, FDA for *Coffee Talk* about the ORA DX.

Tell us about yourself and your role on the ORA DX project.

Hi, everyone! I am the Branch Chief of the Laboratory, Medical Products, and Innovation Branch in FDA's Office of Partnerships. I think most of our state partners are familiar with me through my work with eSAF. I've had the pleasure of being a member of the eSAF team since 2013, which brought me to the PFP IT workgroup and the ORA DX project.

What are some of the benefits or advantages of the DX that you would like to share with the states you support?

I've met so many of our state partners and you always express what a burden dual data entry presents to your organizations. Our ultimate goal is to eliminate that burden in areas where we can, and the DX presents some options to help us do that.

Now naturally System-to-System services (NFSDX) is my favorite of these options, as it really is that seamless flow - you can enter the inspection data into your system, click the button, and off it goes to eSAF.

However, we understand that not everyone is at a point where they can make the necessary system adjustments to utilize the System-to-System option, and for those states we have the Partners Portal (ORAPP). Although this doesn't eliminate the dual entry issues, ORAPP will give you access to search FDA's inventory and the ability to send sample results. Also, have you seen it? Let's be honest – it's way more visually appealing than eSAF (no offense eSAF team).

Looking ahead, is there any particular functionality you would like to see in the DX?

There isn't any functionality in particular, but I'm really looking forward to many of the features we've implemented in eSAF making their way to the DX. We've worked really hard over the past few years to make changes in eSAF that we felt would make the platform more user friendly, and I like to think the users did in fact find them useful and would like them available via the DX as well.

What is your advice for states considering DX?

Be an early adopter! I know how much everyone loves eSAF, but the truth is that the ORA DX is our future. Why not start now? If you have concerns or reservations, I feel very confident that the DX team can talk you through those. Let's get you on board!

Is there anything unique about the DX experience of the state(s) you support that you would like to share (e.g., the state experienced a hurricane during project development)?

I have a special appreciation for the DX. Having worked with eSAF as a Compliance Officer at the State, and then as a State Contract Monitor when I came to FDA, I realize how much of a game changer the DX really is. I cannot imagine having had something like this when I was working at the state. I'm actually jealous.

****

The PFP IT WG thanks Erin Woodom-Coleman and her team for their support of the ORA Data Exchange (DX) program and the PFP. We look forward to continued collaboration with the Laboratory, Medical Products, and Innovation Branch in FDA's Office of Partnerships 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.

https://www.pfp-ifss.org