International Association for Food Protection®

Digitalizing Environment Monitoring Programs to Unlock Their True Value in Ensuring Safe Quality Products

IAFP, 26th May 2021

Moderator: Vidya Ananth, Novolyze, United States

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Introduction of Panelists





Vidya Ananth -- Moderator (Novolyze)
Mike Liewen -- Consultant and Advisor
Mark Moorman -- FDA
Derrick Bautista -- Del Monte Foods
Joe Holt -- OSI Group


Vidya Ananth, Novolyze, United States

Novolyze, United States

Vidya Ananth is a VP of Food Safety & Quality, Application Support and Customer Success at Novolyze. She received her MS in Food Microbiology from Iowa State University and has been in the food industry for over 25 years and has made significant contributions in the areas of food safety, quality and regulatory affairs with a main goal to bend the curve of food borne illness globally. Vidya has held various Food Safety and Quality positions through her journey in the food industry and a few companies to name would be General Mills, The National Food Lab, Safeway, Clorox, Before Brands, Kohana Coffee and now Novolyze. Vidya has helped small and large companies build effective food safety and quality systems using risk-based prevention strategies and has helped build the food safety culture within these organizations. She has collaborated with trade organizations (IAFP, FIMRT, CSPA, PCPC, GMA, ADS) and FDA and USDA, universities and has hosted conferences and chaired many sessions, published patents, papers and a compendium chapter.
An interesting note is that Vidya can converse in 6 languages and engages in humanitarian work during her spare time.

Mike Liewen

Advisor and consultant, United States

Mike is an advisor and consultant to the food industry and allied disciplines with global expertise in food safety, quality assurance, regulatory affairs and organizational design. Over his 35 year career Mike has acquired extensive experience across the food industry supply chain with experience in food manufacturing and distribution, food service, restaurants, and retail and general merchandise sectors. He is an Advisory Board Member for several companies and non-profit organizations.
Mike holds a Ph.D. degree in Food Science with a concentration in Food Microbiology from the University of Wisconsin and is a Certified Quality Engineer from the American Society of Quality.


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Mark Moorman

FDA, United States

Mark Moorman is the Director of the Office of Food Safety at the Food and Drug Administration where he leads a team of professionals focused on improving the safety of our food supply. Prior to joining the FDA, Mark was the Senior Director of Global Scientific & Regulatory Affairs for the Kellogg Company in Battle Creek, MI with responsibilities for emerging food safety and nutrition technical and regulatory issues. Prior to joining the Kellogg Company in 1998, Mark spent 10 years with Silliker Laboratories as the Technical Director of Microbiology. Mark has his undergraduate and Ph.D. degrees from Michigan State University in Microbiology and Food Science.

Derrick Buatista

Del Monte Foods, USA

Derrick received his Masters of Science and Doctorate in Food Microbiology from the University of Guelph. He is currently working at Del Monte Foods, Inc. as a Director – Quality Assurance. He manages several International and Domestic CoManufacturing facilities ensuring compliance standards of both Federal, State and Del Monte Foods requirements. He also serves as a Food Microbiology Subject Matter expert for the company and provides consultation on spoilage investigation, sanitation, process validation, and food safety strategy. Dr. Bautista has also extensive knowledge of the pet food industry where he has implemented a Salmonella Environmental control program with technologies adopted from digitization and the laboratory service network to monitor and mitigate potential foodborne risks. He is a member of several professional organizations, has published articles in peer-reviewed journals and a collaborator of several patents.

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Joe Holt
OSI, United States

Joe received his Bachelor of Science in Food Science and Technology from University of Georgia. Currently he is leading North American food safety operations at OSI Group as Vice President of Food Safety & Quality. He is a member of the OSI global food safety council. Previous roles included global food safety operations for Keystone Foods with special focus in the Asia/Pacific region, Director of Quality, Food Safety & Organic Integrity at Earthbound Farm, and various food safety and operational roles at Gold Kist, a large integrated poultry cooperative.

Joe has extensive experience in the animal and plant protein, fresh cut produce, juice and milling industries.

Over several years, Joe has led digitalization projects impacting continuous improvement efforts in food safety including automating environmental monitoring programs.

