PFP IT WG NEWSLETTER

PARTNERSHIP FOR FOOD PROTECTION INFORMATION TECHNOLOGY WORKGROUP

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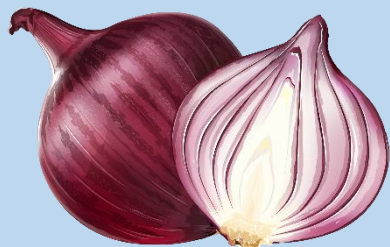
COFFEE TALK WITH
David Kamal

The FDA ORA DX team recently had the pleasure of catching up with our very own David Kamal, Lab IT Program Manager of the Office of Information Systems Management (OISM).

David oversees all the laboratory applications that fall under the Division of Enforcement Systems Solutions. Read about David's job and interesting perspective of the ORA DX program *on page 5*. The Coffee Talk article is also available on the *PFP website.*

FAREWELL LISA CREASON

For the last seven years Lisa Creason led the PFP IT WG and the ORA DX program through their ups and downs, all the while, Lisa empowered the team to achieve great success. We appreciate Lisa's support, guidance, and wealth of data exchange and cross system knowledge. The PFP IT WG extends a heartfelt goodbye. While we are sad that Lisa is leaving the FDA and the PFP IT WG, we wish her all the best in her future endeavors.

"Life is like an onion. You peel it off one layer at a time, and sometimes you weep." – Carl Sandburg

Spotlight on Don Burr

ORA DX Business Subject Matter Expert, Office of Regulatory Science (ORS), FDA

Don received his BS in Biology from the State University of New York at Stony Brook and his Ph.D. in Bacteriology from the University of Wisconsin-Madison (1983). Upon graduating from Wisconsin, Don spent seven years as a Naval Officer in the U.S. Navy's Infectious Disease Program, spending two years stationed in Jakarta, Indonesia. While in the Navy, Don worked on developing vaccines and rapid diagnostics for foodborne pathogens.

> Don is actively involved with FDA's food defense/counter terrorism activities as part of the Food Emergency Response Network (FERN).

In 1991, Don transferred from the Navy to the Public Health Service and began working in the Division of Virulence Assessment at FDA's Center for Food Safety and Nutrition (CFSAN) Mod-1 facility in Laurel, Maryland. While at Mod-1, Don's research activities involved developing animal models for studying the virulence determinants of many foodborne bacterial agents including *Campylobacter*, *Salmonella*, enterohemorrhagic *E. coli*, *Cryptosporidium*, *Vibrio* spp. and *Shigella.*

Since the anthrax attacks of 2001, Don was involved with FDA's food defense/counter terrorism activities as part of the Food Emergency Response Network (FERN). This involvement included developing methods, organizing training programs, coordinating national surveillance programs, facilitating the FERN Proficiency Testing Program, and serving as the FDA FERN Central Region Coordinator.

In 2013, Don transferred from CFSAN to FDA's Office of Regulatory Affairs (ORA) as a Health Scientist Officer in the Office of Regulatory Science. In 2014, Don retired at the rank of Captain and continued as a civilian employee. Don's duties center around the FDA's domestic mutual reliance initiatives supporting the development of a National Integrated Food and Feed Safety System which includes being a member of the Laboratory Flexible Funding Model (LFFM) work group and the PFP Laboratory Sciences work group. Don was a member of the group that drafted the FSMA Laboratory Accreditation for Analyses of Food final rule and is now involved in the implementation of the program.

Don served as the ORA/ORS Lead developing the ORA Data Exchange mutual reliance initiative allowing state and local laboratory analytical data to be reported directly into the FDA Field Compliance Tracking System (FACTS) supporting Mutual Reliance and the Integrated Food and Feed Safety System (IFFSS).

Don at Banff National Park in Alberta, Canada

Don riding a camel in Cairo, Egypt

Outside of FDA, Don enjoys spending family time together especially with the recent addition of his three granddaughters. He enjoys outdoor activities including hiking, biking, camping, and kayaking and is looking forward to continued travel both within the US and internationally.

What colleagues are saying about Don…

"With endless enthusiasm and a warm, radio voice, Don has been a constant source of positive energy, inspiration, and support for our endeavors in public health data exchange."

- Sin Urban, Ph.D., Chief of Environmental Science Division, Maryland Dept. of Health

"Don has been indispensable as a leader of FDA sample related initiatives. He also has a way of making our ORA DX sample data sharing meetings fun with his great sense of humor."

