Lonza

A New End-to-End Automation Solution for Endotoxin Testing

How a Fully Integrated Digital Solution Can Save Time, Reduce Errors, and Drive Data Integrity in Your QC Testing

Lonza Walkersville, Inc.

Pharmaceutical quality control (QC) testing labs face growing endotoxin testing demand and, consequently, relentless business pressure to enhance lab productivity. However, cumbersome and error-prone manual processes pervade current QC testing workflows, hindering laboratory throughput. Until now, QC laboratories have only been able to automate disparate aspects of the QC testing workflow to address these challenges. Lonza's new integrated solution, however, offers the first all-in-one solution to automate the majority of the endotoxin testing process — from sample scheduling right through to data analysis.

Introduction

Endotoxin testing is critical to ensure the safety of all injectables and parenteral pharmaceuticals. However, demand for endotoxin testing is growing, with quality control (QC) testing labs under increasing pressure to increase throughput.

Unfortunately, several challenges in current QC testing workflows bar the path to more efficient and productive operations. For example, many QC teams still use manual pipetting and rely on paper-based processes that demand analysts manually transfer data between disparate and disconnected systems.

As a result, analyst and organizational time is wasted, errors and deviations are more likely, and adhering to data integrity requirements becomes unnecessarily burdensome. In some cases, repetitive manual workflows can even lead to repetitive strain injury, significantly impacting analysts' quality of life and testing throughput.

While several tools and technologies have emerged to help QC teams automate different aspects of their processes to mitigate these issues, **no all-in-one end-to-end QC solution has been available — until now.**

Automating the Endotoxin Testing Workflow

Using its 30+ years of informatics and endotoxin testing expertise, Lonza has developed the first commercial solution for end-to-end QC testing workflows. With it, QC teams can now coordinate automation of many previouly manual processes from scheduling through to execution, data collection, and data analysis.

The solution comprises a new integration of the following Lonza solutions:

The MODA-EM® Module

The MODA-EM® Module is a regulatory-compliant paperless solution that automates QC processes, where users can manage and report on the full spectrum of EM and QC information. The module is designed to seamlessly integrate with commonly used instruments and media in manufacturing facilities, as well as with laboratory information management systems (LIMS). With the MODA-EM® Module, organizations can get timely, accurate QC monitoring through location-based scheduling, mobile data collection, and paperless lab processing. What's more, real-time access to data enables on demand reporting, trending, and visualization capabilities for in-depth process analysis and ad hoc queries.

The WinKQCL® Endotoxin Detection and Analysis Software

Lonza's WinKQCL® Software is an integrated solution for quantitative endotoxin testing, data management, and reporting, and is designed to be compatible with a variety of endotoxin test methods. The software was one of the first CFR 21 Part 11-compliant solutions, built with a robust framework to satisfy the full scope of data integrity requirements.

The PyroTec® PRO Solution

The PyroTec® PRO Automated Robotic Solution is a plate-based system that automates many routine, error-prone manual benchtop tasks in endotoxin testing. The system can be directly integrated with the WinKQCL® Software, and delivers high-throughput sampling in three simple steps. QC labs therefore get the benefits of an automated assay workflow, enabling greater efficiency and productivity, while helping ensure data integrity compliance.

To achieve the seamless integration of an end-to-end QC testing solution, we've added the following features and functionality to augment these three components:

- **Automated barcode scanning and reading functionality** for the PyroTec® PRO Solution
- **New connectivity** for seamless data transfer from the MODA-EM® Module to the WinKQCL® Software
- **Enhanced connectivity** for improved data transfer from the WinKQCL® Software to the MODA-EM® Module
- **Instant alerts** that notify QC teams when data is ready for next steps.

How it Works: Reimagining the QC Testing Workflow

With this new functionality and seamless integration of the three solution components, labs can now significantly reduce manual user intervention. To illustrate, a typical water for injection (WFI)/endotoxin testing workflow using the new solution is summarized below:

1. **Workflow and label creation (the MODA-EM® Solution)**
   To start, a workflow is generated in the MODA-EM® Module, with the system automatically scheduling samples, as well as generating and printing barcode labels. Analysts then add labels to the sample containers before collecting the samples.

