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

## Coffee Talk with Barbara Cassens

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**&**
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The Partnership for Food Protection Information Technology Workgroup (PFP IT WG) recently caught up with Barbara Cassens 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, Barbara! Tell us about your role as director of Office of Partnerships (OP)at FDA.**

Of course! OP is currently located in the Office of Regulatory Affairs (ORA) under the Office of Partnerships and Policy (OPP). I direct and oversee the investments in state, local, territorial, and tribal (SLTT) partners and partner associations that cover foods and medical products. This includes a budget of around $115M to support federal-state initiatives, but it is not just about money. It is supporting and promoting the activities of the regulatory program standards, training, cooperative programs, information sharing and disclosure, laboratory and medical products initiatives and rapid response teams. There are also our coordination efforts with international and federal partners with all FDA offices, and efforts to measure and visualize integration through a series of interactive dashboards. In addition, it involves promoting and advancing Domestic Mutual Reliance (DMR) activities that will get us to One Integrated Workforce under an Integrated Public Health Safety System. I do this successfully through the work of a very talented, forward-leaning, amazing staff in OP. Most days I feel like a coach, mentor, cheerleader, advocate, and conductor all rolled into one person!

**What are some of the ORAs strategies and plans for achieving DMR, working collaboratively with other ORA offices, FDA centers, and external partners (SLTTs, regulatory/public health associations, and the PFP)?**

It really takes everyone – all of FDA, the SLTT and association partners – to make DMR a reality. OP promotes, encourages, and supports partnerships between the state and the field division offices, but it is the states and division offices that do the heavy lift. One of the purposes is sharing resources and mutual support to overall field operations and emergency response activities. A huge part of this is joint work planning and improving the establishment inventory. Each partnership is constructed to be unique to the state and FDA field office considering that each relationship is at a different place on the continuum. And, as I mentioned previously, as it all comes together, we will achieve One Integrated Workforce for the greater protection of public health. One of my goals is to achieve a partnership agreement with at least 25 state agencies and corresponding ORA field offices by 2025, present resources allowing. DMR builds on all the foundational elements, i.e., program standards, rapid response teams to reach a state where we work seamlessly together on public health protection. And DMR sells itself. Those state/FDA partners engaged at this close working level sell the idea to other offices.

**As a global partner that protects public health, what are some of the ways OP fosters funding opportunities to promote DMR?**

We are in ongoing conversations throughout the year with both SLTT agencies and ORA operations, troubleshooting where we can best provide resources to support current needs

and minimize the challenges. $115M in funding annually for federal-state initiatives may sound like a lot of money, but it does not cover all projects we would like to support to advance with an Integrated Public Health System. This dollar amount also supports cooperative agreements with our key associations. These associations perform work that multiplies the program's success and impact. Without leveraging the strengths of our partner associations, we would be limited in what can be accomplished.

**Share OPs vision and goals to improve regulatory data sharing via the PFP and the ORA DX, and how it aligns with the overall mission of the ORA.**

The PFP brings thought leaders together from SLTT and Federal agencies (not just FDA) to think about challenges in the foods arena, and how these challenges might be tackled. While PFP is not a policy setting body, a number of great best practices have been published from the efforts of our diverse work groups. These best practices can be found on the PFP website.

The ORA DX is one of those great projects. Two-way data exchange has been spoken of and envisioned by leadership for over a decade. However, thanks to the PFP IT WG, it is becoming a national reality. I imagine a time in the future where all inspection data, sample results, and the official inventory are readily exchanged between regulatory programs to facilitate immediate follow up and an effective work plan.

**How does OP continue to improve coordination, communication, and information sharing between FDA and SLTTs to ensure a coordinated response to foodborne illness outbreaks and other food safety emergencies?**

At the heart of OPs involvement are the three Rapid Response Teams (RRT) coordinators, holding national calls to discuss procedures and processes for improved response and coordination. They coordinate sharing of "hot wash outcomes," and after action reports so RRTs can learn and borrow best practices from one another. They also host an annual meeting of the RRTs, under an agenda developed by its members, to further share information and improve communication so we all are more effective during an outbreak event. The PFP Response WG complements their efforts through writing national best practices.

**Looking ahead to the next 3-5 years, what are the key priorities for OP in advancing food safety to better facilitate the sharing of critical food safety information among all relevant stakeholders, particularly for the ORA DX?**

- IT systems' compatibility and individual agency's concerns on protecting the data
- Information sharing within the legal framework of federal and SLTT partners
- Enhancing the user interfaces
- Promoting the value of the ORA DX through tangible examples

- Exploring if there is a place for industry or consumers to tap into the data, perhaps on a summary platform

These are just a few priorities, but I am confident the PFP IT WG can handle this!

**What is your vision for the future of data sharing? Do you foresee the ORA DX expanding to support the Field Management Directive (FMD)?**



I do. We need to fully address many operational issues as mentioned above, but I do look toward a time when it is second nature to use the ORA DX.

**What is your advice for regulatory partners who are yet to participate in the ORA DX?**



Jump in – it will be worth your time and effort! Seriously, the ORA DX will become more useful as agencies utilize the platform.

**Finally, is there something fun and interesting about yourself you would like to share? (Hobbies, interests, vacations, etc.)**



Well, regarding vacations, I had planned to go to Turkey in 2020 but COVID had other plans. Right now, I think I will wait until retirement to take any major trips. I love making jewelry and watch repair; I consider myself an armchair archaeologist and enjoy experiencing new cultures. I am also a thrift store surfer – always looking for a great find. Going to thrift and second-hand stores is urban exploring to me. It taps into my creative side and gives me energy.

The PFP IT WG would like to thank Barbara for her support of the ORA DX program and her leadership. We look forward to Barbara's continued direction for expanding the ORA DX program. Contact us at appsdesk@fda.hhs.gov if you have any questions or would like additional information.