Lonza

The QC Testing Lab of the Future

Automation, Digitalization, Smart Solutions

News and views from the
6th Global Endotoxin Testing Summit

About the Global Endotoxin Testing Summit:
The Lonza Global Endotoxin Summit brings together testing experts, researchers, manufacturers, regulators, and conservationists to discuss critical trends and future directions for pyrogen testing in the industry's quality control (QC) sector. Despite the challenges of the COVID-19 pandemic, the 6th Global Endotoxin Testing Summit 2021 went ahead successfully — held in a virtual format for the first time — and covered three time zones, with all recordings available on-demand. Sustainability, automation, and Lab 4.0 were the key themes presented by 24 expert speakers, attracting more than 1,000 attendees from over 70 countries.

It is increasingly crucial for QC laboratories to focus on improving laboratory efficiency. Many companies still use manual testing processes, which are inherently cumbersome, error-prone, and unsustainable for growing product lines. Tedious manual steps also increase the risk of repetitive strain injuries, and with no metadata associated with manual methods, data integrity may be compromised. Now, automation and digitalization are changing the way the QC laboratory is run by reducing manual tasks and streamlining data management and sharing.

Unsurprisingly, a critical focus of discussions at the 2021 Summit was the move from manual processes to automated, more digitalized data management and smart laboratories. In this article, we explore these discussions, unveiling the opportunities of Lab 4.0, key hurdles to realizing it, and several real-world case studies of how companies have begun their digital transformation journey.

QC Lab 4.0 is Within Reach

At the event, a clear image of the lab of the future was provided: Smart robotics would handle intricate and routine tasks, with minimal intervention from employees; all information would be stored in one place, with protocols and standard operating procedures (SOPs) relayed by voice-activated lab assistants; you'd never run out of consumables, as their availability would be directly integrated with electronic lab notebooks (ELNs) and lab information management systems (LIMS).

While many technologies are still in their infancy, the lab of the future is surprisingly closer than you might think. Lab 4.0, as it is known, includes the ongoing automation of traditional manufacturing and industrial practices using modern smart technology. Providing in-depth examples of the lab of the future, Aoife Barron, National Institute for Bioprocessing Research and Training (NIBRT), spoke about some of the ground-breaking ways that new technologies could revolutionize the QC lab. For example, virtual reality (VR) may provide a new dimension for training QC laboratory personnel. Intended to support on-the-job training, users are immersed in a realistic learning environment, allowing consequence-free familiarization of procedures.

Excitingly, many applications of smart technologies are available to QC labs now. Josh Huang, BeiGene, introduced some of these devices including smart glasses with SOPs and work instructions, smart robotics, automated guided vehicles for materials sampling, and virtual tools for remote auditing and training. With continued development, augmented reality (AR) may soon combine the real environment with projected SOPs for instant access to instructions.

Such smart technologies have a number of advantages:

- Saving resources and time through more efficient processes
- Cost-saving through reduced retesting
- Faster results
- Data integrity compliance
- Advanced trouble shooting options
- Improved communication across sites leading to higher quality processes

With an ability to optimize lab work and future-proof processes, it's clear that these smart tools should be more urgently considered and swiftly embraced by the QC industry.

Driving Efficiency by Going Digital - the First Step to Lab 4.0

Digitalization — the use of digital technologies — is fundamental to optimize and transform operations in the QC laboratory. While many organisations still use paper records, results are harder to track, and they lack permanency due to fading and physical degradation. Through digitalization, a world where results are easily reviewed, approved and shared is possible, and the enthusiasm for this modernized approach was expressed by speakers throughout the Summit.

Digitalization brings several advantages to the QC laboratory by not only helping to better preserve records, but by also making data more easily accessible. As globalization of modern medicine production increases, digitalization plays a growing role in harmonization across sites. Multi-plant operating companies can be streamlined with data being shared and accessed by anyone, regardless of where they are located.

The first step towards digitalization is the transition from paper-based to digital processes. In fact, reducing, and eventually eliminating, paper is one of the easiest and most effective changes you can make to drive lab efficiency. Commercial solutions are already available to help and are supporting powerful digitalization across the QC space.