   Once samples are delivered to the lab, they are scanned and reconciled in the MODA® Software before the testing stage is executed.

2. **Sample queuing and test template creation (the WinKQCL® Software)**
   The WinKQCL® Software creates a queue of samples for testing, pulls samples onto a test template, and then passes this information over to the PyroTec® PRO Solution, ready for sample preparation and assay execution.

3. **Sample prep and assay execution (the PyroTec® PRO Solution)**
   An analyst adds the sample tubes, reagents, and consumables onto the robot deck, before the PyroTec® PRO Solution automatically scans the barcode labels to confirm that the right samples are in the correct location.

   Once sample and sample location are confirmed, the PyroTec® PRO Solution automatically actions sample preparation steps. (Importantly, the PyroTec® PRO Solution can handle even complex sample preparation, such as that involving serial dilutions and treatments.) After sample preparation is complete, the robot runs the analysis.

4. **Results approval (the WinKQCL® Software)**
   Upon assay completion, sample data goes through a two-party approval workflow within the WinKQCL® Software, after which the data is eligible for automatic transfer to the MODA-EM® Module.

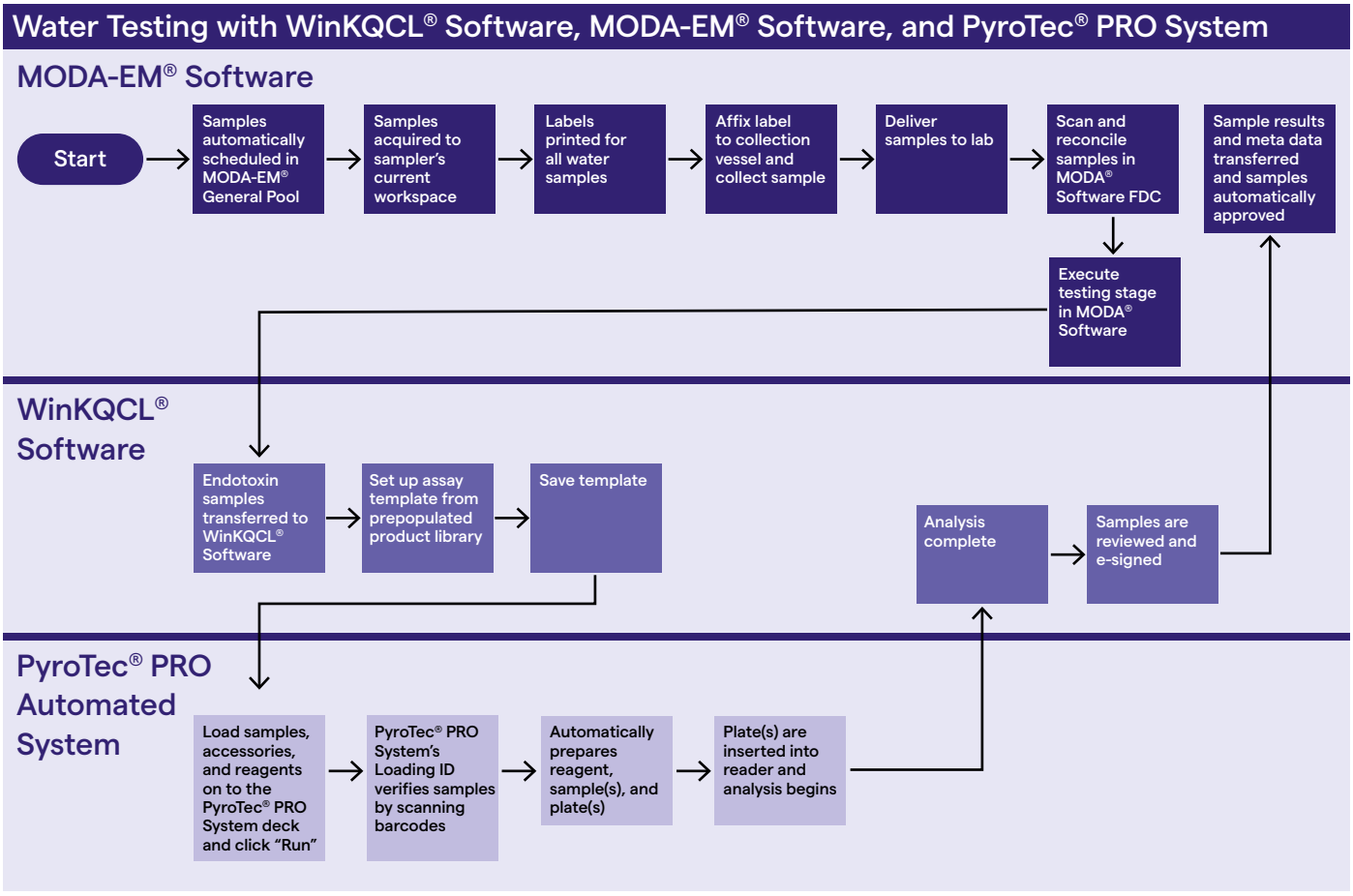
   Users can configure the MODA-EM® Module to systematically approve passing results, minimizing the need for approval in multiple systems.

