Enabling a Healthier World

Lonza

Automation and Digitalization

The Key to Boosting Your Lab's Efficiency, Productivity and Quality

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Across the board, laboratories are facing ever-increasing pressure to achieve more, in less time and with fewer resources – and it is widely recognized that automation is key to achieving that. However, while most labs have incorporated some degree of automation, there are many aspects of the workflow that remain manual.

Introduction

Manual processes are frequently cumbersome, time-consuming and tedious to perform. In addition, they are prone to inconsistency and error. In contrast, automation not only accelerates workflows, but also results in fewer errors, fewer repeats and reduced waste. It also frees scientists from the mundane so they can focus on more value-added tasks.

Further to automation, digitalizing processes and removing the need for paper records eliminates the challenges associated with manual data input (including transcription errors), filing and data storage, and traceability. Currently, most laboratories are still heavily dependent on paper for managing their data or, in some cases, have adopted a hybrid approach with some devices and systems capturing data electronically but this is done predominantly in silos. For highly regulated GxP facilities, in particular, digitalization simplifies compliance and provides full, easy-to-access audit trails that meet the needs of regulators.

In this White Paper, we look at three different aspects of laboratory operations and explore options to automate key processes: bridging the gap between QC and manufacture, and going paperless; running QC assays that are optimized and scaled to your needs. These automation solutions are designed to help you maximize your laboratory efficiency, speed time-to-market and reduce your overall costs.

More Science. Less Paper.®

For organizations that are currently reliant on manual processes for data capture and that seek to ensure better quality, compliance and efficiency gains, the first step in their strategy to become an automated laboratory should be to remove paper from the process. Making this data available in real time also enables faster and more effective reactions to any deviation or investigation. Digitally enabled labs can then build on their automation initiatives and realize further benefits by integrating data from multiple sources into a single source.

The MODA® Solution enables QC departments to quickly and easily move towards this strategic vision of an integrated automated laboratory. The software encompasses automation of the full spectrum of QC activities including environmental monitoring (EM), utility testing, and product testing. The MODA® Solution also provides out-of-the-box integration with commonly used instrumentation and media found in manufacturing facilities, production and laboratory areas.

Organizations gain timely and accurate QC monitoring by utilizing location-based scheduling, mobile data collection, and paperless lab processing. The MODA® Solution also delivers on-demand reporting, trending, and visualization capabilities to allow in-depth process analysis and ad hoc queries by decision makers.

With the MODA® Solution, QC departments can:

- Automate data collection from devices and people
- Eliminate redundant data entry and transcription errors
- Gain direct traceability of QC microbiology programs
- Increase worker efficiency
- Improve regulatory compliance
- Make sound product quality and release decisions
- Quickly advance green initiatives

Going paperless to reduce sample collection time by 50%

Manual, paper-based process steps create a significant burden for today's QC microbiology laboratory, including paper scheduling, marker labelling of sample media, manual reconciliation, paper logbook entry, and manual notification of deviations.

In fact, the typical paper-based process for a sample collection regimen is roughly about 8 hours per person, per shift. Using the MODA® Solution for sample collection, your process time can be cut in half to roughly 4 hours per person, per shift. These savings have significant implications when applied to a multi-technician, multi-shift operation over the period of a year.