One of the technologies discussed at the Summit that enables digitalization is the MODA® Platform. The MODA® Platform serves as a micro-lab information management system to automate data collection from devices and people. It also eliminates redundant data entry and transcription errors, improves regulatory compliance, and enables real-time decision making on product quality and release.

Natasha Pain, Lonza, highlighted the powerful time-saving capabilities of digitalization by presenting a case study of Nikon CeLL Innovation Co. Ltd (NCLi). As a start-up for customized gene and cell therapy manufacturing processes, NCLi wanted to maximize the efficiency of their QC labo-

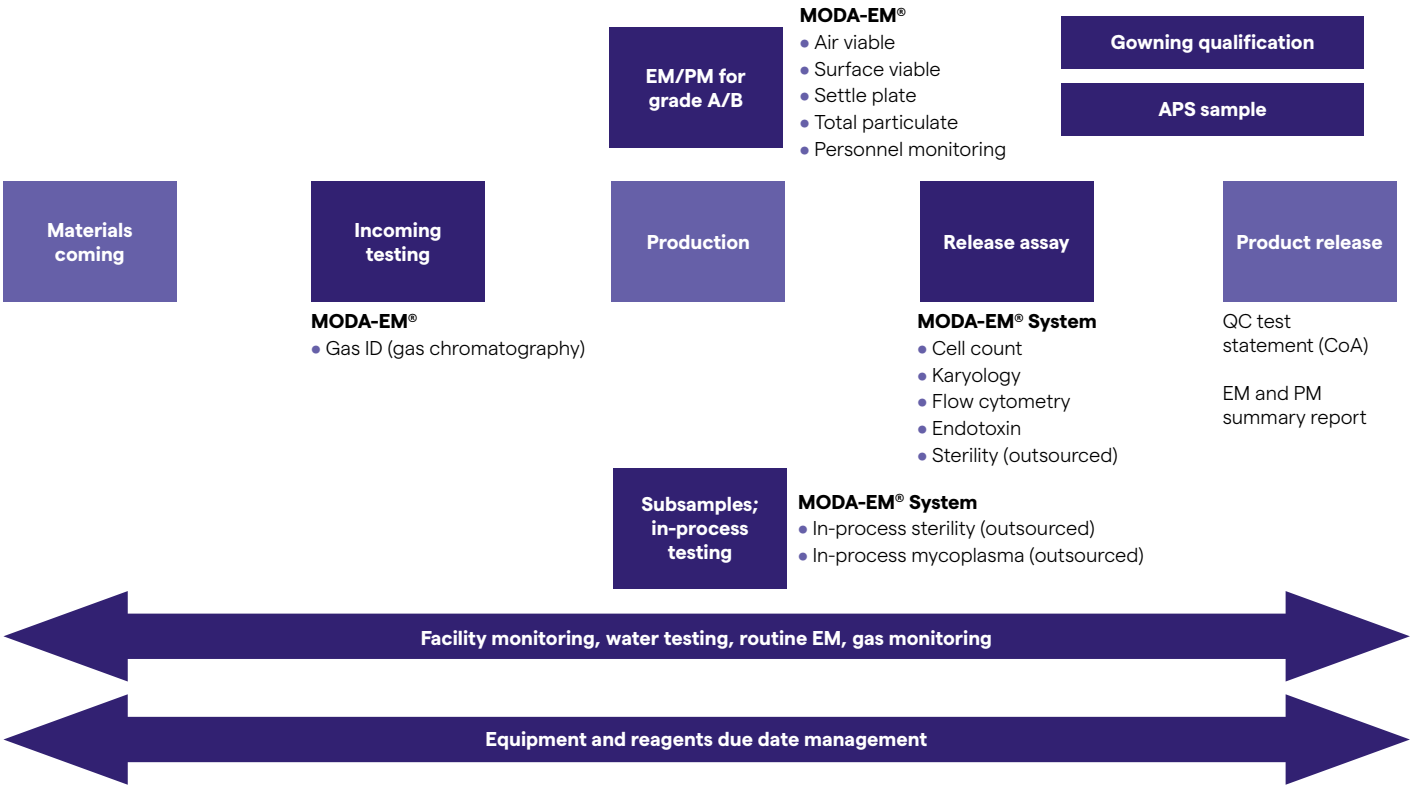


Figure 1.
Schematic to show how the MODA-EM® Solution is used by NCLi. [Source: Microbiology and More – Unleashing the Power of the MODA-EM® Solution.]

