ORA Data Exchange (ORA DX)

Coffee Talk with Ellen Buchanan

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Interviewed by Barbara Thiel

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The Partnership for Food Protection (PFP) Information Technology Workgroup (IT WG) recently had the opportunity to catch-up with Ellen Buchanan, Director, Audit Staff, for *Coffee Talk* about the ORA DX.

Hello Ellen, tell us about yourself and your role and responsibility as Director of Audit Staff at OHAFO/AS. Could you briefly highlight the activities of the Audit Staff and their role at FDA?

The role of the Audit Staff originated in 2011 in the Office of Regional Operations (ORO), as part of the Regulatory Program Standards effort for Integration. Senior leaders at the time had a vision for a small certified team of auditors to work with external stakeholders to evaluate/verify/validate their food safety systems. Domestically we perform assessments with state regulatory programs enrolled in food, animal feed and egg program standards. Internationally we work with Center for Food Safety and Applied Nutrition (CFSAN) International Affairs Staff (IAS) on System Recognition with Foreign Governments. We co-chair the Food Safety Modernization Act (FSMA) Third Party Program with our friends in CFSAN, evaluating Accreditation Bodies and Certification

Bodies doing third party assessments of foreign food manufacturing firms. I was lucky enough to be hired as the Audit Staff Director in 2013. Our team of American Society for Quality (ASQ) certified auditors evaluate regulatory foundations, training, inspection protocols, quality assurance programs, emergency response capability, compliance and enforcement, outreach, resource needs and lab capabilities for our external stakeholders in each of the domestic and foreign programs we participate.

Are the audits event driven or are they set up in advance with a schedule or a combination?

The domestic Regulatory Program Standards have a requirement for any enrolled state programs to sit for an audit every two years. System Recognition has a five-year audit cycle and the Third Party Program provides various audit cycles, depending on how their programs are structured. Each of the external stakeholder programs have an audit component, providing FDA with understanding and confidence in work performed by the programs. This allows FDA to assign our own resources based on risk in areas not covered by these external stakeholder programs.

You are a longtime member of the PFP IT WG, over the years, are there any moments that you think were key to the success of the IT WG and the DX program?

I was one of the founding workgroup members of the PFP IT WG. FDA's Caleb Michaud and Drew Polulak (formerly) of Pennsylvania Department of Agriculture were the first co-chairs. Over the past few years, I have delegated this important work to my team members, Clinton Priestley and Matt Colson for scheduling availability and their interest and knowledge of the IT systems, both at the state and with FDA.

I think the commitment from the very beginning of PFP to recognize the importance of IT and to form the PFP IT WG was wise. From the beginning, the PFP IT WG was involved in the USAFoodSafety System which was built with cooperative agreement funding from FDA. Their commitment and vision from the very beginning on the details of the data elements collected by FDA and states was an indicator of the variety of systems states use and how we were going to work toward exchanging two-way data in real time.

There was a quick realization this effort would require a long-term commitment and would be achieved incrementally. To me, it was the commitment and the vision, and continual dedicated effort from FDA and the states in the PFP IT WG community. The PFP IT WG has been a stable group over time, with little turnover of work group members. That means that there is interest, people are curious, people are committed, and everybody involved should get a little bit of that credit because as you know, it is no easy task and complex.

I receive many notes from PFP IT WG members saying, please leave me on even though I cannot join the call, I listen to the recording and I read your meeting notes. I really do

think that a lot of people, even if they can't actively participate, are getting a lot of information. And for some, it is the sole source of information about what is going on. So we are trying to come up with a way to get members more active in our WG meetings. From your feedback, is there something PFP IT WG could be doing differently or better to get people to be more active again?

I am over the moon ecstatic that when you send notes out to state workgroup members they ask to be left on the invite because they read the meeting notes and listen to the recording. At the point when it is feasible for a state to onboard, they will have the knowledge and background needed to move forward. You never know which state is going to be at the moment of ready, so I'm glad they're engaged even if they can't attend the meetings or fully participate. Additionally, there are components in ORA who work closely with our state partners that might be able to provide assistance on when a state might be ready to fully engage with electronic transfer of data (DX). As you know, it takes money, resources, and commitment – which ebb and flow in state government, just like in ORA.

Yes, I completely agree and what pops into my mind is that we have worked with some states for several years, and recently they are energized and moving fast right now. It is very encouraging because often we would have meetings with them and they were planning on moving forward, then something would happen to prevent them from onboarding. We conduct monthly sample meetings with states and several are very active right now.

I think that's a great sign. Even if there are a few false starts, the state programs are interested and committed, as their long-term involvement indicates. Not unlike ORA, resources may get reallocated to an emergency and IT development funds are redirected to other public health protection work. I encourage you to keep engaging the states. As long as they are coming to the table to meet, this is a clear success! Having 200+ members in the PFP IT WG is an indicator of effort of the PFP team. So again, everybody's helping, committed, and believes in it. Slowly over time, we'll get there.

I agree. The feedback we often get with impeding the DX participation is often a resource issue (both budget and staff) so it crosses over into so many different areas and funding is a significant one.

The whole reason we are working for IT integration is to free up resources to focus on the public health work and eliminate the double data entry or manual effort/analysis. It's that push and pull for what you have resources to do today but also what is the investment in resources long term. It is not necessarily only funding, could be human resources, could be equipment. Resources can be a real constraint for IT development and improvement.

How has your participation in the PFP and ORA DX been a benefit to your role at FDA and more recently as the Audit Staff Director? How can the Audit Staff play a role in the future direction of the IT WG and the DX program?