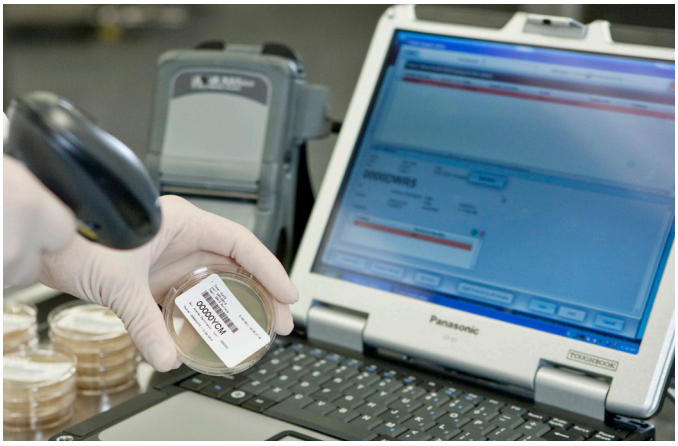
Laboratories can also realize additional benefits beyond workflow efficiencies by making data available in real time. On paper, the value of the data is limited as trending and reporting typically require significant effort to gather the information and then analyze it in a format that can facilitate decision making. Normally, this is sometime after the fact and only provides a retrospective view of what is going on in the facility. With the MODA® Solution, data is made available in real time with multiple options to access that data. Dashboards provide a snapshot of the overall program and ad hoc queries facilitate timely investigations and insight into operations. Advanced mapping tools enable visualization of data in a room or area and the comprehensive reports package, comprising 40+ validated reports, significantly reduces the time needed to create trend reports and communicate these™ to management or during audits.

Boost efficiencies through greater connectivity

Building greater connectivity between enterprise systems and laboratory devices offers greater automation and efficiencies. The MODA® Solution enables seamless integration to many of the common laboratory systems and devices, with out-of-the-box interfaces to particle counters, organism identification systems and Lonza's WinKQCL® Endotoxin Detection and Analysis Software. Bringing all the data together in a single system offers the ability to trend all of this data together.

Bridging the gap between manufacturing and QC

The MODA® Platform bridges the gap that currently exists between manufacturing and QC to provide a single batch record with a review and approval interface. It is a combined electronic batch record and lab execution software that automates data capture for expedited product release. With GMP compliance and tracking at its core, the MODA® Platform combines data capture and error prevention with the flexibility to capture and trend key quality and performance metrics, both in the laboratory and on the production floor. Designed with Lonza Informatics know-how and Lonza's manufacturing experience, the MODA® Platform is cost-effective to adopt, maintain and deploy for medium and small biotech organizations with a lower total cost of ownership than other solutions like customized laboratory information management systems (LIMS). The MODA® Platform provides a solution to the industry that is flexible and easy to configure at a price that allows the entire manufacturing industry to go paperless.



MODA® Solution enables seamless integration to many of the common laboratory systems and devices.

Reduce repeats and increase throughput with assay automation

Laboratories conducting bacterial endotoxin testing help guarantee the safety of parenteral medications, fluids and implantable devices. This testing is an essential part of QC and is required for all raw materials, in-process control and final product release. Errors or inefficiencies in testing can create production backlogs delaying product release and increasing costs. Automating endotoxin testing can improve efficiencies by reducing human error and optimizing process throughput.

As demand increases, so does the need for automation

There are many types of endotoxin tests, but all require numerous pipetting steps and data entry to achieve sample mixing and correct dilutions for a range of sample types. Any testing program requires readers, reagents, consumables and software that must work together to reliably test for endotoxin throughout the manufacturing process.

As the number of samples for testing increases, the stress, strain, errors and limitations of manual processes become more significant. Through highly precise, robot-controlled liquid handling steps, extremely accurate measurements can be performed, day in and day out, reducing the human intervention required for manual tasks. Optimized integration with data analysis software further enhances efficiencies by reducing manual data entry, providing auditable reports and ensuring 21CFR part11 compliance.

Streamlining endotoxin testing workflows

Automation platforms not only enhance the quality of the data generated by endotoxin testing, they also help streamline process workflows. The latest automated systems are capable of processing large volumes of samples with optimal accuracy and precision, enabling right first time delivery of results and the release of products in an accelerated timeframe, ultimately helping the speed up time-to-market.

A key advantage of robotic testing platforms is that they are able to operate continuously without fatigue while also minimizing manual intervention. Once a run is initiated, these systems automatically dilute and mix solutions, prepare standard curves and transfer plates in and out of the reader at the appropriate times. Hands on time is reduced and experienced team members can focus on higher value tasks, such as results analysis, preventing further bottle necks in product release timelines. Capable of running 24/7, modern automation systems for endotoxin testing workflows can significantly increase sample throughput and operational efficiency, ultimately reducing the cost of performing each test.

