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

Coffee Talk with Tim Mueller

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The Partnership for Food Protection Information Technology Workgroup (PFP IT WG) recently caught up with Tim Mueller for a coffee talk about the ORA Data Exchange (DX) program. 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, Tim! Tell us about your job role and involvement with the ORA DX program.

My role as the director for the Division of Integration in the Office of Partnerships is to support an incredible team of public health focused individuals to lead three critical areas:

1. International engagement between the FDA and foreign competent authorities
2. Advancement of FDA's support of an Integrated Food Safety System (IFSS) through collaboration with state partners under Domestic Mutual Reliance (DMR)
3. Capture the return-on-investment of FDA funded and unfunded programs through data visualization

The DX team is a critical part of my division's engagements. We constantly leverage the efforts of the program team to support collaborative communication and data sharing between the FDA and its regulatory partners.

Based on your role as director and key DX stakeholder, share your thoughts on some of the benefits for states participating in this program.

My work focuses on collaboration, which is not possible without strong communication – this is why the ORA DX program is so critical. By exchanging data, FDA and its partners are better able to share information securely and efficiently within FDA legal structure.

What are the goals of the DMR program, and what are some of its key accomplishments?

DMR is a seamless partnership that enables FDA and states with comparable regulatory systems to rely on, and leverage each other's work/data, and actions to ensure a safe national food supply. Through collaborative efforts between ORA's field divisions and state partners, we have seen many positive impacts on consumer health. These include a reduction in duplicative inspections, joint enforcement actions, coordinated responses to outbreaks, and protecting consumers from harmful products. Recent examples of DMR accomplishments are in the "What's New" section of the DMR page on the FDA website.

Tell us about the DMR Partnership Agreements and associated activities.

Partnership Agreements are a specific type of memorandum of understanding that details the relationship between FDA and state partners responsible for carrying out the mission of advancing public health. These formal documents clearly define goals, activities, and responsibilities of each partner, and help us to work toward an IFSS. This enables partners to build a workforce with training support from FDA to protect consumers, coordinate food safety inspection efforts, share data, leverage resources, focus on preventing outbreaks, and better respond when one occurs. More information is available on the DMR Partnership Agreements page on the FDA website.

What are some of the challenges, if any, that states might experience due to mutual reliance efforts? How can they be mitigated?

I am in constant awe of the passion, dedication, and effort from everyone entrusted to protect consumers and advance food safety within their states and the nation at large. However, these individuals are also incredibly busy, and finding time to document and further advance these efforts can be challenging. To assist, my team of partnership facilitators are available to help capture and advance these efforts in a structured and strategic manner, consistent with the goals of the DMR framework.

How do you see the ORA DX program supporting and enhancing DMR for the states and FDA?

Part of our process in implementing DMR Partnership Agreements is identifying Subject Matter Experts (SMEs) across the partners who can support the areas of collaboration which is critical to the integration efforts. SMEs are the leaders within the ORA DX program who can provide the education, information, and insights in how to leverage FDA IT systems. Some of which, like the inventory reconciliation tool, are specifically designed to advance information sharing and collaboration.

Looking ahead, what would you like to see for the future of the DMR Partnership Agreements?

My hope for the future of DMR is that through Partnership Agreements, we document a path to one integrated workforce, one where the nation's food safety efforts are based on a risk profile that recognizes and considers the work of FDA field investigators and state partners. By increasing the number of new partners, expanding the use of DX by current partners, enhancing the DX capabilities, and continuing to leverage SMEs to drive strategic collaboration and build trust, I think we will be able to make this hope a reality.

Are there particular enhancements to the ORA DX program that you think would help advance DMR efforts?

The critical element of working seamlessly with state partners is the ability to share information. The enhancements I believe will most benefit our partners are finding ways to continue to create secure pathways for timely information sharing that require minimal human interaction. We have seen this through the development of tools like the ORA Partners Portal (ORAPP) and the System-to-System services (NFSDX). As we move forward, we will need to identify automation of specific modules, like the inventory reconciliation tool, that can alleviate some of the manual data entry and review. That way, if ORA field divisions and states are not ready to advance a large IT effort, they can instead select smaller pieces to drive incremental information sharing efforts. Also, IT enhancements to coordinate inspectional assignments in real time between FDA and partners could help avoid duplication of effort and reallocate resources to other risk-based activities to best protect consumers.

What other ways do you see your division being involved in the ORA DX program in the future?

My team will continue to rely heavily on the incredible support of the ORA DX team to advance information sharing that is paramount to collaborative success! We look forward to working in tandem with the ORA DX program to support more activities and partners through the incredible tools created by the team.

The PFP IT WG would like to thank Tim for his support of the ORA DX program and the partnership. We look forward to continued collaboration with Tim and expanding the ORA DX program. Contact us at appsdesk@fda.hhs.gov if you have any questions or would like additional information.