As the Audit Staff Director, I take it very seriously my team is trained, skilled, and certified to make our assessments meaningful. Providing FDA confidence in states work, enabling exchange of both contract and non-contract inspections counted towards our work plan. We know states food safety systems and their daily work are designed for maximum public health protection. As the Audit Staff Director, I'm in a position to lead a competent staff to make those evaluations on behalf of FDA allowing ORA to allocate resources to other places of risk. So while it is a very small piece and it might not directly influence, there certainly is a degree of influence on overall integration with our external stakeholders as we work with state programs. Additionally, having our auditors directly working with states provides another feedback loop to ORA IT. Auditors can identify trends and IT needs across many programs, regions, or commodities.

If you could speak directly to the states, what would you want to tell them regarding the benefits or advantages of participating in the ORA DX program? What is the best way for us to communicate the benefits of ORA DX participation with the states?

First, I would give a big thank you to the states for the time, funding, interest, and effort. It is optional for states to participate and support our IT integration efforts, yet they willingly chose to do that for the benefit of public health protection. The benefit for both states and FDA is the same benefit we described when we stood up the PFP IT WG, it was for the seamless two-way transfer of data to improve public health protection. We eliminate duplication of data entry or transfer of hard copy paper files, reduce time in file review and share updates to firm inventories.

A current initiative, New Era - is about data driven decisions, quick access to the data is key for public health protection and an integrated food safety system, regardless the office you call home. Participation in the DX decreases time to the data used to inform decisions.

What is the best way we can get this message to the states? I think in the IT WG we are doing our best (meetings, newsletter, conferences, etc.), but if you were to say, what are the ways to best get this information to the states?

OISM is/has actively participated in getting messages to states. You manage the PFP IT WG meetings, you attend meetings where states participate and stand at the podium and provide updates, thoughts, and future state of IT/DX. You author newsletters which states read. I don't know if there is any better strategy for OISM to communicate about the DX with state partners. If states aren't actively engaged and you ask if they want to leave the group and their response is no, you're doing it right.

The engagement with Association of Food and Drug Officials (AFDO) is helpful. The states are hearing similar information from the PFP IT WG and through the initiative at AFDO with support from the ORA Office of Partnerships. I really think you are doing a great job in keeping the states engaged. It is a long-term commitment, not for the faint of heart.

Thinking back to the very early days with the PFP IT WG, there were a lot of unknowns, trying to figure out what direction to go in, what states to involve first, what capabilities to implement first, so over the years this has become more clear to the leadership.

Yes, and I think intuitively, people think this should have been done a long time ago. It seems so simple and basic, even though we know it's very complex. The business case that helps support the DX is the FSMA inspection frequency mandate and the realization is FDA does need to partner with states. We need to be able to accept all inspections that help FDA meet our workplan. NCI started out with five or six criteria which must be met before we accept non-contract inspections and that is proving to be a good model. There really is that commitment and a basis for a business case for the DX.

One of the things that I think has accelerated senior management getting onboard is the successes. The more successful the DX is, the more capabilities we roll out and the more states we have onboard. I think that it really does build upon itself.

You're right. Again, that goes back to the dedication and commitment of the PFP IT WG and everybody involved every day. This is what they do and they're doing it well, so more states are coming on.

What is your advice/guidance for states considering participating in the DX?

Encourage them to keep participating. Eventually the moment will present itself where full engagement is possible. If they're at the table, they'll be ready. Stay engaged.

We recently conducted an IT WG survey and learned that the states are very much interested to participate in the DX, but some of them are struggling with resources. Is there any advice from the leadership perspective that we could give so they can make the decision a little bit quicker?

Perhaps providing the states a one-page document that shows a visual timeline of ORA IT milestones. A state can study the timeline and determine when in the future the opportunity presents itself for engagement with the DX that makes sense for the state program. The decision to participate with the DX is most likely a long-term decision in a strategic plan. Provide them what you can about milestones in the future state.

Perhaps a one-page document on how the DX can help states – what's in it for them exactly. Why should they participate? We know why it is important from our perspective: we need to illustrate clearly how this is worthwhile for them as well. We ask our state partners to participate in many FDA programs, helping them understand how the DX would facilitate participation and decrease resource usage as a result of IT integration.

Do you have any insight to share about state participation in the ORA DX Non-Contracted Inspection (NCI) capability as OHAFO closely manages the NCI rollout to states?

The key is NCI gets to the heart of domestic mutual reliance, it's an example of the power of the collaboration and trust that goes both ways and it allows for reallocation of

resources based on risk. That's really what this all is about, so we're not doing double inspections at the same facility, we share compliance and enforcement, we can assist with recalls, and this gives all parties involved more information to help make the best public health decision in the moment. If there's a crisis or emergency, everybody wants as much information as there is available about a firm or an event. NCI really gets us there as we are not only limited to information that we get during contract inspections. NCI is a key win for the domestic mutual reliance effort and increased public health protection.

Looking ahead, is there any particular functionality you would like to see in the DX? What are some of the ways the DX could modernize and strengthen the FDA workforce to improve public health response?

New area of functionality to consider would be animal food or produce, any of the cooperative programs where data is key – both for trending and reviewing and standardizing. Let's ask the states what data they could benefit from in DX. Pie in the sky? NCI expansion in the System Recognition arena, talk about complexities to resolve 😊.

The key thing is getting more states involved. As far as functionality in the DX, I think it is exactly what it needed to be. That doesn't mean we won't change and improve. It means the functionality is where it needs to be for this moment in time.

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The PFP IT WG thanks Ellen Buchanan and her team for their support of the ORA Data Exchange (DX) program and the PFP. We look forward to continued collaboration with Ellen and the Audit Staff Team 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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