5. **Data retrieval and reporting (MODA-EM® Module)**
   The MODA-EM® Module periodically sweeps the WinKQCL® Software database according to a configurable schedule, automatically retrieving eligible sample data several times per day. From here, analysts can generate a variety of reports, all of which have the same structure to ease data reviews.

The only manual interventions throughout the optimized QC testing workflow are:

- **Collecting and delivering samples to the lab**
- **Affixing labels on sample tubes**
- **Scanning and reconciling samples in the MODA® Software**
- **Selecting a prepopulated assay template**
- **Loading samples, reagents, and consumables onto the PyroTec® PRO Solution deck and clicking "Run"**
- **Reviewing and e-signing sample data**

All other manual interventions are now automated (Figure 1).



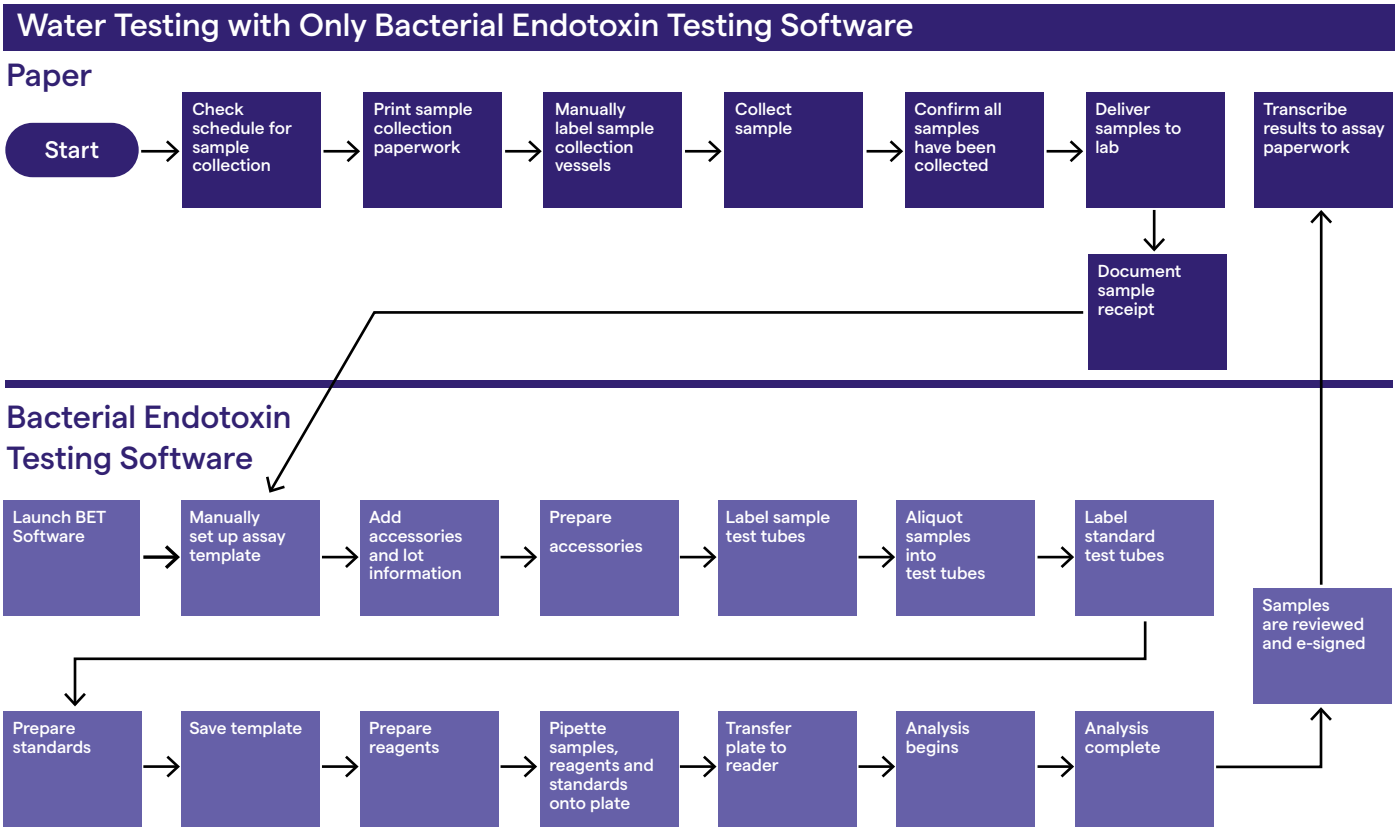


Figure 1. Side-by-side illustration of QC testing workflow with and without the integrated Lonza solution, highlighting where manual steps occur in each.

Software Integration Efficiencies	
Touch-time (manual testing)	93 minutes
Touch-time (PyroTec® PRO Solution)	14 minutes
Touch-time reduction	**85%**
Sample collection time (manual, paper based)	~8 hours
Sample collection time (MODA-EM® Software)	~4 hours
Sample collection time reduction	**~50%**
Manual testing repeat rate	6%
Automation (PyroTec® PRO Solution) repeat rate	1%
Samples saved / year	1,000
Labor savings	**85%**
Reagent/consumables cost savings	**4%**

Figure 2. Estimated time-savings for a laboratory testing 20,000 water samples per year using a manual kinetic chromogenic plate-based method including interference controls (positive product control, PPC) with each sample.

Realizing the Benefits in Your QC Lab

With the new integrated solution, labs can optimize their QC processes in several ways.

Further simplified and streamlined processes

