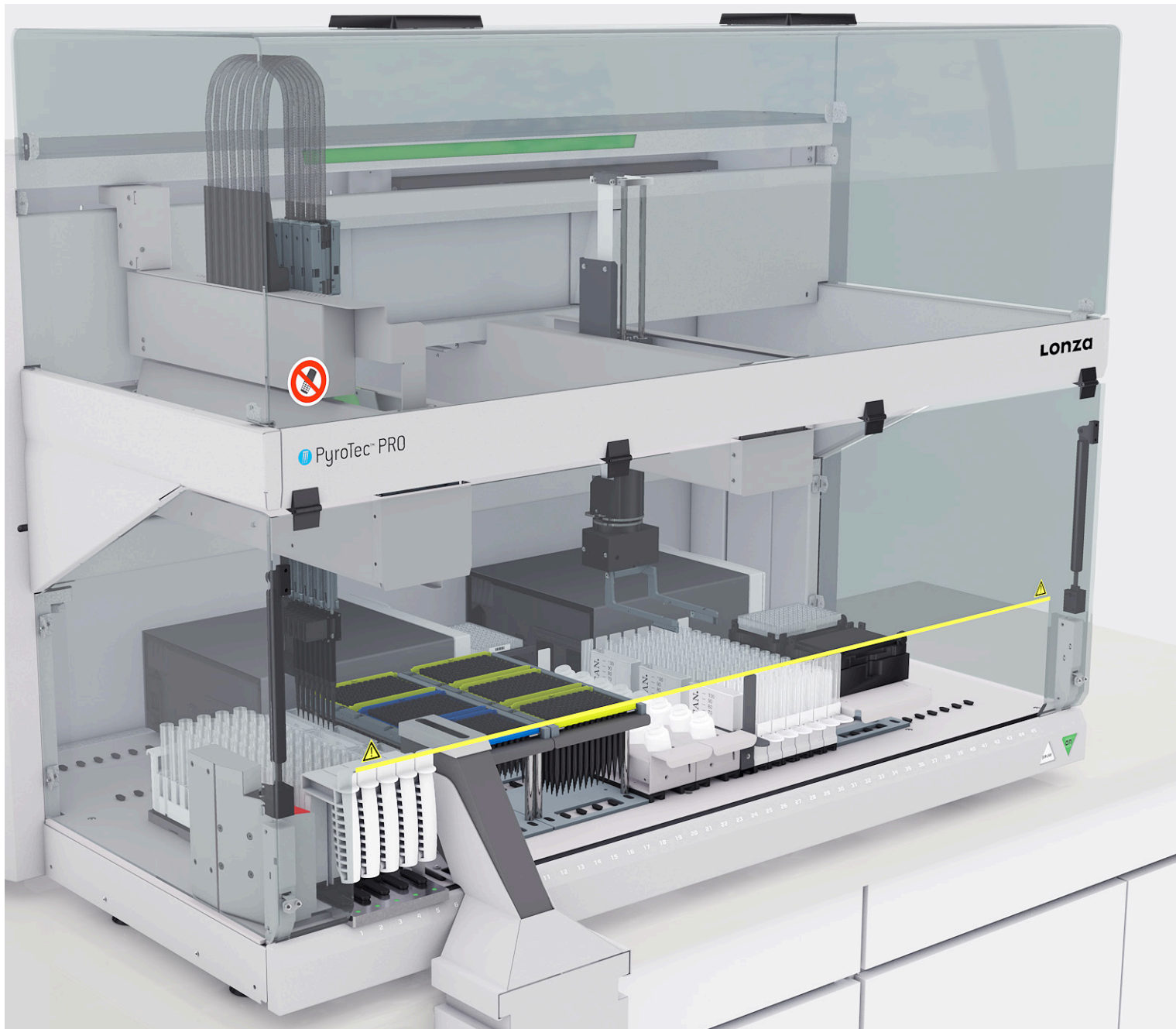# PyroTec™ PRO

An Automated Robotic Solution for Endotoxin Detection
Integrated within WinKQCL™ Software

PyroTec™ PRO brings the automation of the Bacterial Endotoxin Test to a new level. This innovative use of automation technology provides a seamless integration of robotic liquid handling with a proprietary dynamic control system that offers unparalleled ease-of-use combined with maximum flexibility for high-throughput sample processing that other systems have never achieved.

