A Frost & Sullivan Virtual Think Tank

Transformation Strategies for Achieving the Environmental and Food Safety Testing Laboratories of the Future

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Why Testing? Why now?

The COVID-19 pandemic fortified the need for food and environmental testing laboratories (labs) to stay ahead of sudden changes in their businesses and those of their customers and operations suppliers. Like most businesses, labs are under tremendous pressure to cut costs and delivery times of their analyses and results, while ensuring compliance with regional regulations. The role that new technology and automation can play in foreseeing these business shifts and achieving cost and time improvements is the main discourse between food- and environmental-testing-lab industry leaders and a leading analytical solution supplier, panelists at a recent webinar moderated by Frost & Sullivan.

Pre-pandemic, the global analytical instrumentation and services market was driven by several automation factors, including:

- A higher demand for digital connected products and services with the advent of the Internet of Things (IoT)
- A greater need for fast and reliable operations and the need to de-skill the analytical testing lab field as a whole to address staff shortages
- The need for software to be product-focused and evolve into workflow and lab management
- An emerging need for software that will help integrate devices from multiple vendors with cloud and data analytical capabilities

The cost of upgrading to new products and software continues to be a key challenge for accessing new capabilities. Customer concerns about digital solutions, data breaches, and cybersecurity have held back the adoption of these solutions.

Since the start of the pandemic, lab services vendors and their customers have been compelled to change their workflow processes to remote modes, such as the sharing of test results. These growth drivers are hastened by the need for additional testing to assess and understand the pathogen presence of COVID-19, and further support public health and safety measures.

The interest in and demand for safe food and water sources show no signs of diminishing. This increase in safety testing for known and emerging contaminants of concern, combined with globalization, is a trend that is driving an exponential increase in demand for food and environmental testing services. The quality of all products available, and public health and safety concerns, will drive the need for testing like never before. Increased global demand leads to a need for increased production, often in shorter time frames. While most supply-chain stakeholders are up for the challenge, the pressure to meet these challenges inevitably leads to a need for better product and sample testing that meets all required regulations and certifications.

Long before COVID-19, testing soil or groundwater for hazardous substances was important. The pandemic has enhanced the need for better testing and certification as a matter of public health and safety. Food testing labs have been in the forefront of testing for food authenticity, pathogens, meat speciation, pesticide residue, allergens, and mycotoxins for years, but several global trends, including an accelerated change in lifestyles brought about by the pandemic, a rise in food-borne illnesses, and the emergence of new and unidentified micro-organisms, have increased the need and importance of providing high quality and accurate food testing services from labs that specialize in these services.

Public health and safety are paramount for both governments and private entities, and environmental testing labs provide such critical services as genetic, chemical, radiological, and microbiological analyses. These services will continue to ensure compliance with safety standards and regulations set by governments and related bodies across the globe.

Newer and stricter detection limits and, in the case of food analytical testing, lower detection requirements are always on the horizon, and the list of new and emerging environmental contaminants continues to grow.

> The panel of thought leaders at a recent webinar included Kirstin Daigle, corporate quality director at Pace Analytical; Amy Jo (AJ) McCardell, president of Certified Laboratories; August Specht, vice president (VP) of research and development (R&D) for the Chromatography and Mass Spectrometry Division at Thermo Fisher Scientific; and moderated by Kiran Unni, VP of industrial technologies practice at Frost & Sullivan.

How Can the Testing Lab of the Future be Reached?

When asked what was most important to their customers, an overwhelming majority (over 60%) of the webinar audience said that speed to achieve results takes precedence over the quality of research, followed by the cost of achieving those results. Unsurprisingly, the poll results are clear that achieving speedier results is directly correlated to the level of automation in these labs, from the preparation of the sample to the final reports. In this context, advanced data analysis, and the

use of software that can produce reports more quickly and accurately and enable a rapid review of flags for samples of concern, become paramount to testing-lab capabilities.

Our personal lives are becoming increasingly automated with new technologies such as artificial intelligence (AI), machine learning (ML), and the IoT. With tighter and stricter regulations, testing labs are forced to adapt and adopt new automating technologies and processes. Lab information management systems (LIMS) have enabled testing labs to automate their workflows during sample processing, preparation, and testing for several years. However, until recently, implementing LIMS could have remained analog and on paper and still provided a high level of efficiency. Small steps into automation and digitalization of labs began with the incorporation of radio-frequency identification (RFID) tags to tag and track samples through their lab journey. Arguments that only expert human perception can determine whether a step is successful during sample preparation are slowly being debunked with the advent of optical technologies and cameras—visual cues that can be analyzed through the use of algorithms and ML techniques.