- Omari Fennell, ORA DX Outreach Coordinator, FDA ORA

"Don is our champion in advocating for the public health laboratories. Few highlights from his professional career: 23-year participation in the U.S. Public Health Service, which he retired from as a Captain in 2014, co-chair of the PFP's Laboratory Science workgroup, one of the designers of the FDA's FERN and LFFM cooperative agreement, and the recipient of APHL On the Front-Line Award. Don is a great person to talk to and interact with after a long meeting. Over the years, Don is no longer an FDA liaison but a dear friend to us."

- Maria Ishida, Director, NY Dept. of Agriculture and Markets Member of PFP Governing Council

"It is hard to imagine a civilization without onions." – Julia Child

What colleagues are saying about Don... (continued)

"I have worked with Don many years and the one thing that really stands out about Don is that he has that rare ability to make everyone and every team he works with better. He goes about in such a calm, steady way it often goes unnoticed!!!! You look back and are really amazed at what he has accomplished for the public health mission. No doubt that is what drives him."

- Dr. Paul E. Norris, DVM, MPA,
Director of Office of Regulatory Science, FDA ORA

"I've had the pleasure of working closely with Don on several projects over the past few years. By having him be part of a workgroup or team always guarantees an invaluable level of experience and dedication. He is a true advocate for our state partners and makes sure their needs and concerns are brought to the forefront."
- Erin Woodom-Coleman, PM, FDA ORA

"Don is one of the nicest most knowledgeable people I have had the pleasure to work with at FDA."

- Barbara Thiel, PFP IT WG PM,
FDA ORA DX

Don Burr Received the 2022 On the Front Line Award from the Association of Public Health Laboratories (APHL)

"Throughout the long-standing partnership between APHL and FDA, Don has always shown up with grace, humility, curiosity, and sincerity. The value of his expert guidance through myriad group discussions is eclipsed only by the generosity behind his smile. I appreciate all that he shared with me and my APHL colleagues over the years and wish him happiness in his future adventures."

- Shari Shea, APHL Food Safety Program
PFP Laboratory Science WG PM

"Don is the most cordial and super friendly person in ORS. I remember when CMS began to work with the team, Don did not want to make any changes without first meeting in person. Don's friendliness emanates in the projects and teams he works on, leading them to success."

- Angela Samuel, Enforcement Systems Branch Chief
Div. of System Solutions, FDA ORA

"I'm always impressed with Don's commitment to ensuring that state and local laboratory voices are heard in various national efforts, such as the LFFM cooperative agreement, ORA DX efforts, FERN, and more -- particularly in his role as a tireless leader of the PFP Lab Science Workgroup. We were so pleased that Don was awarded APHL's On the Front Line Award this year in recognition of all he's done to build partnerships between the states and FDA and advance efforts to build an Integrated Food Safety System."

- Robyn Randolph, MS, APHL

"Don was one of the very first people I worked with at FDA, and I am forever grateful for his mentorship. His dedication to the ideals of FDA/state integration and boundless kindness for his colleagues across the nation has always impressed and inspired me!"

- Lauren Yeung, Health Scientist, FDA ORA

"I consider Don Burr to be a mentor for me here in FDA. Don Burr's accomplishments are significant to the modernization efforts towards a National Integrated Food Safety System. His contributions in building the Food Emergency Response Network, implementing the Food Safety Modernization Act--Laboratory Accreditation for the Analyses of Foods Program, building the state partner laboratory data portal (ORA DX/NFSDX), building, and implementing historical Cooperative Agreement Programs and the new Laboratory Flexible Funding Model are milestones of his effort. Don's support of federal and state food safety initiatives through collaboration with national food safety organizations such as the Partnership for Food Protection, the Association of Public Health Laboratories, and Association of Food and Drug Officials are fundamental to achievements realized. He has been the epitome of a true "team player" both within the FDA and through partnerships. Don's sense of humor, keen memory, professional manner, and attention to detail facilitated progress along what can sometime seem a long road. Don is a true public servant, having dedicated his career to food safety by his service in the Public Health Service and as a career federal food safety professional."

- James (Mike) Farrow, Health Scientist, FDA ORS

"An onion can make people cry but there's never been a vegetable that can make people laugh." – Will Rogers

ORA DX Capabilities

INVENTORY
- Firm Search 🌐⚙️
- Firm History 🌐
- State to State Firm Search ⚙️
- Produce Safety Farm Inventory 🌐
- Firm Inventory Reconciliation 🌐

Inventory Data Sharing
Provides regulatory partners robust inventory related capabilities to search and view FDA's inventory, reconcile state's inventory against FDA's inventory, share inventory with other regulatory partners and exchange Produce Safety Farm Inventory with FDA.

