Seamless Software Integration Allows for Enhanced Automation of the Entire Endotoxin Testing Workflow

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Purpose

Laboratory automation includes the integration of software and hardware to enable new and more efficient processes. By integrating an electronic batch record system along with endotoxin detection and analysis software, laboratories can automate their endotoxin testing workflow in ways not previously possible.

WinKQCL® Endotoxin Detection and Analysis Software

Lonza's WinKQCL® Software is an integrated solution for quantitative endotoxin testing, data management, and reporting, and is compatible with a variety of endotoxin test methods. This software is CFR 21 Part 11-compliant and is compatible with the PyroTec® PRO Automated Robotic Solution.

MODA-EM® Paperless QC Microbiology Software

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 seamlessly integrates with commonly used instruments and media in manufacturing facilities, as well as with laboratory information management systems (LIMS).

The PyroTec® PRO Solution

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

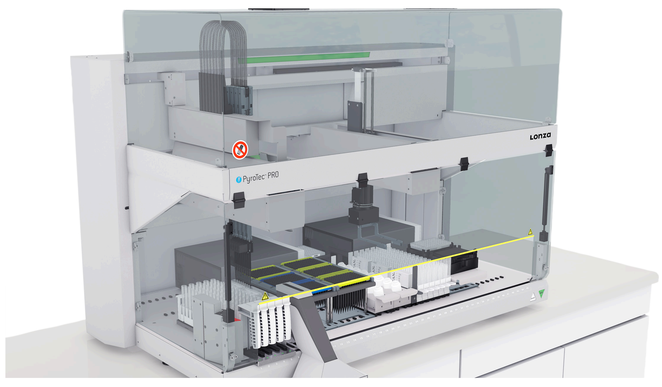
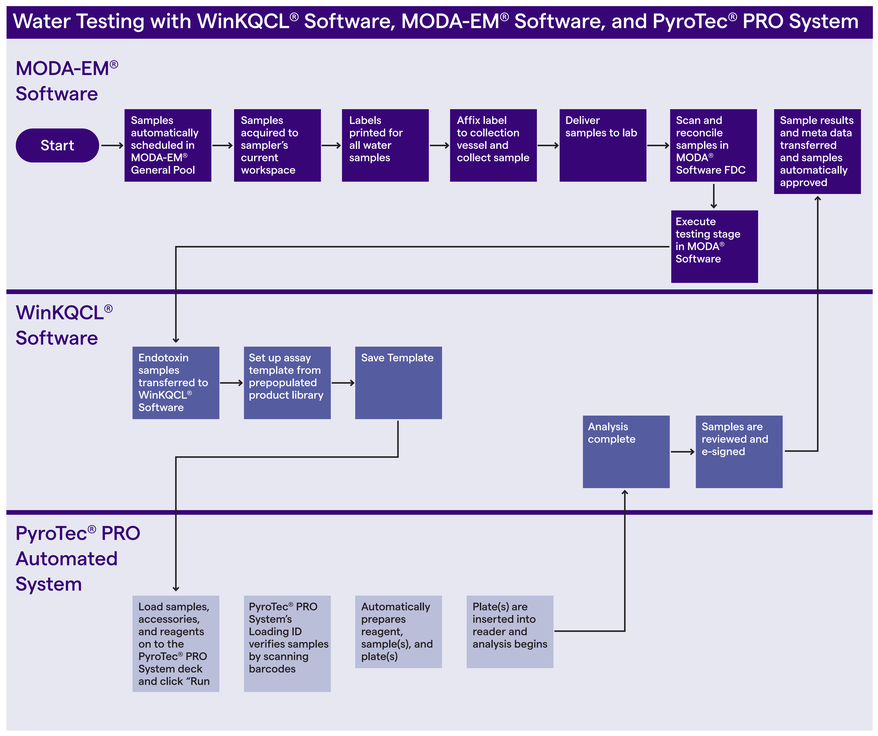


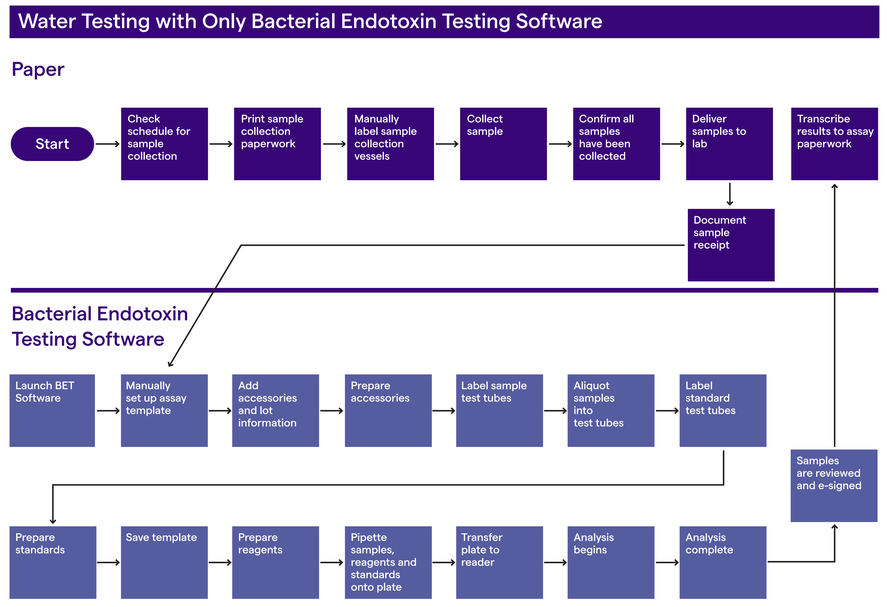
Figure 1. PyroTec® PRO Automated System equipped with air displacement pipetting arm, robotic arm, two microplate absorbance readers, and LoadingID 1D barcode scanner.

Reimagining the QC Testing Workflow

Water Testing with WinKQCL® Software, MODA-EM® Software, and PyroTec® PRO System



Water Testing with Only Bacterial Endotoxin Testing Software



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®)	~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.