> **Lab mangers were often plagued by valid challenges brought by the automation of their labs, including high upfront costs, training their staff, re-arranging and renovating their labs, and ensuring that legacy hardware was compatible with new equipment and software.**

No business entity would entertain added costs and new challenges without a real assessment of the return on investment (ROI) and a clear path to preventing the transfer of these costs to their customers.

The debate that the benefits of adding automation techniques to labs far outweigh the challenges they pose was corroborated by all panel members. August Specht from Thermo Fisher, an analytical instrument hardware and software supplier, was clear that, “there’s an ever-increasing demand to stay ahead of emerging contaminants. And the industry can rely largely on, for example, increasingly sensitive and easier-to-use triple quad mass spectrometry and Orbitrap high-resolution accurate mass spectrometry to streamline testing on the hardware side, and corresponding analysis solutions that integrate algorithms, cloud spectral libraries, and more to enable smarter, intelligence-driven lab workflows from an automation and Industry 4.0 adoption perspective. I see our customers increasingly focused on 4 major trends. First, the increased automation of workflows through robotics—automated algorithms that can connect to the instruments remotely. Second is the increase in onboard diagnostics to predict events before they happen and offer guided assistance to users. Third is the ability to better connect data and people in a global environment, and, lastly, the need to train and communicate with employees and customers remotely.”

All these trends are valid in the food- and environmental-testing-labs space. Globalization, changing lifestyles, and the massive supply chain of products and ingredients make it imperative to ensure food safety through rigorous quality control and adherence to regulations. The fact that food supply chains are truly global today makes it important for food testing labs to adhere to both local and international governing rules. Assessing contaminants, known and unknown, is equally important as the need for accurate labeling for nutritional and regulatory purposes increases. Stricter regulations are also leading to the lowering of detection limits.

AJ McCardell from Certified Laboratories, a leading food and cosmetics testing lab, made a good point about what food safety means when the real question to pose is—what is food? She questioned that routine contamination analysis for salmonella and e-coli is augmented by analytical nutritional analysis to better understand what is in the food, and also provide clear and accurate labeling as required by regulatory bodies and the end consumer. She stated, "So, the standard strategies have been to have control of the microbial content or the shelf-life of a product. Now, people want to know and change their food. They want to reduce the salt. They want to reduce the fat. They want to reduce the dependence upon preservatives. And, so, alternative materials are now being used as well as fortification. So, when you look at the traditional ways that people would fortify products or the food industry would fortify products, they're now really going out there and looking at other sources, such as botanical materials. So, what that means is when you're testing these different types of ingredients, it creates new challenges in terms of the potential contaminants, like the heavy metals, the pesticides, those sorts of things. So, I am expecting an increased demand for analytical services and data analysis and a lowering of the limits of detection." This is corroborated by Frost & Sullivan's research estimates that the food-safety testing-services market was about $18 billion–$20 billion globally in 2019, and is expected to grow at a healthy compound annual growth rate (CAGR) of 7–9% during the next 5 years, despite the pandemic.

> **Fear of food-borne illnesses and changing lifestyles and food habits of the global population are leading the growth factors in this market.**

Environmental testing labs are faced with a different challenge when it comes to automation. While food testing is driven mainly by end-consumer trends and demands that enable policies and regulations, environmental testing is dictated mainly by regulations and the bodies that impose them. Automation in an environmental testing lab is dependent on the ROI presented to customers, but mostly by the decrees of the regulatory body in question and its perception of the need to add automation techniques. The speed and rate of adoption of new technologies by regulatory bodies such as the United States Environmental Protection Agency (EPA), play a big role in the adoption of automation technologies by the labs themselves.

"I am not surprised that survey polls show that our customers consider speed of results as the most important feature of working with labs like ourselves," said Kirstin Daigle from Pace Analytical. "Although advancements in technologies have proven higher sensitivity and selectivity in process[es] and results, we have not been able to capitalize on some of the newer technologies that would allow us to move faster, due to some of the regulatory constraints as an organization. One of the areas that we're focusing on is business intelligence and data analytics, a very strong culture of continuous improvement, and which is also emphasized in the [International Organization for Standardization] (ISO) standards and quality system standards that we need to follow." This cements the trend that environmental testing labs are willing to take on newer automation technologies, but the barriers they face are the influence of regulations and standards and the slow pace at which the regulating bodies adapt to new ideas and technologies.