While each of the standalone solution components can streamline QC testing, the new features of the fully integrated solution unlock additional ways to simplify QC testing.

For example, because the PyroTec® PRO Solution's LoadingID barcode scanner enables automatic confirmation of correct sample ID and location, analysts no longer have to manually ensure assay components are correct before assay execution. The resultant reduced risk of errors therefore significantly reduces the need for cumbersome assay re-runs.

The new and enhanced connectivity between the three solutions also enables automatic and direct data transfer among the systems throughout the entire workflow. Analysts therefore don't need to manually transcribe data between systems, and no documents end up left on lab desks awaiting further action (which can lead to costly delays). Similarly, instant notifications that inform analysts when data is ready for analysis means lab staff don't have to wait for colleagues to confirm that data is ready, eliminating another step in a paper-based QC testing process.

Perhaps most importantly, with the system being all-in-one and designed by a single vendor, customers get reduced validation burden, system components that are designed to work together seamlessly, and a strong support network with expertise spanning the entire system. Labs can, therefore, significantly reduce the complexity of system deployment and maintenance.

Easier data integrity: enhancing data accuracy, traceability, and security

The new integrated solution also enables labs to confidently meet stringent data integrity requirements. With greater assurance that your samples are correct and in the right place on the PyroTec® PRO Solution deck, and with the automation of manual data transcription, the risk of errors is drastically reduced, meaning labs can be more confident in their data accuracy.

Not only that, broader automation of tasks, combined with automatic real-time data and metadata capture and audit trails, helps ensure data is complete and more traceable.