Food Safety and Quality meets Digital Transformation

Environmental Monitoring History and Transformation to Digital Programs

Mike Liewen

May 2021

Environmental Monitoring

History

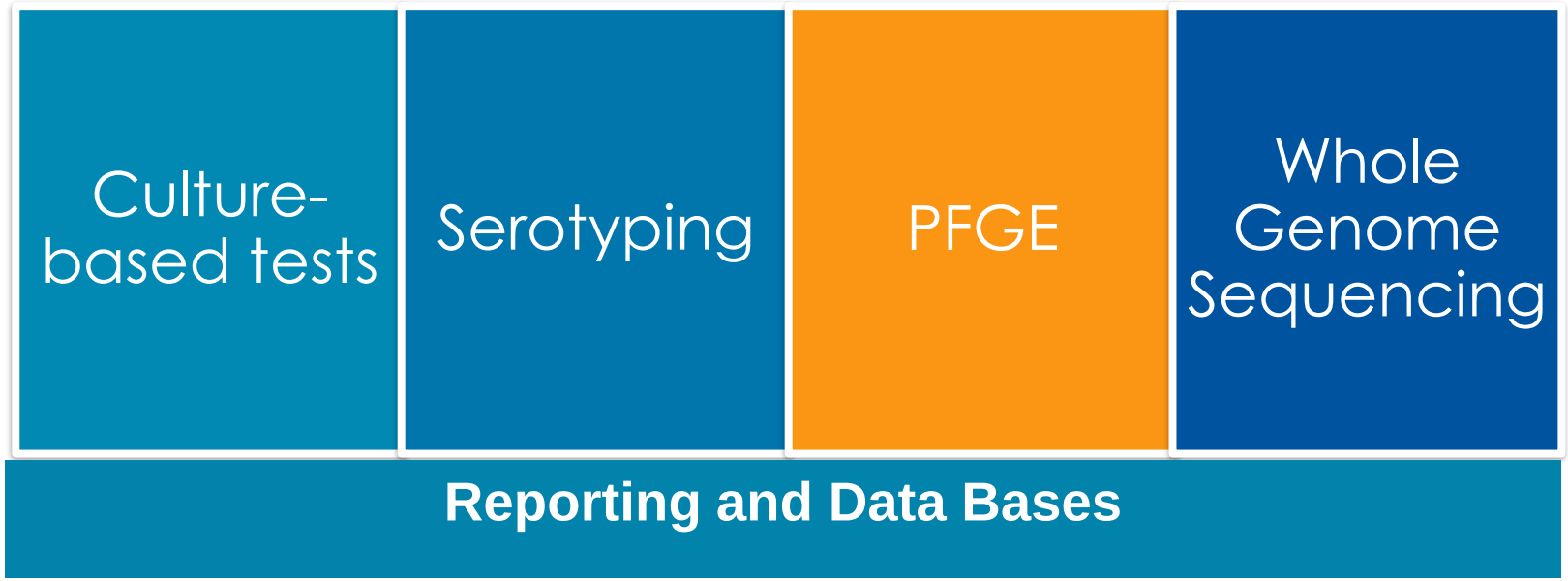
What Drove Environmental Monitoring?

Predictvie Analytics - *what features should a good digital environmental monitoring program have?*

Environmental Monitoring - Technology History

Developments in microbiology in combination with more demanding compliance standards have influenced environmental monitoring

Quantum Leaps in EM



Drivers of Environmental Monitoring

- Listeria Outbreaks in Dairy
- Salmonella Outbreaks in Cereal and other RTE Products
- Peanut Butter
- Leafy Greens
- FSMA
- Digitization

Effective Digital Programs for Environmental Monitoring

Effective record keeping & reporting

Corrective action and verification

Connecting data to drive improvement

Food safety data

Predicitve models

Insights & actions

Individual vs Population

Virtual Reality and Gaming

GMP education

Sampling

Mark Moorman, Ph.D.
Director Office of Food Safety

US Food and Drug Administration

FDA FOOD SAFETY MODERNIZATION ACT

Tech-enabled Traceability and Outbreak Response

Smarter Tools and Approaches for Prevention

Welcome to FDA's New Era of Smarter Food Safety

New Business Models and Retail Modernization

Food Safety Culture

Del Monte Foods, Inc.

Nourishing Families. Enriching Lives. Every Day.®

Del Monte's Journey to Digitizing EM programs

May 26th, 2021

Derrick Bautista

Director Quality Assurance

What were the reasons to implement EM Program?

- There was a need
  - Pet Food days
    - A big concern about Salmonella in the environment;
    - let's find it first before FDA
  - Foods for People
    - There is a BRC requirement for Environmental monitoring program
      - **BRC Global Standard for Food Safety: Issue 8**

4.11.8	Environmental monitoring
SOI	Risk-based environmental monitoring programmes shall be in place for pathogens or spoilage organisms. At a minimum, these shall include all production areas with open and ready-to-eat products.

    - This includes canned Food facilities

Why did we want to Digitize?

- Manual coordination and consolidation is a PAIN !!
  - Each facility wanted to have their own identifiers of sites
    - Had to develop a coding system
  - Assembling results and trending by spreadsheet is laborious
    - For Pet Food, it took 1.5 days to organize the data and consolidate data
    - This included trending the information by plant (i.e., weekly) and summary report to upper management
  - Manual identifiers was prone to errors
    - Problematic when logging samples to Sample Analysis Request forms (SARFs)
    - Extend time for consolidating and organizing data
  - CAPA generation and follow ups were unreliable

How did Digitizing help the EM Program?