With the PyroTec® PRO Automated Robotic Solution integrated with the WinKQCL® Endotoxin Detection Software, QC departments can:

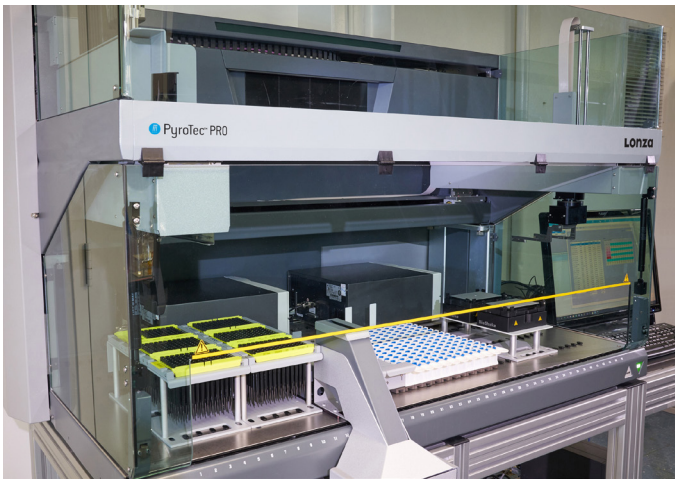
- Improve efficiencies and reduce human error
- Accurately process large volumes of samples
- Provide auditable reports and ensure 21CFR part 11 compliance
- Improve reporting, trend analysis and flagging of errors
- Integrate with LIMS or CAPA systems to eliminate manual transcription of data
- Ensure confidence in data used to safely release products to market

Efficiency savings illustrated

The example in Table 1 highlights the estimated time-savings that can be achieved by automating testing with the Lonza PyroTec® PRO Automated Robotic Solution.

Automation efficiencies	
Touch-time manual testing	93 minutes
Touch-time with automation (PyroTec® PRO Solution)	14 minutes
Touch-time savings	**79 minutes**
Manual testing repeat rate	6%
Automation (PyroTec® PRO Solution) repeat rate 1%	1%
Samples saved / year	1,000
% labor savings	**85%**
% reagent/consumables cost saving	**4%**
ROI	**1.9 years**

Table 1.
Estimated time-savings for a laboratory testing 20,000 water samples per annum using a manual kinetic chromogenic plate-based method including interference controls (positive product control, PPC) with each sample.



Significant time-savings can be achieved using Lonza´s PyroTec® PRO Automated Robotic Solution.

The increased simplicity and convenience offered by the PyroTec® PRO Solution extends to system set-up, with the latest run-control software applications eliminating the need for complex and time-intensive robot programming steps. Other software features, such as the availability of microplate templates that provide operators with a layout of the robot deck, allow operators to quickly duplicate runs or apply common parameters and reduce the need to repeat tedious tasks. By making these efficient systems intuitive and easy to use, modern automation platforms and run-control applications are helping to deliver highly accurate results faster and more efficiently than ever before.

Realize the benefits of automated QC

With precise and efficient endotoxin testing essential for the delivery of safe parenteral medicines and medical devices, amid growing pressure to reduce costs and increase productivity, growing numbers of laboratories are realizing the benefits of automated testing systems. Thanks to the latest advances in robotics and integrated software, new automated endotoxin testing platforms are enhancing the accuracy, speed and efficiency of these important workflows.

Conclusion

With considerable recent advances in automation and software solutions, there are no longer technical reasons why laboratories should remain using manual testing processes. Particularly when the latter can be hugely time-consuming, inefficient and error prone. In fact, there is plenty of evidence to show that automation can help laboratories reduce errors and waste, while also improving quality, efficiency, compliance and cost-effectiveness. It also liberates scientists from tedious manual processes to allow them to work on more valuable activities and help to accelerate time-to-market.

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RT-SP024 08/22

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