Because Lonza developed this integrated solution, we have full visibility into the internal data workingsof each component. Lonza can therefore ensure clean, smooth, safe, and direct data flow among the component systems (something which is not possible when integrating multiple proprietary solutions from several vendors). With direct data transfer, no data is exposed, eliminating the risk of man-in-the-middle exploits, driving better data security in the QC lab.

Time and cost savings

Simplified processes that involve less cumbersome manual work, fewer errors, and a lower-effort route to data integrity all combine to deliver another significant benefit for QC labs: significant time and cost savings. Indeed, with this end-to-end integrated solution, labs can reduce their sample collection time by up to 50%, and their WFI testing touch-time by up to 85%, freeing up talented, highly trained QC staff to focus on more value-adding and productivity-enhancing work.

A strong foundation for digital transformation

Ultimately, with greater automation and connectivity in the QC lab, companies can not only save time and unlock the full potential of their highly trained scientists, but they can also create a strong foundation for broader digital transformation, helping to drive not just the QC lab, but also the business, forward.

Case Study:

A Robust, Flexible Solution that Meets the Needs of Modern Pharmaceutical QC Facilities

How Lonza's proof-of-concept collaboration with a customer helped drive the integrated solution's unique functionality

The challenge: A need to drive further efficiencies
One of Lonza's pharmaceutical customers is a committed early adopter of advanced digital tools in their manufacturing and QC workflows, always on the lookout for ways to maximize efficiency and ease the path to data integrity compliance.

The customer became aware of an automation gap in their QC operations and wanted to adopt the Lonza PyroTec® PRO Solution to close it. Moreover, the company was still manually transcribing data between some of its digital systems, which added to staff workload and project timelines.

A solution in waiting: Lonza's prototype integrated system
Lonza had developed an early model of the new integration between the MODA-EM® Solution, the WinKQCL® Software, and the PyroTec® PRO Solution, including the loading ID component of the PyroTec® PRO Solution and a way to transfer files among the three components. Lonza was keen to test it in the real-world to get a better idea of how these connections would and should be made.

The collaboration: An opportunity with mutual benefit
Discussions between Lonza and the customer revealed mutual benefit in deploying a prototype of the new integrated solution at the customer's site. Lonza could evaluate the solution in a real-world setting to optimize its functionality, and the customer could secure early access to a tool to further drive operational efficiency. So, the collaboration commenced.

During the collaboration, the two teams meticulously tested the solution in a large number of common and uncommon scenarios, challenging the integrated solution's functionality. Throughout, Lonza provided timely and comprehensive support on many key challenges and shared ideas to help further improve the new integrated solution. Working together the teams identified many the issues and opportunities, carving the best path forward for their full resolution or implementation.

The outcome: A robust, fit-for-purpose QC automation tool
The extensive testing of the new integrated solution in a working QC facility (rather than in a sanitized commercial testing environment) helped Lonza refine the system, helping to ensuring that it was fit for the complex processes and myriad challenges of the modern QC lab.

"The comprehensive real-world testing process was critical for the new integrated solution's development," said Josiah Hosie, Product Strategist, at Lonza. "We've come out of it with a powerful and unique automation solution that could reshape how customers approach QC workflows. Our customer is already noticing the stark efficiency gains of its recent deployment."

Lonza can now offer the new integrated solution via a standardized implementation, complete with a range of templates for various scenarios, meaning customers can get up and running quickly to realize the benefits of greater QC automation more easily.

Unlocking the Future of Pharmaceutical QC Testing, Today

Pharmaceutical QC labs today face several challenges — from growing demand for endotoxin testing and strict data integrity requirements to increasing pressure to achieve more with fewer resources and less time.

Despite being able to automate several aspects of their workflows, QC labs still face several cumbersome manual steps that bar the path to more efficient, productive, and accurate testing.

With Lonza's new integration of the MODA-EM® Solution, WinKQCL® Software, and the PyroTec® PRO Solution, QC labs get a comprehensive system that automates most of the QC testing workflow, making simpler, more accurate, and more resource-efficient QC testing a reality, all while maintaining strict data integrity compliance.

Ready to simplify and streamline your QC testing programs? Contact one of our QC testing experts to learn more about how the new integrated solution can support transformation of processes in your QC lab.

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RT-SP039 10/23

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