INSPECTION
- Contracted Inspection/Attachments ⚙️
- BSE Checklist and Seafood Inspection ⚙️
- Non-Contracted Inspection 🌐⚙️

Inspection Data Sharing
Regulatory partners can submit Contracted Inspection results including attachments and Non-Contracted Inspection results to FDA, thereby reducing double data entry.

SAMPLE
- Sample Receipt and Analysis 🌐⚙️
- Sample Collection (State collected sample only) 🌐⚙️

Sample Data Sharing
Provides regulatory partners flexible options for submitting sample collection, analysis and receipt data leading to improved information sharing for faster compliance decisions by FDA.

Legend: ⚙️ System to System (aka NFSDX) 🌐 ORA Partners Portal (ORAPP)

ORA DX Regulatory Partner Participation

States Participating in ORA DX
49 TOTAL

Last modified: 8/29/22

- 47 states participating in PFP IT WG or Sample WG
- 66 partner agencies participating in ORAPP
- 26 partner agencies participating in System-to-System or Enhanced DX Client
- In certain cases, there is more than 1 partner/agency per state
- Some partners are in the process of onboarding
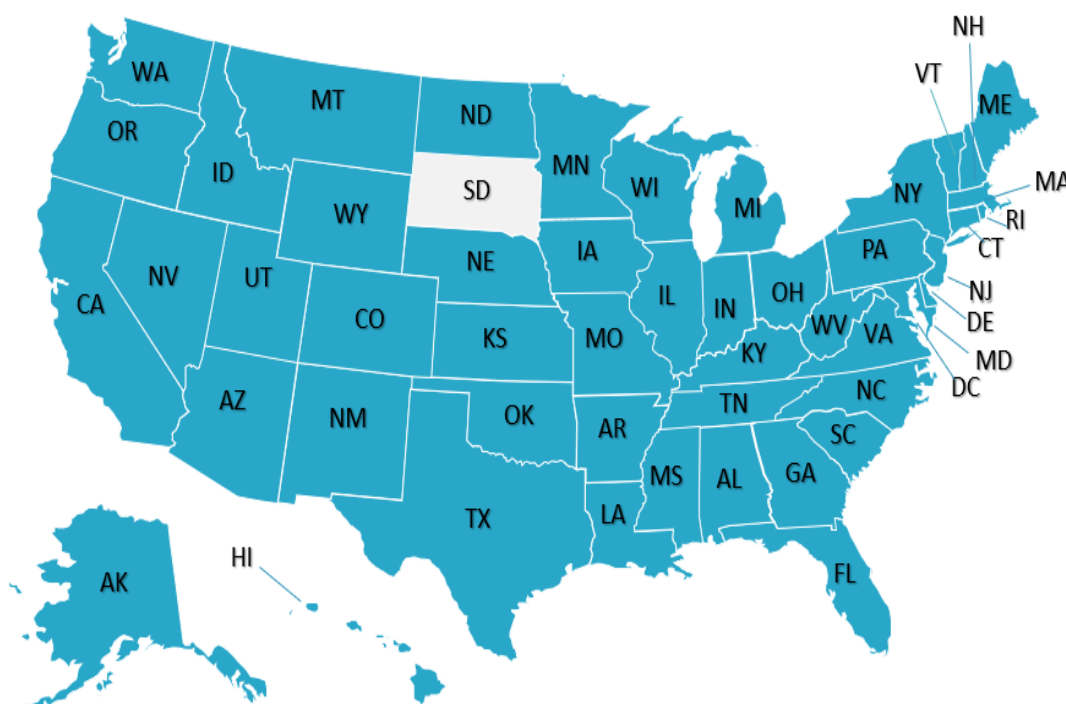
"Mine eyes smell onions: I shall weep anon." – William Shakespeare

Coffee Talk with David Kamal

LAB IT PROGRAM MANAGER

OFFICE OF INFORMATION SYSTEMS MANAGEMENT (OISM)

Hello David! Tell us about yourself, your job role, and your involvement with the ORA DX Program.

I am the Lab IT Program Manager, and my role involves providing high-level oversight, establishing requirements, and defining the roadmap for all lab IT activities. I am the co-lead for program management of the sample domain within ORA DX for state labs' submissions. I also manage emerging lab systems and legacy lab modules. My background with legacy IT systems helps me to ensure the continued collaboration with the ORA DX program. My goal is to share guidance and build a feasible solution for the FDA labs and state labs.

How does FDA collaborate with state labs to determine sample data sharing enhancements for future ORA DX releases or to streamline sample data submission?

FDA actively engages state labs to review planned data sharing features or capabilities, as well as solicit feedback regarding ORA DX enhancements prioritization. Upon approval, the features become part of the upcoming sample data sharing enhancements.