ratories by digitalizing their processes. With no additional LIMS required, the MODA-EM® Solution was implemented as a single system and adapted to NCLi's QC workflow, shown in Figure 1. NCLi succeeded in removing paperwork from QC monitoring and analysis — the only remaining printout is the barcode label on the sample, reagents, equipment, and rooms. Overall, going paperless cut sample processing time from 8 hours to 4.

Future-proofing High-throughput QC Laboratories with Automation

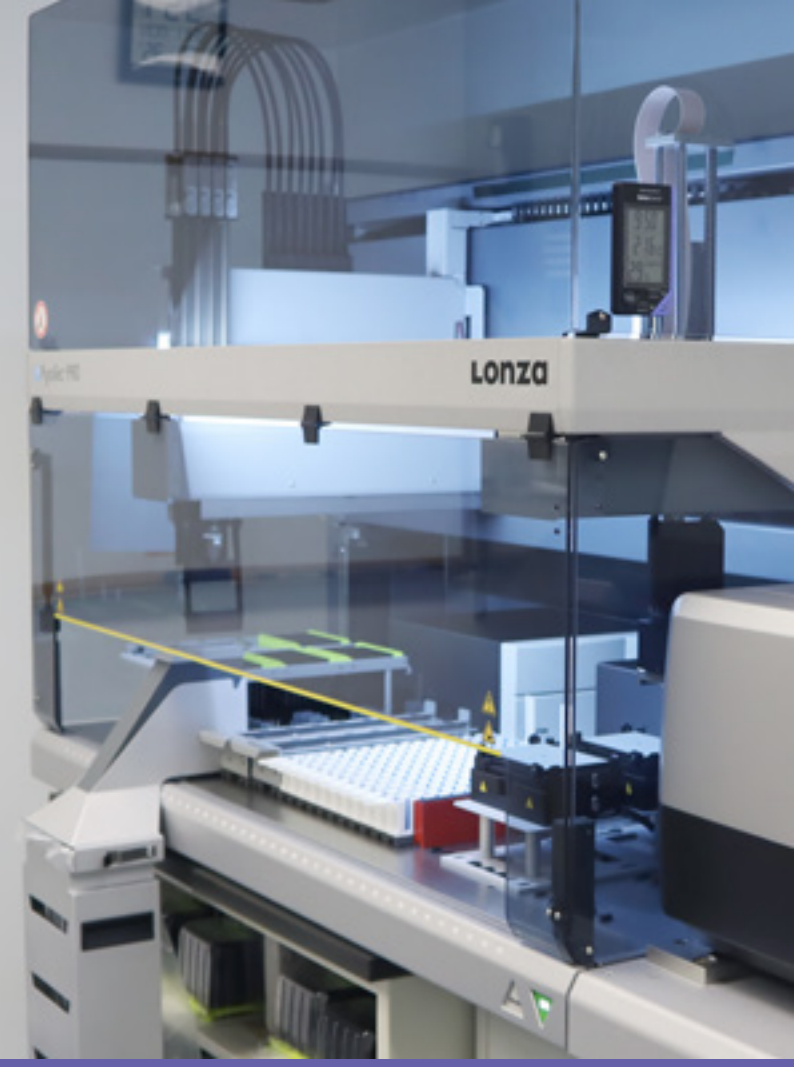
By removing physical paperwork and having results online, digitalization lays the groundwork for automation. The Summit explored several areas where automation is driving significant efficiencies in laboratory workflows — namely data capture and manual tasks.