PyroTec™ PRO is the first fully integrated flexible plate-based solution available to the endotoxin market, designed intrinsically to follow the FDA's Process Analytical Technology and Data Integrity Initiatives. The system combines the speed and reproducibility of a robotic liquid handling platform with an elegant and extremely powerful software module that makes testing of both simple and complex sample combinations a quick and easy 3-step task for the user.

Lonza's creative new automation module that will be released in Version 6.0 of Lonza's market leading WinKQCL™ Endotoxin Software, will now take any new and existing templates and dynamically 'script' the instructions to an automation template with almost no effort from the end-user, regardless of how complex your sample/diluent type or

testing requirements. The system requires no programming or script writing skills to operate and offers unprecedented flexibility in the sample layout within the microplate.

PyroTec™ PRO improves assay robustness and reproducibility, significantly reducing manual intervention and simplifying laboratory workflows. The system can be implemented without the need for product re-validation, does not require expensive cartridge-based reagents and fully follows the BET assay as described in the BET monograph in USP Chapter <85>, providing rapid, consistent endotoxin testing results time after time.

With the introduction of Lonza's WinKQCL™ Version 6.0 software, our new endotoxin assay automation module now provides a complete, dynamic integration of the robot setup and control, linked to our endotoxin analysis and reporting tools already proven by hundreds of systems worldwide. Our goal for our endotoxin testing customers is quite simple yet profound, "Less Work for Quicker and Better Results":

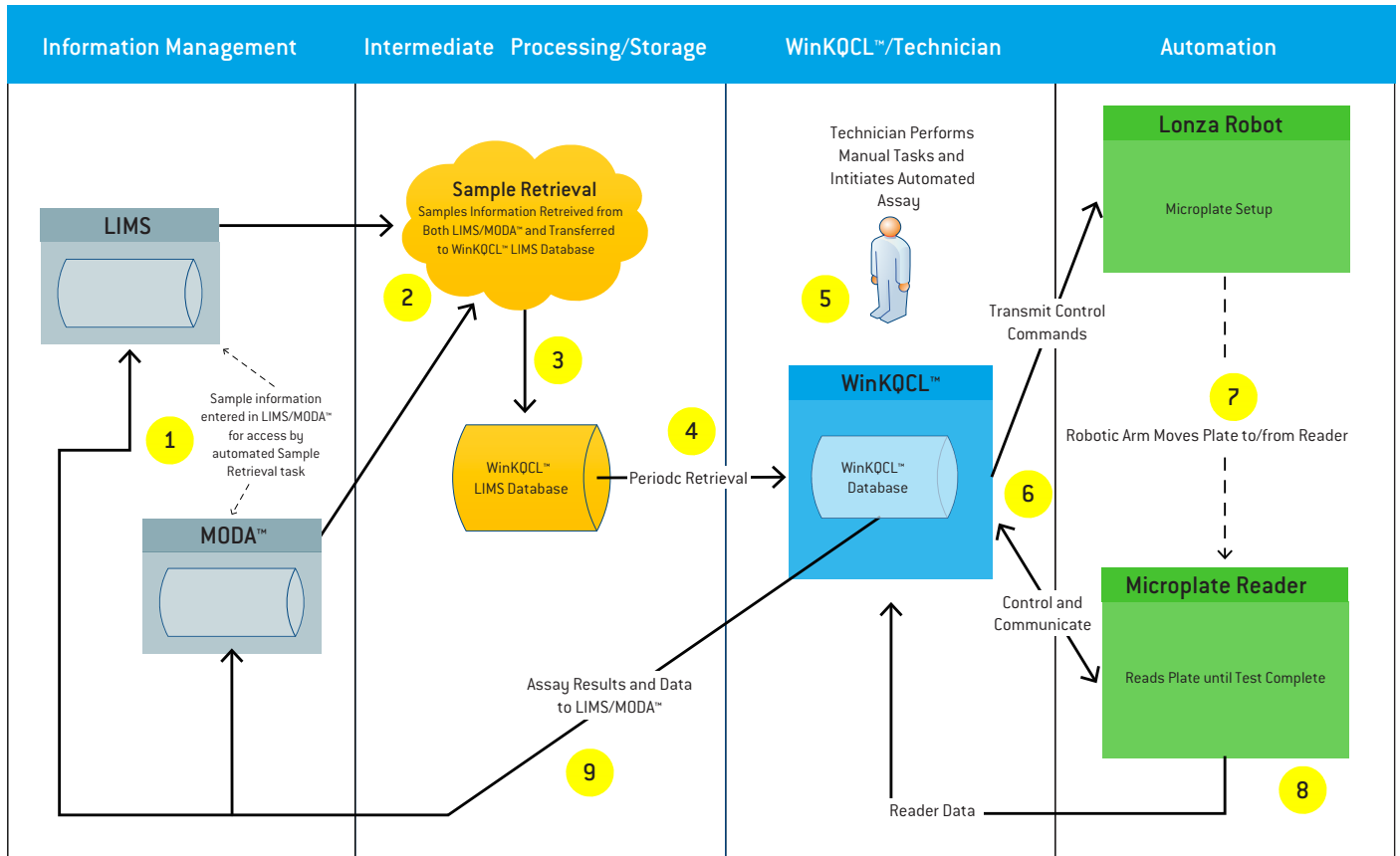# Transform A Manual Benchtop Workflow to An Automated System

