Making the Medicines of Tomorrow

Lonza
Specialized Modalities

The road to QC automation

Securing Investment for a Next-generation Automation Platform

How Lonza worked with medical device company Ethicon to successfully justify and implement the Lonza PyroTec® PRO Automated Robotic Solution for efficient, future-proofed QC operations.

Introduction

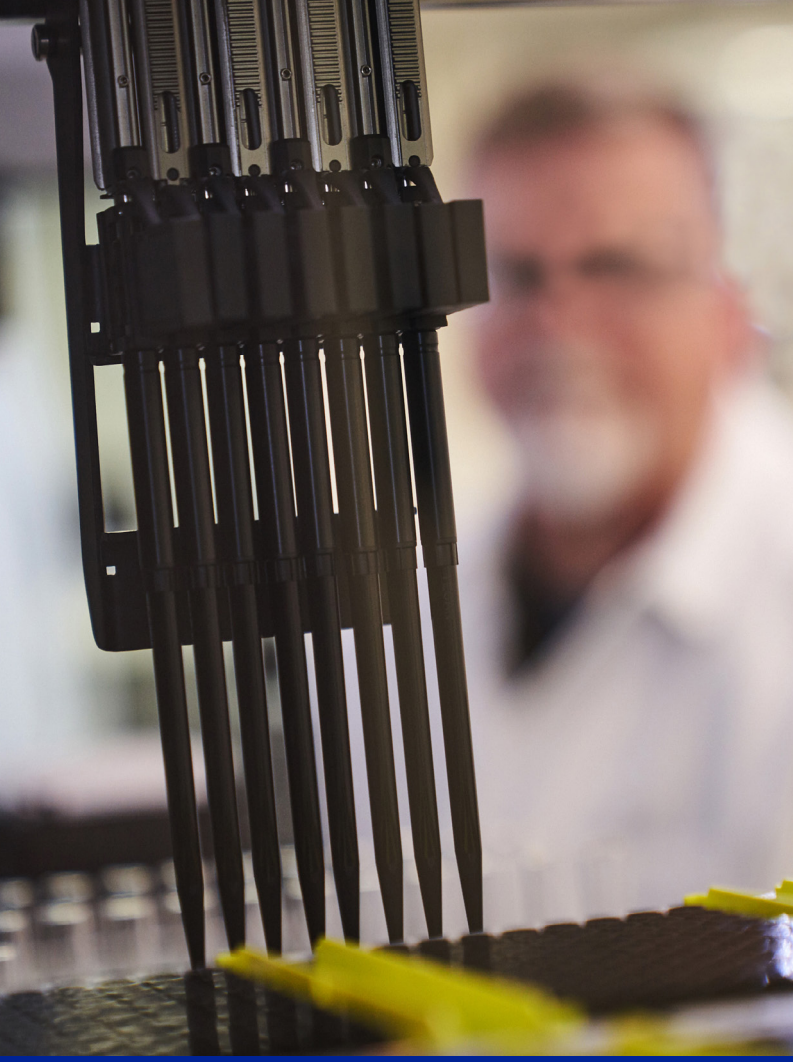
Endotoxin testing is key to meeting quality control (QC) requirements across parenteral pharmaceutical and implantable medical device manufacturing. Currently, most endotoxin testing is performed manually, which is costly and cumbersome. Switching from a manual to automated process is required to drive laboratory productivity and efficiency, by reducing the more laborious tasks.

Implementing an automated endotoxin testing system offers many benefits:

- Improved accuracy, reduced human error, and minimized risk of repetitive strain injury (RSI) owing to fewer manual pipetting steps
- Fewer retests due to greater process robustness and consistency
- More comprehensive, streamlined data collection and management through elimination of paper records and manual transcription
- Integration with other systems such as laboratory information management systems (LIMS)
- Ability to grow and expand for new product lines without needing to increase personnel for manual tasks

A need to embrace endotoxin testing automation

Ethicon, a Johnson & Johnson medical device company, manufactures surgical sutures and wound closure devices, providing 85% of the world's sutures. As part of its QC processes, extrusion quench tank process water must be tested for endotoxins. However, the company's testing system stopped being supported by the manufacturer in 2019, meaning Ethicon required a new solution.



