

# MODA™ Automated QC Micro Processes

## Case Study



« ... a validated system with electronic signatures for complete process traceability and audit trail. »

### 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 required QC staff from 11 to 8 FTE's through attrition and reassignment and sustained reduction
- Added multiple new cleanrooms and Utility Loops without vendor assistance
- Reduced producing trend reports from weeks to seconds and removed all paper trend reports using electronic document sign-off
- Eliminated miscellaneous costs such as for binders, autoclaving and off-site paper storage
- Utilized trending data for hundreds of customer and regulatory audits and received positive feedback on trending program

## Lonza Group Ltd

Lonza ([www.lonza.com](http://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 2016, the company had sales of CHF 4.130 billion.

## Executive Summary

The Walkersville, Maryland facility has been using the MODA-EM™ Platform for 10 years. The sustained improvement in multiple areas of QC Microbiology has made the Microbiology group more focused on the science and not the paperwork.

- More effective customer and regulatory audits
- Completely paperless trending with no printed reports
- Eliminated omissions errors
- Improved long term trending capabilities to make better decisions about how to deal with seasonal trends in our cleanrooms.
- Expanded utilization of MODA-EM™ Platform into room qualification, aseptic process simulations, and water system qualifications

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

QC Microbiology Manager, 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™ Software, an environmental monitoring software for paperless QC micro data collection and management, in three of the site's clean rooms. After using MODA-EM™ Software 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 based on more than one hundred recommendations from Lonza's analysts, then utility monitoring (for water loops) was added, further increasing ROI. In addition to MODA-EM™ Software, the MODA™ Platform today also includes MODA-VIP™ Software, a Visual Intelligence Portal to improve insight into sampling data, and MODA FDC™ Software, 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 QC Microbiology Manager at Lonza Walkersville, added: "I have utilized LIMS systems in the past for Microbiology data and nothing fit the microbiology workflow or data models. The MODA™ Platform provides our staff the ability to schedule, sample, enter results and organisms, review and approve and trend the data without the need for any customization of the software solution. It is definitely built for Microbiology instead of trying to fit Microbiology in LIMS."

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. After the acquisition the MODA™ Solution was globally deployed within Lonza to 9 sites worldwide. This allowed Lonza to globally recognize the benefits that were seen at the Lonza Walkersville site.

## Improvements

### Improved Trending and Expanded Use of MODA™ Platform

Lonza became an early adopter of MODA™ Technology and has been using the software solution for 10 years. During this time Lonza Walkersville has added multiple cleanrooms and utility systems and using MODA™ System we were able to easily and quickly add these new areas to the MODA™ System through simple configuration in the system. They expanded MODA™'s use by utilizing they system to capture cleaning validation and qualification data during commissioning of these new facilities and utility systems. This allowed review and approve of these protocols to occur much faster than past qualification efforts because the data was trended out of MODA™ Solution as soon as the information was entered.

Lonza Walkersville also improved its trending process by completely eliminating the trend reports to be printed on paper. A project to export these files into .pdf files and utilize them in conjunction with the document management system allowed for electronic sign-off of monthly, quarterly and annual trend reports. This saved time because people were not printing them out, putting them into binders and archiving them offsite. It also freed up much needed space in the QC microbiology lab. The consistency of the trend reports allows for long term trending to be more efficient because you are comparing the same data in the same format.

## 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 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 contaminants 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 printing the results and hours of manual data entry during sampling. The system also provides more than 35 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 This gave Lonza immediate benefit and has led to additional operational efficiencies through use for better trending and qualification/commissioning processes.



## 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 without any additional headcount. 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 21CFR 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 turn-around 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, QA staff can access the MDDA™ Software directly. This allows the staff to generate the specific information an auditor requests.

### User Adoption

In addition to microbiology analysts, more than 100 QC and manufacturing personnel across age groups and varying educational backgrounds use the MDDA™ System. User adoption was quick and very high. As people started using the system, they immediately 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 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. This not only helps the company, but everyone's job satisfaction as well.

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