With this in mind, our automation module is "template-driven" in that it dynamically generates both the robot deck layout map and the robotic control code required to run a Lonza endotoxin assay based entirely on the microplate template selected by the user. As you add new products or even when new products are detected in WinKQCL™, the software will intuitively configure and auto-populate the deck layout by assigning how the liquid handling instrument processes the product. This is all based on your product's testing requirements for sample dilution and endotoxin limits.

Customers can now implement a robotic workstation solution without the need to learn the robotic software and how to write scripts. The system includes a pre-defined platform size to accommodate tips, reagent troughs and 96-well plates. The robotic arm picks up tips, prepares standards, samples and reagents, dispenses them to

96-well plates and ultimately places the plate in the microplate reader for final analysis. The robot executes all processing required to complete the run, including microplate transfers in and out of the reader at the appropriate times. When the microplate setup is complete, the WinKQCL™ Software automatically receives the results from the microplate reader and saves the results to the database. Operation is straight forward; the intuitive WinKQCL™ Software user interface in version 6.0 optimally combines pipetting, robotics and scheduling of samples through LIMS or MODA™ Solution also available from Lonza.

Automation has Never Been so Paperless When Combined with LIMS or Lonza's MODA™ Solution!
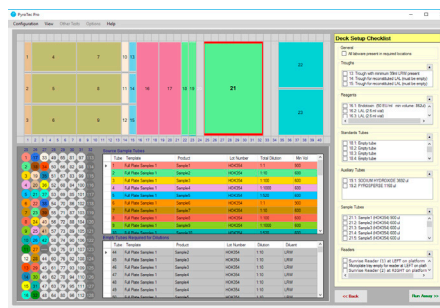
Endotoxin Automation High-level Process Flow

Information Management	Intermediate Processing/Storage	WinKQCL™/Technician	Automation

LIMS

Sample Retrieval
Samples Information Retrieved from Both LIMS/MODA™ and Transferred to WinKQCL™ LIMS Database

2

3

1
Sample information entered in LIMS/MODA™ for access by automated Sample Retrieval task

MODA™

WinKQCL™ LIMS Database

4
Periodc Retrieval

Technician Performs Manual Tasks and Intitiates Automated Assay

5

WinKQCL™
WinKQCL™ Database

6
Control and Communicate

9
Assay Results and Data to LIMS/MODA™

Reader Data

Transmit Control Commands

Lonza Robot
Microplate Setup

7
Robotic Arm Moves Plate to/from Reader

Microplate Reader
Reads Plate until Test Complete

8

Steps are numbered in process order above.