Data analytics and business intelligence in this context are going beyond providing the situation at any given time. The insights that customers get from historical trends, and the changes in testing strategies or sampling programs based on those insights, are highly valuable to testing-lab customers. Connecting sample data from the plant and/or field to the lab electronically, and seamlessly connecting that chain-of-custody for sample submission all the way and not from when it arrives at the lab, is a luxury that most lab managers are asking for.

"Sometimes we like to say in our laboratory that every day is like Christmas because we don't know what we are going to get every day," AJ McCardell interjected. "Like boxes show up and we open the boxes. And then we figure out what is inside. Submission of that request, information in advance, selected electronically, can really transform the speed with which we are able to begin to process those samples, and also, I think, enable some of these other data insights where you could begin to collect more metadata on the samples before they come in."

COVID-19—the Harbinger of New Technology Adoption?

Less than 24 months ago, when asked about adopting data collections and connection technologies, testing-lab customers would cite cyber and IT security concerns. Since then, and the onset of forced work-from-home and remote work situations across the globe, those perceptions have changed dramatically. With large numbers of employees connecting remotely and continuing to be productive, it is possible to share collected data with customers. Since 2020, there is a new openness to working effectively in virtual environments, reinforcing the need for higher connectivity. An overwhelming majority of survey respondents rated the offering of data management tools as the priority with food- and environmental-testing-lab services, and expect these tools to be used to demonstrate results and monitor compliance.

During the last year, testing labs were forced to manage the loss of staff and technicians, and personnel working remotely across time zones. Techniques and processes to train staff remotely and see results earlier than with conventional timelines, for example, using the 3-hour gap between the United States coasts, were advantages that sprung from this global pandemic. Kirstin Daigle said not-so-wistfully, "What if this was to give rise to the possibility of the virtual audit? Every laboratory is challenged with the number and frequency of audits. Until recently, these had to be conducted in person. The testing lab of the future could be equipped to provide virtual audits."

Another point to note is that, since the beginning of the pandemic, demand for testing has not declined in the United States. While some government funding for clean sustainability programs was redirected during the early phases of the pandemic, temporarily stalling the growth of regulation-driven environmental-testing services, there is a realization that clean water and soil are imperative to move society out of the pandemic.

> In food testing, COVID-19 has intensified the need to test for unknown and new contaminants and caused only a small decline in market growth, mainly in the first 3 quarters of 2020.

Other Automation Techniques to Improve Turnaround Times

One way to view automation in a testing lab is at the bottom or task level. Increasing the use of robotics for mechanical tasks and algorithms can speed up results.

"The other method is, in a way, more destructive and more complicated," said August Specht. "And that's what's called end-to-end re-imagination. And that's where we say today if there are 5 tasks that a human does, if we automated those tasks, could those 5 be combined into 1 simple task, for example? Or, could we change the way that those samples are entered into the lab or leave the lab? So, that's kind of the more disruptive version of it. Both are difficult and both require thinking about how to automate it." Mr. Specht continued, "There's this other element about automation, in the sense that automation is great as long as your process is well understood and well characterized. If there is noise in how you do things, automating it just amplifies that noise and makes things worse. So, that's the other element as we talk to customers. It's finding that sweet spot of what's wrongly characterized and what makes sense. But we definitely see there's a lot of interest in those categories of technologies."

> Lab managers and their customers agree that automating data collection and transferring information about samples is important and desirable.

Capturing that information for electronic transfer directly into the system will significantly speed the process. Currently, the process is manual, especially in environmental testing labs that are heavily dependent on data collection and the transfer rules of regulating bodies. "The regulators are very happy with the paper copy of the chain-of-custody," said Kirstin Daigle. "And there has been some advancement in this area and some application to it with some companies who use barcodes, and we can label that. But as long as the administrative code in a [United States] state code says, 'thou shall label the sample container with X, Y, and Z,' we have some limitations on how we can capitalize on that technology to really get a return on investment because, as business leaders, we're going to be reluctant to spend money on the new technology unless we can use it for all of our customer base," Ms. Daigle continued, driving home the point that, while they are open to new technologies, environmental testing labs such as hers are constrained by administrative codes of regulating bodies that do not adapt to new technologies as quickly as their customers would like.

Despite these barriers, Ms. Daigle acknowledged that, while regulations compel labs to operate in the same way, automation can demonstrate differentiation and diversification. She envisions getting out of the transactional—simply obtaining a sample from the customer and

providing it with the data—and into the consultative relationship by providing customers with all transcriptions, meeting their testing needs, providing the data in the format they require, and transferring them to customers' databases. Ms. Daigle sees her lab as a one-stop-shop for her customers that is somewhere between a general-purpose and a completely specialized consulting lab.

