Pharma&Biotech

Lonza

Automating QC micro processes with MODA™ platform improves efficiency, ease of compliance and costs for Lonza

MODA™ solution case study

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Lukas Utiger, Head of Lonza Biosciences

Issue

Paper-based quality control microbiology (QC micro) processes were labor-intensive, time-consuming, error-prone, and expensive.

Solution

MODA™ mobile data acquisition platform for automated, paperless, QC processes

Return on investment

Significant improvements in QC efficiencies, ease of regulatory compliance, cost reductions and employee utilization

- Reduced time to perform environmental monitoring by 4 hours per-person, per-shift
- Reduced required QC staff from 11 to 8 FTE's through attrition and reassignment
- Reduced analysis of sampling data and trending from weeks to seconds
- Eliminated miscellaneous costs such as for binders, autoclaving and off-site paper storage
- Improved regulatory compliance efficiencies with validated system and full audit trail traceability

Lonza Group Ltd

Lonza (www.lonza.com) is one of the world's leading suppliers to the pharmaceutical, healthcare, and life science industries. Its products and services span its customers' needs from research to final product manufacture. Lonza is headquartered in Basel, Switzerland and is listed on the SIX Swiss Exchange. In 2010, the company had sales of CHF 2.680 billion.

Executive summary

The Walkersville, Maryland facility was challenged with the typical paper-based quality control microbiology (QC micro) processes:

- Autoclaving particle-generating paper
- Capturing sampling data on paper
- Reconciling data to correct for numerous omissions and errors
- Re-entering data manually into a MS® Access® database
- Creating trend reports manually in MS® Excel® – limiting scope and timely insights into trends
- Storing volumes of paper documentation – increasing the time and complexity of FDA audits
- Requiring microbiology analysts to devote half their time to non-QC micro activities

« The MODA™ platform provided a complete solution for QC micro with mobile computing technology and advanced visualization tools. It enabled paperless and timely collection of data at sampling points, automated workflow processes, and provided data analysis and trending in seconds instead of weeks. »

John Semon, Associate Director, QC Testing Services, Lonza Walkersville

As part of a company-wide Lean Six Sigma initiative to eliminate waste and reduce lead times, Lonza Walkersville beta-tested MODA-EM™, an environmental monitoring software for paperless QC micro data collection and management, in three of the site's clean rooms. After using MODA-EM™ for a year, results were so impressive that system implementation was expanded to all 13 clean room suites at the Walkersville site. The software was upgraded with more than a hundred recommendations from Lonza's analysts, and utility monitoring (for water loops) was added, further increasing ROI. In addition to MODA-EM™, the MODA™ platform today also includes MODA-VIP™, a Visual Intelligence Portal to improve insight into sampling data, and MODA FDC™, a mobile computing capability using tablet PCs and other devices for Field Data Capture of sampling data in clean rooms.

The MODA™ solution solved Lonza Walkersville's micro QC issues in numerous ways with:

- Clean room-compatible computer equipment interfaced to laboratory equipment (air particulate counters)
- Real-time, one-step, electronic capture of sampling data, eliminating paper forms and redundant data entry
- Significant reduction in data errors and elimination of omissions through mandatory, self-checking, data-entry fields
- Generation of trending reports in real time with a wide variety of report formats
- Flora trending by person, site, room, facility, etc.
- Client-specific reporting for contract manufacturing
- Automatic assurance that sampling is performed with only calibrated equipment and non-expired materials and media

"The MODA™ platform provided a complete solution for QC micro with mobile computing technology and advanced visualization tools. It enabled paperless and timely collection of data at sampling points, automated workflow processes, and provided data analysis and trending in seconds instead of weeks," said John Semon, Associate Director, QC Testing Services, Lonza Walkersville.

Susan Harrison, Senior Manager, QC Microbiology, Lonza Walkersville, added: "The system's value proposition of 'More Science, Less Paper' manifested in higher process efficiency, ease of regulatory compliance, significant cost reductions, and better use of employees, increasing their job satisfaction."

After three years of working with the MODA™ platform, Lonza began expanding the system across its plants globally and acquired the emerging company, MODA Technology Partners. "Based on our first-hand experience, we recognized how the MODA™ technology would benefit our customers and partners in life sciences industries, as well as other types of companies with regulated manufacturing, such as food processing," said Lukas Utiger, Head of Lonza Biosciences. "The acquisition clearly strengthened our Bioscience division's capabilities with comprehensive, automated, quality informatics to meet the critical needs of regulated quality control environments."