Rather than manually uploading testing data onto your system, automated systems can collect and collate data without user input, making it readily accessible. To access some of the benefits, Rahul Songire, Cadila Healthcare Ltd, emphasized that a step-by-step approach can be helpful when implementing automation: starting with digitalizing individual systems, and then adding data integration across several analysis platforms.

Automating data capture and manual tasks helps meet many of the challenges associated with increased BET workloads and streamline processes. Ruth Noé, Lonza, detailed key benefits of automated BET. Not only can automation speed-up workflows by facilitating high-throughput analysis, but automating manual tasks also frees up key resources. However, there are unique obstacles to overcome in adopting automated strategies for BET specifically. For example, it was noted that labs analyzing complex, diverse samples requiring different assay templates often struggle (e.g., for dilutions of viscous samples). The complicated and diverse nature of BET requires constant changes in the automation platform setup.

New platforms, such as The PyroTec® PRO Automated Robotic Solution, dynamically create the code required to perform an assay based on the selected template, eliminating any need for expert programming skills to run an assay. The system can pivot between different assays, test viscous samples with configurable liquid classes, and analyze simple and complex sample matrices side by side in the same plate run. With this flexibility, alternative and more sustainable BET approaches, such as recombinant Factor C (rFC) assays, can be more easily evaluated and implemented — streamlining the training and additional equipment required to run different test methods.

With the power to reduce human error, free-up personnel from repetitive and mundane tasks, and unlock new levels of efficiency, automation can ensure the QC testing industry stays viable and adaptable to future needs. The consensus among the speakers was clear: Automation should be — and will be — increasingly adopted in QC laboratories.



The PyroTec® PRO Automated Robotic Solution

Effectively streamlining and error-proofing BET processes demands flexible automation

- Simple 3-step operating procedure
- Deals with both simple and complex assay templates
- Flexible approach to use of different assay methodologies
  - Kinetics chromogenic
  - Kinetic turbidimetric
  - rFC
- Single or dual reader configurations
- Built on Tecan® Freedom Evo™ Platform
  - Well established technology
  - Excellent technical support

Overcoming Obstacles to Implement Lab 4.0

The path to successfully embracing Lab 4.0 can be a challenging one. Speakers at the Summit gave their advice on two of the main hurdles to overcome on the journey: the need for a business case, and how to change perceptions and foster collaboration.

While smart labs are attractive, they aren't cheap. Without a strong business case you're unlikely to be able to justify the expenses required to implement these new technologies. Putting together a compelling business case can be tricky, and there is a lot of vital information required to effectively support your proposition.

Detailed insights were shared at the Summit on how to successfully construct a business case. Firstly, it's important to determine what exactly the needs of your laboratory are. "You can map out the workflow and follow the data: Which information do you need to capture, and when in the process is it available? How do you want to use the data to make life easier for the end-users?" Sinéad Cowman, Lonza, posed as questions that should be addressed.

Johannes Oberdörfer, Boehringer Ingelheim, introduced the financial parameters that are important to factor in when building a business case. For cost calculations associated with implementing the new system, he suggested first including the operating cost of the existing method. Then, consider capital investment, tech and software training, system qualification, method validation, and preventive maintenance for the proposed solution. The recommended steps involved in developing a business case are illustrated in Figure 2.

As a real-world example, Rachel Gibson, Ethicon, used a business case to clearly demonstrate how a fully automated system would cost 4–5x less than their current capital expense through outsourcing. To highlight the benefits of implementing the Lonza PyroTec® PRO Automated Robotic Solution, the team needed to present the impact of the system through a favorable return on investment (ROI) assessment. Using an ROI calculator to help better evaluate all factors — from consumables to training costs — Ethicon strengthened their business case, enabling them to easily justify implementing the new system to senior management.

Aside from building your business case, there are other hurdles to overcome before you can reap the rewards of automation — namely, company inertia and platform implementation. Sinéad Cowman discussed how changing perceptions is crucial. "There's a huge culture change involved in implementing solutions and new methods, and it's really important to encourage the culture to accept change — it's ultimately going to make the analyst's day-to-day life easier."