The PyroTec® PRO Automated Robotic Solution – the result of 25+ years of expertise

Endotoxin testing was subsequently contracted to an external company, incurring high costs including expenses for retesting, which is common in a manual system. Outsourcing endotoxin testing also led to increased time on projects, as samples needed to be shipped. Additionally, a lack of integration with LIMS meant data had to be entered manually, increasing risk of transcription errors.

Alongside existing testing, Ethicon recently started testing several different suture lines for endotoxins due to changes in regulations. These requirements will continue to grow, increasing the testing volume two-fold across product lines. Ethicon realized there may be a different solution that could overcome these challenges.

In seeing the benefits of switching from manual testing to an automated system — reduced human error, improved data accuracy, integration with LIMS, and reducing hands-on time by around 80-85% — Ethicon began exploring options.

Identifying a flexible and cost-effective solution

When considering a replacement system, Ethicon defined its requirements based on current bottlenecks within the company. They wanted a solution that retained the lower pipetting effort of the previous system, allowed LIMS integration, and came with expert software and hardware support. Ethicon evaluated its current contract testing workflow against two automated systems: the Lonza PyroTec® PRO System and a competitor.

Ethicon considered various financial aspects of the two automated systems, including the total cost of ownership, and factored in the cost of the instrument and consumables. Outsourcing endotoxin testing was costing up to five times the capital expense of a fully automated solution per year, so moving the testing in-house was more cost-effective.

After comparing options, the Lonza PyroTec® PRO Solution was the clear choice. Importantly, the system offered flexibility over the competitor, accommodating multiple testing types. It was also found that the price difference between the two systems would be recovered within two years of implementing the PyroTec® PRO Solution, due to reduced consumables costs.

The PyroTec® PRO Automated Robotic Solution

Lonza has led the way for automation in endotoxin testing for more than 25 years. The first Windows® version of its WinKQCL® Endotoxin Detection and Analysis Software was developed in 1996, bringing semi-automated endotoxin testing to market. Lonza subsequently released the first-generation Lonza PyroTec® Robotic Endotoxin Testing Solution in 2008, for high throughput customers testing simple solutions.

The PyroTec® PRO System is a next-generation endotoxin testing platform that, through process optimization and automation of routine manual tasks, streamlines and improves the performance of the QC laboratory.

The PyroTec® PRO System enables:

- Elevated patient safety through better control of QC processes, leading to quicker results
- Patented dynamic scripting, introducing effortless flexible assay and complex sample handling
- Improved reproducibility through elimination of several manual steps
- Reduction of repeat samples or entire assays
- Elimination of existing manual workflows without the need to fully revalidate
- Enhanced operations, quality, and time to results while cutting costs
- Accommodation of novel, sustainable testing methods
- Improved data integrity through capture and analysis of the robotic metadata in the Lonza WinKQCL® Endotoxin Detection and Analysis Software

Building the business case

Once the Ethicon team had determined the Lonza PyroTec® PRO System was right for the company, the next step was to obtain investment from senior management. This involved creating and presenting a business case to justify implementing the new system. To do this, a project manager at Ethicon needed to show that the Lonza PyroTec® PRO System would be less expensive than the current contract laboratory, and be a better fit for the company's needs and goals.

"Lonza has been instrumental on this project. The Lonza team was with us every step of the way to make sure we met all of our in-house requirements, and helped get the system up and running as quickly as possible."

— Rachel Gibson,
Scientist III, Ethicon, Inc.

What makes a compelling business case?

A powerful business case should give a clear-sighted analysis of the pain points associated with your existing process and an understanding of how the proposed solution will alleviate these challenges. Additionally, it must highlight the risk of not investing and align the project to strategic company goals.

When building your business case for automation, take a logical, phased approach (Figure 1), and use tools like return on investment (ROI) calculators to enhance clarity and maximize your chances of success. This provides solid, convincing evidence that is crucial to supporting your case.

The vendor is key to understanding all aspects that impact cost savings when determining the ROI of an automated system. For example, when calculating labor costs, factoring in sample and standard preparation time is necessary, as well as the time required to manage repeat testing (including any deviation investigations and reporting). Correctly estimating the impact on training is vital: manual sample preparation training in particular can be very time consuming, depending on the number and complexity of the samples to be tested.