The future vision of the ORA DX program is to increase FDA collaboration with states. This will support active bidirectional activities and listening sessions for increased state input into the ORA DX roadmap including user support, priorities, and potentially reducing the complexity and number of required data elements for sample submissions.

Please share your insight about the ORA DX onboarding experience with the state lab(s) from the ORA DX systems perspective.

The state labs establish and lead their own ORA DX onboarding timeline. The ORA DX teams support the state labs during the onboarding process. Once complete, labs can practice submitting real-world data in the ORA DX Pre-Production environment. ORA's Office of Regulatory Science (ORS) reviews the submissions, provides feedback regarding the data quality, and shares any additional tips and tricks for data entry before allowing the state labs to submit data in the ORA DX Production environment.

How can state lab(s) improve their ORA DX onboarding experience?

Most of the state labs work closely with their Laboratory Information Management System (LIMS) contractor to review the "Sample Integration Guide" and perform data mapping exercises for ORA DX onboarding. Having both the laboratory expertise and IT skills ensures a smooth onboarding experience. I share the following tips for the labs:

- **Network** with other state labs as many have the same LIMS software and/or LIMS vendors
- **Pool knowledge** to collectively work through the onboarding process
- **Participate** in Sample Data Sharing - IT Implementation and the PFP IT Workgroup meeting series
- **Volunteer** in User Acceptance Testing (UAT) for an upcoming ORA DX release to preview the release and practice their DX skills

The PFP IT WG thanks David Kamal for his support of the ORA DX program and the PFP. For more on David's insight and ways state lab(s) can improve their ORA DX onboarding experience, continue reading the rest of the conversation, *here!*

Welcome Mark Siegal

The PFP IT WG welcomes Mark Siegal as our new Co-Chair, joining our Co-Chairs Phillip Fruechting and Jacob Fleig to guide us into the next chapter of data sharing achievements. Mark has 16 years of experience across federal IT systems and website redesign and management initiatives. Mark has been the Program Manager of the ORA DX program and a member of the PFP IT WG for two years. He brings knowledge and strengths that will be an excellent addition to the PFP IT WG leadership. Welcome aboard, Mark!

"It doesn't matter how precisely the onion is cut as long as the person chewing is happy." – Padma Lakshmi

September is National Food Safety Education Month!

CLEAN   SEPARATE   COOK   CHILL

Source: (Administration, 2022)

Resources and Useful Information

- **PFP Website** and **Twitter**
- **PFP IT WG Page**
- **ORA Partners Portal Homepage**
- **ORA DX FAQs**
- **AFDO Newsletters**
- **Presentations at MFRPA Conferences**
- **Contact Us at AppsDesk@fda.hhs.gov**
- **PFP Strategic Plan**

This month take an active role in preventing foodborne illness, also known as "food poisoning." The Federal government estimates that there are about 48 million cases of foodborne illness annually – that's about 1 in 6 Americans each year. Each year, these illnesses result in an estimated 128,000 hospitalizations and 3,000 deaths. Following simple food safety tips can help lower your chance of getting sick.

- Social Media Toolkit - Help us spread the word about food safety
- Education Resources - Learn how to lower your chance of getting sick
- New Era of Smarter Food Safety - Explore FDA's new approach to food safety

To learn more about ways you can help spread the word about the importance of food safety *read more*!

Information Corner

Contact us at APPSDesk@fda.hhs.gov

ORA DX e-Learning Courses are Here!

The PFP IT WG is excited to announce the arrival of ORA DX e-Learning! Training is now available on the new ORA Partners Portal (ORAPP) Training page! After successfully logging in to ORAPP, access the e-Learning tab of the Training page to view the following courses:

- ORA DX Program Overview (10 minutes)
- ORA DX Onboarding (6 minutes)
- ORA Partners Portal (ORAPP) Overview (6 minutes)
- ORA DX Firm Search and Firm History (10 minutes)
- ORA DX Non-Contracted Inspection (NCI) Overview (10 minutes)
- ORA DX Non-Contracted Inspection (NCI) Submission (10 minutes)
- ORA DX Non-Contracted Inspection (NCI) Errors, Correction, and Resubmission (8 minutes)

e-Learning courses for the various ORA DX capabilities are in development and will be available soon! Check out the ORAPP Training page regularly to view the latest e-Learning courses and upcoming instructor-led courses.

To register for upcoming courses, or to find out more information on ORA DX   e-Learning, please contact us at APPSdesk@fda.hhs.gov.

"It doesn't matter how precisely the onion is cut as long as the person chewing is happy." – Padma Lakshmi