Another argument for automating testing labs is the declining number of trained technicians available for open positions. In environmental testing labs, there is a distinct shortage of personnel with the right background and training, and with older technicians aging out of the system it is imperative to use more advanced automation technologies. In food testing labs, new contaminants are discovered every day and there is an on-going need for lab technicians to maintain awareness and stay ahead of the technology curve.

"The testing laboratory that gets their hands on new workflows that can trace the latest and emerging contaminant is the one that can get the data online and basically garner the biggest share of the market, taking advantage of being the first-mover," declared AJ McCardell, driving home the need for labs to be prepared with automating technologies and the right advanced analytical solutions at their disposal.

> When a survey of testing-lab customers yielded that data collection and management are highest on their list of priorities, our panel members were not surprised, and the testing lab representatives insisted that they focus on employing quality software for data and document management and automating workflow processes.

The Role and Impact of IoT

Food testing labs are governed heavily by regulatory bodies including the United States Department of Defense (DoD) and the EPA. Recent policies on cybersecurity by the DoD limit the possibilities of data transfer through the internet unless it is through secure portals, which are yet to become the norm. "That concept has been a part of the [Food and Drug Administration] (FDA) and good [non-government organizations] (NGOs) for a very long time but has yet to catch on in environmental testing," said AJ McCardell. "There hasn't been as much focus on validating software; that's whether it's cloud-based or otherwise. We're beginning to see that tighten down a little bit for data transfer. So, where I really see us being able to capitalize on this is that, again, is with the connectivity; we're able to do remote work, so just taking advantage of time frame

differences and even expanding on that," she continued. "At the same time, IoT is very relevant when it comes to servicing international customers."

Less dependent on regulatory body vagaries and more on the next contaminant, food testing labs see the advent of IoT in a more flexible light. The nature of the data requirements and changing demographic of the workforce seem to encourage the trend toward internet and cloud-based platforms. "Given the nature of our workforce, which tends to be a pretty healthy mix of millennials and younger, we see them driving us to the sort of platform that is common in the consumer space," said Kirstin Daigle. "Everybody wants to be able to look at their smartphone and be able to have things at their fingertips. And, so, I think there are opportunities for the industry to look at that we could borrow from the consumer marketplace."

For the analytical solutions manufacturer, the future of instrumentation and software goes much further than the mere implementation of IoT. Vendors such as Thermo Fisher are constantly reviewing and seeking deeper partnerships with their customers to support the possibility of incorporating Industry 4.0 technologies, such as the digital twin that will provide a representation of lab processes and environments. This moves the needle from predictive to prescriptive analytics on the automation scale. "As we design our next generation of solutions, we're able to think about how to put a dramatically increased number of sensors and equipment, such that we can have a true digital representation," said August Specht. "I remember, if you can hear a triple quad pump was about to die, you would hear this really awkward noise. If no one's in the lab to appreciate that, how would you know that it's about to die? And, so, we're looking at all kinds of vibration sensors to have a more accurate representation. It's not going to be overnight, but it's something that we're building into our next generation of equipment such that we can offer." This comment elicited whole-hearted approval from the other panel members for more sensors on instrumentation.

"We are well positioned to provide industry-leading scientific and laboratory operational excellence, paired with an extensive offering of digital capabilities and solutions to aid in transformational initiatives from lab automation, data management, and digital partnerships to give lab operations managers complete control and oversight of their facilities," added August Specht.

Conclusion

Food and environmental testing labs are about to evolve the automation of their processes and workflows. From all commercially available Industry 4.0 technologies, such as robotics, AI, ML, blockchain, and digital twins, possibilities of automation are coming from more advanced data management tools and analytics. Barriers to automation stem from a heavy dependence on how regulatory bodies adapt to these new technologies. The impact of the pandemic during the last year has opened up many possibilities to use IoT and cloud-based platforms. Recent events have hastened the need for lab employees to work remotely and share sample data and analysis virtually with their customers. Analytical-testing solution providers are no longer instrument vendors to testing labs, and are using their extensive knowledge to incorporate smart solutions that are beyond servicing single instruments and more focused on lab and enterprise solutions that are intelligent and user-friendly. Some, such as Thermo Fisher Scientific, have built these capabilities to be the personal assistant to the scientists of the future. Frost & Sullivan believes both parties in the analytical-lab value chain are on the brink of an automation acceleration curve.

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