- EM programs standardize codification of samples
  - Significantly reduces entry errors
    - Some will generate labels for sample collection
- Automated Sample Analysis Request Form generation
  - Reduces time by plant personnel to fill forms
  - Forms are directly sent to lab for processing
    - Automated population into LIMS (Lab information management system); no manual entry
- Results are entered back to digitized software automatically
  - Graphs are generated; simplifies trending
  - Maps are often included to locate problematic area(s)
- Automated CAPA event generation
  - Forms can be automatically generated/assigned for Root Cause/Corrective action
  - Requires sign-off when complete

Journey with CoMans for Digitizing EM Programs

- We are still assessing the situation
  - If they have EMP system is place and can successfully manage, they sometimes do not see a benefit of automating the EMP especially if it is a smaller facility
- Biggest hurdle is cost
  - If we “strongly” suggest, it will come down to who will pay for it
    - Given the previous bullet point, CoMans will push back and Del Monte would likely absorb the costing
- Gaining alignment
  - It is easier if there is GFSI process on establishing EM Program or regulatory requirement
  - If not, the mentality is to minimize it as much as possible
    - Most difficult with commercially sterile products

Lessons Learned on the Road to Digitalization

Environmental Monitoring Programs

Smarter Tools and Approaches for Prevention

May 2021

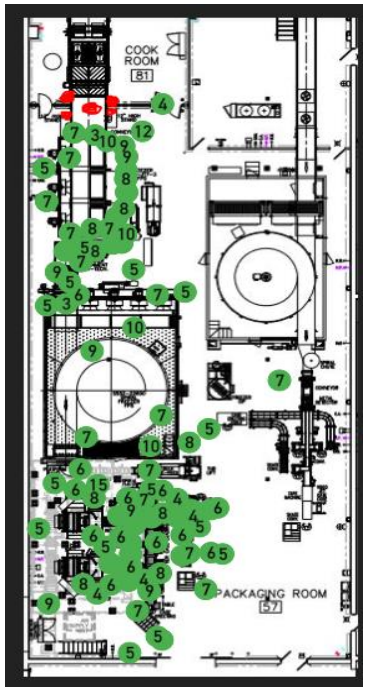
OSI Group, LLC.
World Headquarters | Aurora, Illinois, USA
630.851.6600 | www.osigroup.com