Process Workflow in Three Simple Steps

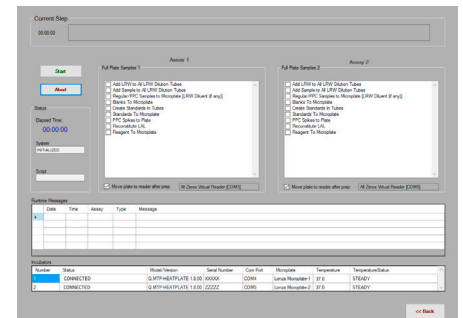**Step 1** Select the template
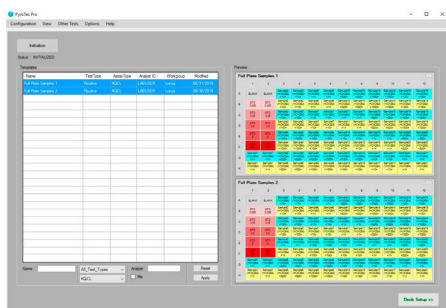
Step 2 Set up and confirm the robot deck

According to the deck layout instructions generated dynamically by WinKQCL™ Software based on the template selected

Step 3 Initiate the assay

Overall Benefits

- Elevated patient safety through better control of process leading to quicker results
- Improved reproducibility, through elimination of a high proportion of manual steps
- Introduction of robotic handling usually results in reduction of repeat samples or entire assays
- Complete reduction of existing manual workflow without the need to fully revalidate
- Positively impact operations, quality, and time to result with the added benefit of cost reduction
- Improve data integrity organically with the capture of new metadata into the growing analytical capabilities of WinKQCL™ Endotoxin Detection and Analysis software

Laboratory Benefits

- Reduce human error by minimizing the liquid handling portion of the assay
- Lessen retest rates and Out Of Specification (OOS) or Out-Of-Trend results (OOT)
- Increased accuracy and precision versus manual pipetting methods
- Performs assays with equivalency for every run
- Defeat the need to manually prepare your standards
- Eliminate manual sample preparation time with the most complex sample types
- Perform complex validation studies and leverage the WinKQCL™ Software's full feature set
- Minimize the manual liquid handling portion of the assay by reducing workflow.

Data Integrity Benefits

- Ability to capture the meta-data from the automated preparation in the software with traceability into tracking, trending and audit controls
- Reduce manual input of data and template creation that might otherwise lead to possible errors in data entry
- Remove transcription/input error by integrating with LIMS or MODA™ Solution to be fully paperless
- Strengthen compliance with standard operating procedures by reducing workflows and steps prone to manual errors
- Reduced OOS and OOT deviations, improving overall metrics within the lab
- Full traceability of sample lifecycle with LIMS integration

Features and Advantages

- High-throughput capability:

	PyroTec™ Pro	Cartridge Based Platform
Maximum Samples Per Run	42	60
Time to Completion	>3 hours	4.5 hours
Standard Curve	5 Point Standard Curve	Archived Standard Curve
Negative Controls	Yes	No

- Significant cost savings per test vs. automated platforms utilizing a cartridge based system
- Highly flexible sample configurations with up to 128 sample dilutions to utilize per run
- Low assay set-up time: less than 10 minutes for 42 samples
- Fully compliant with US and European Pharmacopeia BET guidance
- Maintains standard curve integrity as found in classical LAL assays
- Automated flexible primary (LRW) and auxiliary dilution (i.e. beta-glucan blocker) parameters that allow simple or viscous sample types that can be run simultaneously
- Proper liquid classification data allows to test extremely viscous sample types which at times can require advanced pipetting skills
- Strong repeatability statistics showcasing high accuracy/low coefficient of variation between replicates

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