Labor Savings	Training Savings	Reagent Costs	Accessories Costs
Sample preparation	Training hours	Lysate	Plates
Making the standards	Course costs	CSE	Tips
Repeat assays		Additional costs for repeat assays	Troughs
Administration costs (OOS and OOT investigations)			
QA and QC costs (OOS and OOT investigations)			

Table 1. Factors considered by the ROI calculator that have the potential for significant cost savings

Figure 1. A framework for creating a strong business case.

To help Ethicon's project manager with their business case, Lonza provided extensive support by assigning a dedicated coordinator and account manager. Together, they were able to determine Ethicon's user requirement specification (URS) and validate the cost using an ROI calculator.

The calculator considered all expenses involved in testing, from purchase costs and system implementation to human resource requirements (shown in Table 1). The business case also included key additional system benefits associated with LIMS integration (improved data integrity, fewer transcription errors), in-house trending (to evaluate process drift), and the ability to reallocate internal resource to more value-added tasks. As a result, Ethicon's project manager crafted a compelling business case and easily secured approval for investment, particularly when considering cost implications over a two-year period and beyond.

Supporting Ethicon to streamline validation

When implementing a new piece of equipment in a regulated environment, it must be validated to ensure that it has been implemented correctly and is fit for purpose. This process is extensive and requires ongoing periodic review every three years.

To comply with regulations, Ethicon needed to validate the PyroTec® PRO System by producing 15 different deliverables in accordance with the company's procedures. As part of this process, a Lonza project coordinator and a team of implementation engineers conducted significant pre-installation planning. The on-site vendor qualification was successfully completed on schedule. A Lonza sales representative also worked with Ethicon to further validate Annex 11 and 21 CFR Part 11 assessments in compliance with FDA and EU requirements.

Having successfully implemented the PyroTec® PRO System, the Ethicon team plan to further explore the benefits of automation though interfacing the system with LIMS to reduce analyst time and eliminate transcription errors.

Executive Summary

- Ethicon needed a new endotoxin testing system to replace their outdated manual system that was no longer supported by the manufacturer
- Their approach of outsourcing endotoxin testing was expensive, and restricted Ethicon's control over the process
- After careful comparison with a competitor's automation solution, the Ethicon team chose the Lonza PyroTec® PRO System for their testing needs

A powerful business case should give a clear-sighted analysis of the pain points associated with your existing process and an understanding of how the proposed solution will alleviate these challenges.

- Lonza worked with Ethicon to prepare a business case justifying the system to senior management, and sup ported Ethicon with implementation

Impact

- With the help of Lonza's Return on Investment (ROI) calculator, Ethicon was able to show significant ROI to facilitate securing investment
- The Lonza PyroTec® PRO System offered flexibility to accommodate testing for Ethicon's growing product lines, a key part of the ROI calculation
- Through pre-installation planning support and system application qualification by Lonza, Ethicon achieved a right first time BET automation qualification milestone

Conclusion

Automation addresses the specific challenges of current endotoxin testing by eliminating costly and error-prone manual processes, increasing process efficiency, and improving results quality. However, creating an impactful business case for automation platforms is challenging. By working closely with Lonza, Ethicon developed a compelling business case that easily justified adoption of the PyroTec® PRO System.

The Lonza PyroTec® PRO System offers an affordable automated endotoxin testing solution that minimizes manual steps and can flexibly accommodate multiple and novel test types to support future-proofed QC operations.

For further support in building your business case, or to learn more about the Lonza PyroTec® PRO Solution, please visit: www.lonza.com/endotoxin-automation.

Contact Us

North America

Customer Service: +1 800 638 8174 (toll free)
order.us@lonza.com
Scientific Support: +1 800 521 0390 (toll free)
scientific.support@lonza.com

Europe

Customer Service: +32 87 321 611
order.europe@lonza.com
Scientific Support: +49 221 99199 400
scientific.support.eu@lonza.com

International

Contact your local Lonza Distributor
Customer Service: +1 301 898 7025
scientific.support@lonza.com

Learn more.

Lonza Walkersville, Inc. – Walkersville, MD 21793

RT-DS055 06/25

lonza.com/endotoxin-automation