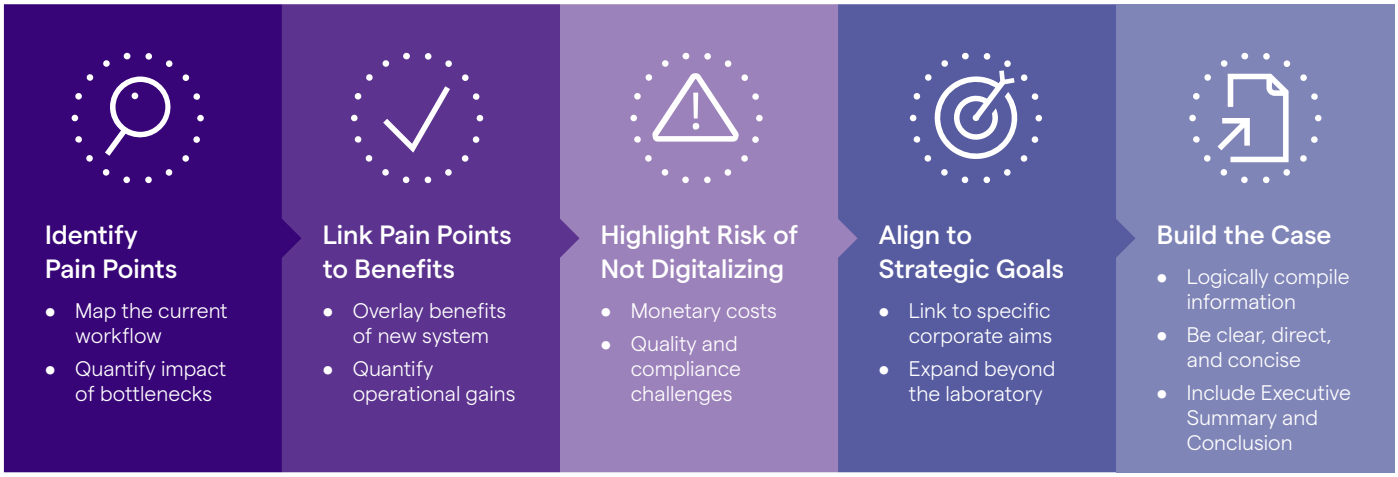


Figure 2.
A framework highlighting the steps needed to create a strong business case. The business case should clearly demonstrate how the new solution overcomes existing pain points and provides strategic benefits beyond the laboratory. [Source: Lonza How to Guide - Building a Business Case for a Digitalized QC Platform.]

Speakers highlighted that team effort is also essential to adopt these new solutions. The successful implementation of automation needs to include other departments beyond the QC laboratory, including IT, finance, and procurement. Dr. Johannes Reich, Microcoat Biotechnologie GmbH, explained the importance of teamwork in affecting change: "Automation and digitalization need an interdisciplinary team. IT departments should help choose the right software tools and integrate them into the existing environment, and HR teams should take care of training for end-users."

Collaboration with expert vendors and trusted partners can also help to ease the implementation of automated devices. Rachel Gibson, Ethicon, Inc., spoke about the quick, one-week setup of the PyroTec PRO® Platform they experienced, including CFR Part 11 and Annex 11 requirements. "The Lonza team was with us each step of the way," she highlighted.

Powerful Tools to Achieve Valuable Results

Digitalization and automation can bring great benefits to the QC lab, unlocking future-proofed and more cost-effective processes. However, it's important to focus on implementing the solutions that address your laboratory's specific issues. Pavan Kumar, Baxter India, explained how even simple automation — such as replacing hand-written labels for tubes and plates with printed, barcoded labels — makes lab management easier. You may not need to go entirely paperless or to fully embrace Lab 4.0 to reap the benefits of digitalization.

Crucially, collaboration and knowledge sharing — with your organization, stakeholders, and through wider industry events, such as the 6th Global Endotoxin Testing Summit 2021 — will continue to be key as QC labs look to productively and sustainably thrive in this dynamic sector.

This blog post is the second of a two-part series highlighting discussions at the 6th Global Endotoxin Summit. You can also read the first blog post on forging the path to sustainable pyrogen testing here.

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