Objectives

Reduce the time and resources required for micro QC processes

Lonza became an early adopter of MODA™ technology through the efforts of microbiology analysts like Jeremy Tanner. "We faced multiple issues with the paper-based system just as other QC microbiology labs do," said Tanner. "From planning and scheduling, through collecting and processing samples, to entering data into a database and spreadsheets for analysis and trending, our QC process involved more than 30 steps, and 20 of them were manual tasks. Typing information from paper forms took up half my day. We then spent an excessive amount of time generating trend graphs in Micorsoft® Excel® that were not very insightful. And when we completed trend charts, we had to compare them back to the paperwork for verification because our process could not be validated."

More than 100 QA and manufacturing people are involved in capturing sampling data at Lonza Walkersville. Because of the volume of work and the number of end users, data correction delayed the review and approval of data.

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Susan Harrison, Senior Manager, QC Microbiology, Lonza Walkersville

Solution

MODA™ mobile data acquisition platform

The MODA™ platform provided Lonza with software and cleanroom compatible hardware that automated the capture and entry of sampling data directly into a computer system at the points of sampling. The platform includes PC tablet computers and associated equipment, such as carts, thermal barcode printers and barcode scanners. All the equipment is easily sanitized with familiar pharmaceutical cleaning agents such as bleach and sporicidal agents to keep from adding contaminates to the clean room environment. The MODA-EM™ software also allows for data entry from other computing devices such as fixed workstations and qualified laptops in the controlled areas.

The MODA™ system integrates directly with the air particulate counters used at Lonza. The information is pulled directly into the MODA™ platform and sent to a server – eliminating the need for hours of manual data entry during sampling. The system also provides more than 25 out-of-the-box reports for trending as well as the VIP module for viewing results in any way Lonza chooses to investigate the data. The automated reporting and quick, flexible analysis capabilities provide insight into issues that Lonza would not have been able to find with its paper-based processes.

A typical automated sampling process at Lonza now involves:

- A person entering a clean room with the MODA™ mobile computing environment on a cart
- Searching the system for the room/site the person is in
- Identifying the samples in the room to be collected
- Printing barcode labels for the samples requiring media (plates, bottles, vials, swabs, etc.)
- Using the MODA™ platform to operate particle counters in capture of non-viable particle count data, which is directly fed to a database

The result is one data-entry step, no transcription and immediate access to the sample information. For the entire micro QC process at Lonza, the MODA™ solution eliminated all 20 manual steps, including the backend work associated with data monitoring and trending.

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Return on investment

Improved efficiency, ease of compliance, costs and employee utilization

By removing paper from the process, Lonza was able to increase the number of samples it could take and manage – increasing QC capacity. Ease of regulatory compliance improved from a higher quality process – due to the elimination of manual errors and omissions, the addition of a validated system compliant with FDA 21 CFR Part 11, and capabilities to perform data trending in ways not previously possible with a paper system.

Regulatory compliance

The MODA™ platform provided a validated system with electronic signatures for complete process traceability and audit trail. Users can only access portions of the system needed to complete their job function. Instant turnaround of trend reports also improves compliance efficiencies. Reports can be generated as soon as sampling results are in the system, which allows for rapid response to any possible contamination events.

"The system's ease of use also simplifies compliance audits," said Tanner. "QA staff can access MODA™ software from their computer and show exactly the information an auditor requests. Our MODA™ capability has dramatically shortened audit times, impressed auditors.

User adoption

In addition to microbiology analysts, more than 100 QC and manufacturing personnel across age groups and varying educational backgrounds use the MODA™ system. "User adoption was quick and very high," said Tanner. "As people started using the system, they saw the value. When we ask employees if they would like to go back to the paper system, most say absolutely not."

For the QC analysts like Tanner, who were trained for science, more time can be spent on analyzing information and making decisions so that clean rooms, water and utility systems, raw materials and Lonza's end products can meet the highest standards of microbial control. "All employees involved with QC micro processes now complete more meaningful, value-added tasks," said Harrison. "This not only helps the company, but everyone's job satisfaction as well."

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