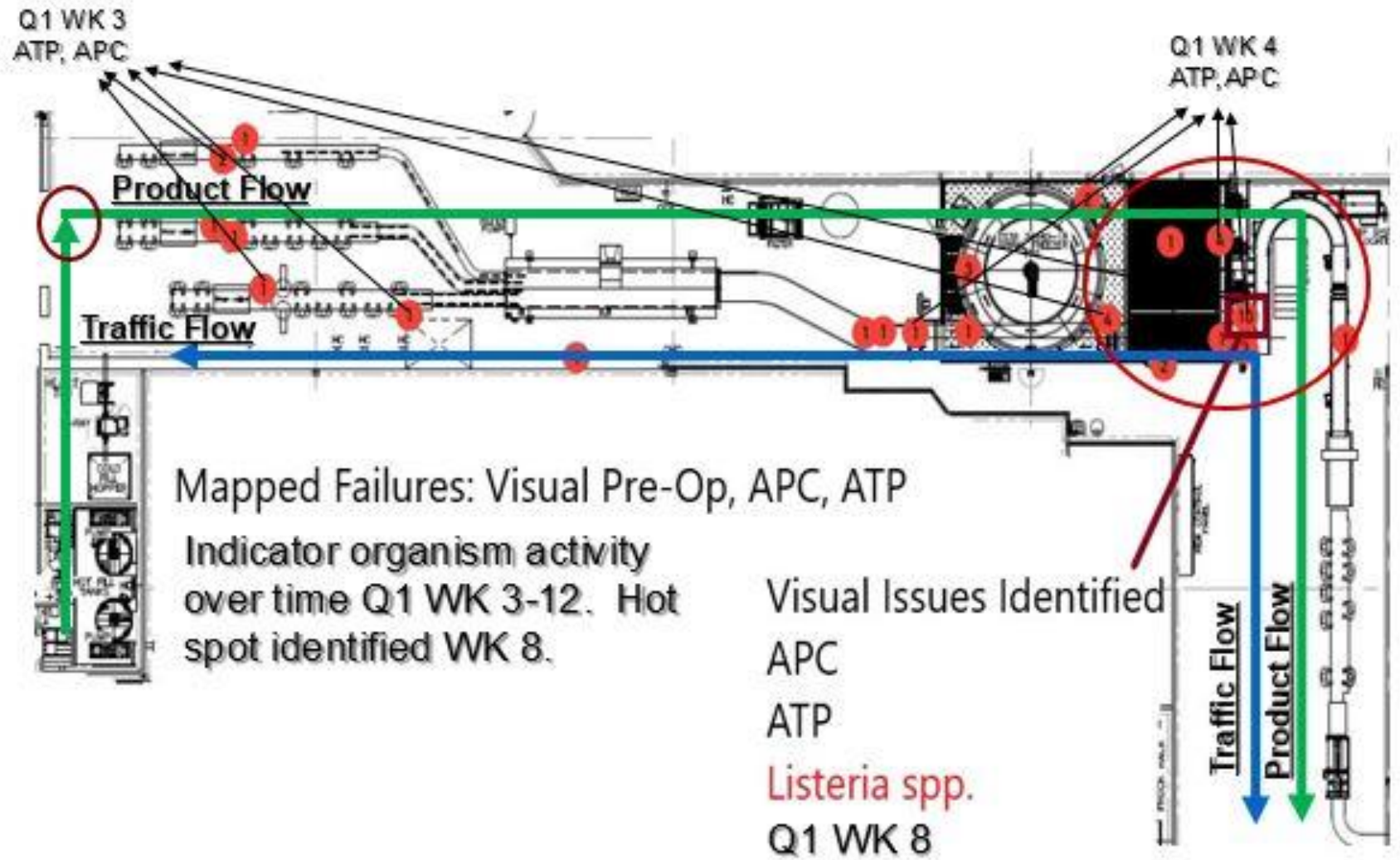
OSI Digital Journey

- **Why Go Digital? Harmonize sanitation standards across our global network**
  - **Elevate standards – Seek & Destroy**
  - **Capacity building & improve performance**
  - **Adopted zero tolerance for *listeria* in any product globally regardless of country requirements**
- **Visualize anything that can be evaluated in space and time**
  - **Visual inspections**
  - **Swabs: microbiological/A.T.P/ Allergen**
  - **Foreign Bodies**
- **(We've been working on it for a while)**

Benefits of a Digitalized Environmental Monitoring Program

- See things in context
- Identify trends
- Assess cleaning frequencies
- See effects of traffic flow
- Improve collaboration between departments





OSI Digital Journey – Lessons Learned

- **Data Governance Process**
  - One Facility, or Many
  - Harmonize Terminology – Important for Reporting & Prevents Drift
- **IT Considerations**
- **Laboratory Partner Considerations**

OSI Digital Journey – Lessons Learned

Goals	Challenges	Lessons Learned	Results
Establish a data-driven approach that compliments global sanitation strategies and drive continuous improvement	Linking all sources of information visual inspections, lab data, ATP Swabs, product and traffic flow into a single visual tool	**Spend time understanding current data flow. Don't try to everything at once. Prioritize a line, process room, or data type.**	**Digitized EMP Monitoring Globally** Visibility to all facilities – Benchmarking across global zones **Verifies effectiveness of our preventive programs**
Improve collaboration using digital visual tools	Harmonizing data. Variations in EMP program terminology, naming conventions and slight variations in data entry can confuse reporting.	**Adopt System Governance: create clear definitions for test types, zones, etc. I.e. "RTE" v/s "Fully Cooked" or "Zone 1 v/s Zone One"** **Have a process for allowable variations (fewer, better ones). Think about how you want reports to look. If planning to digitize multiple plants, gather requirements for every facility and harmonize between plants where possible.**	**Supplies metrics for impact of food safety cultural development** **Digital platform serves to determine effectiveness of related programs: cleaning frequencies, traffic control, preventive maintenance as the impacts can be seen visually and trends can be quickly identified & preventive actions before a critical incident occurs.**

OSI Digital Journey – Lessons Learned

Goals	Challenges	Lessons Learned	Results
Reduce manual entry of test results and bridge islands of data.	Automated scheduled sampling plans can become messy.	Audit the data flow frequently. Deal with exceptions (missing lab results, skipped sample plans. Don't let them build up. Seek root causes for problems.	Regular quality control on the data prevents confusion and clutter.
	Data exchange with Labs – LIMS, particularly multiple lab providers	Collaborate with third-party lab IT team and the EMP software developer on a file format specification.	Smoother data exchange with fewer exceptions.
	Hardware and internet bandwidth challenges	Need IT Involvement throughout the process	
	Overcoming drift back to 'the old way'	Collect feedback and suggested improvements within the first 3 months of implementation to ensure best use of the system.	Even slow adopters catch up when they have a few successes.
	Ongoing Training	Share best practices and tips and tricks regularly. Utilize any vendor-provided training, but consider creating task specific training sessions. Break training into 5-minutes "how-to" videos with subtitles for guidance and refresher training	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