Enabling a Healthier World

Lonza

MODA® Solution

Informatics for QC Micro

Eliminate unnecessary time and cost associated with paper-based QC methods.

MODA® Solution

The MODA® Solution delivers a comprehensive informatics platform that automates quality control (QC) processes for all regulated manufacturing in the Life Sciences industry. As a user of the MODA® Solution, Lonza has direct experience with its value – providing improved decision making, regulatory compliance, and productivity across our own global manufacturing facilities.

A comprehensive solution

The MODA® Solution encompasses automation of the full spectrum of QC activities including environmental monitoring (EM), utility testing, and product testing. MODA® Software easily integrates with commonly used instrumentation and media found in manufacturing facilities, specifically production and laboratory areas.

Organizations gain timely and accurate QC monitoring by utilizing location-based scheduling, mobile data collection, and paperless lab processing. MODA® Software also delivers on-demand reporting, trending, and visualization capabilities to allow in-depth process analysis and ad hoc queries by decision makers.

Mobile Data Acquisition

The MODA® Solution integrates with Laboratory Information Management Systems (LIMS) to bridge the communication gap between QC and production.

Components include

MODA-EM® — Lonza's flagship software for paperless EM automates your QC Micro data collection and management (EM, utility, and product test-ing).

MODA-VIP® — Visual Intelligence Portal provides improved insight into your manufacturing operation and testing data.

MODA-FDC® — Field Data Capture lets you quickly collect, label (barcode) and track test samples for EM, utilities, and products at points of sampling within all critical areas.

Sample collection time reduced 50%

The typical paper-based process for a sample collection regiment is roughly about 8 hours per person, per shift. Using the MODA® Solution for sample collection, your process time is cut in half to roughly 4 hours per person, per shift. This savings has significant implications when it is applied to multi technician, multi-shift operation for a one year period.

Fully Equipped

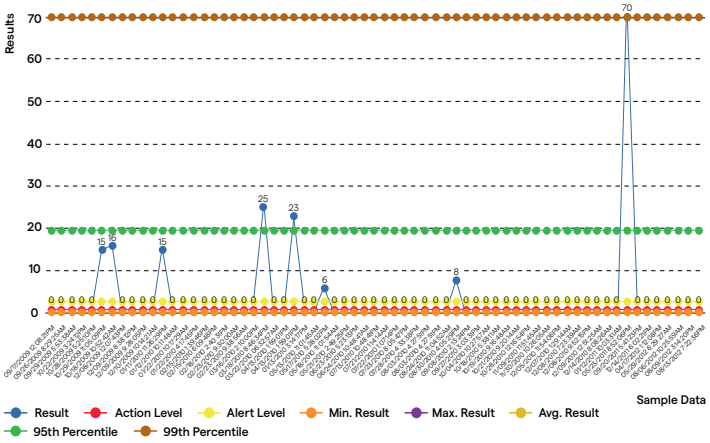
The MODA® Solution is equipped with hardware, software, and implementation services required to get you into production quickly – allowing time and resources to be directed toward higher value initiatives and paths to operational excellence.

Featured: MODA-FDC® Platform

- Stainless steel cart
- Ergonomic tablet PC
- Docking station
- Thermal label printer
- Barcode scanner gun
- Proximity reader for RF badges
- Space for equipment
- Space for growth media

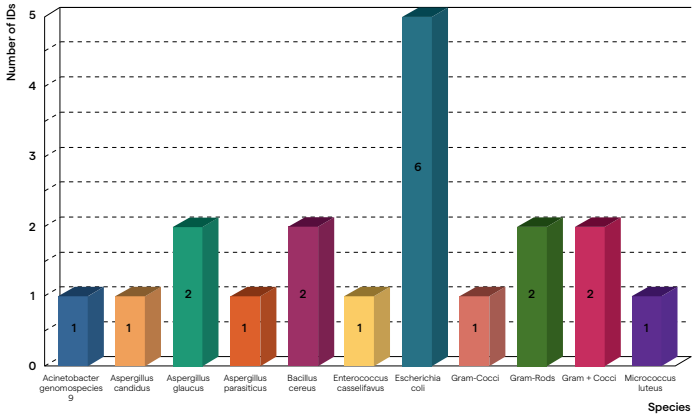
Mobile, field data capture for all critical areas.

Trend »



Visualization Mapping Tool

Enable a correlation of test results with floor plans of your physical facility. This can be easily configured to match the zone classifications on the processing plant floor. MODA® Solution is compatible with facility maps developed with industry standard drawing packages such as AutoCAD® and Visio®.



On-demand Analytics

Tabular Views such as a Deviation Summary report.

Trend Reports for user-selected tests and timeframes.

Gain complete insight into your manufacturing operations.

Quickly access reports and trends on your quality data – at the click of a button.

More Science. Less Paper.®

By combining automated scheduling, workflows, mobile data acquisition, device integration, and advanced analytics, the MODA® Solution delivers efficiencies across your organization.

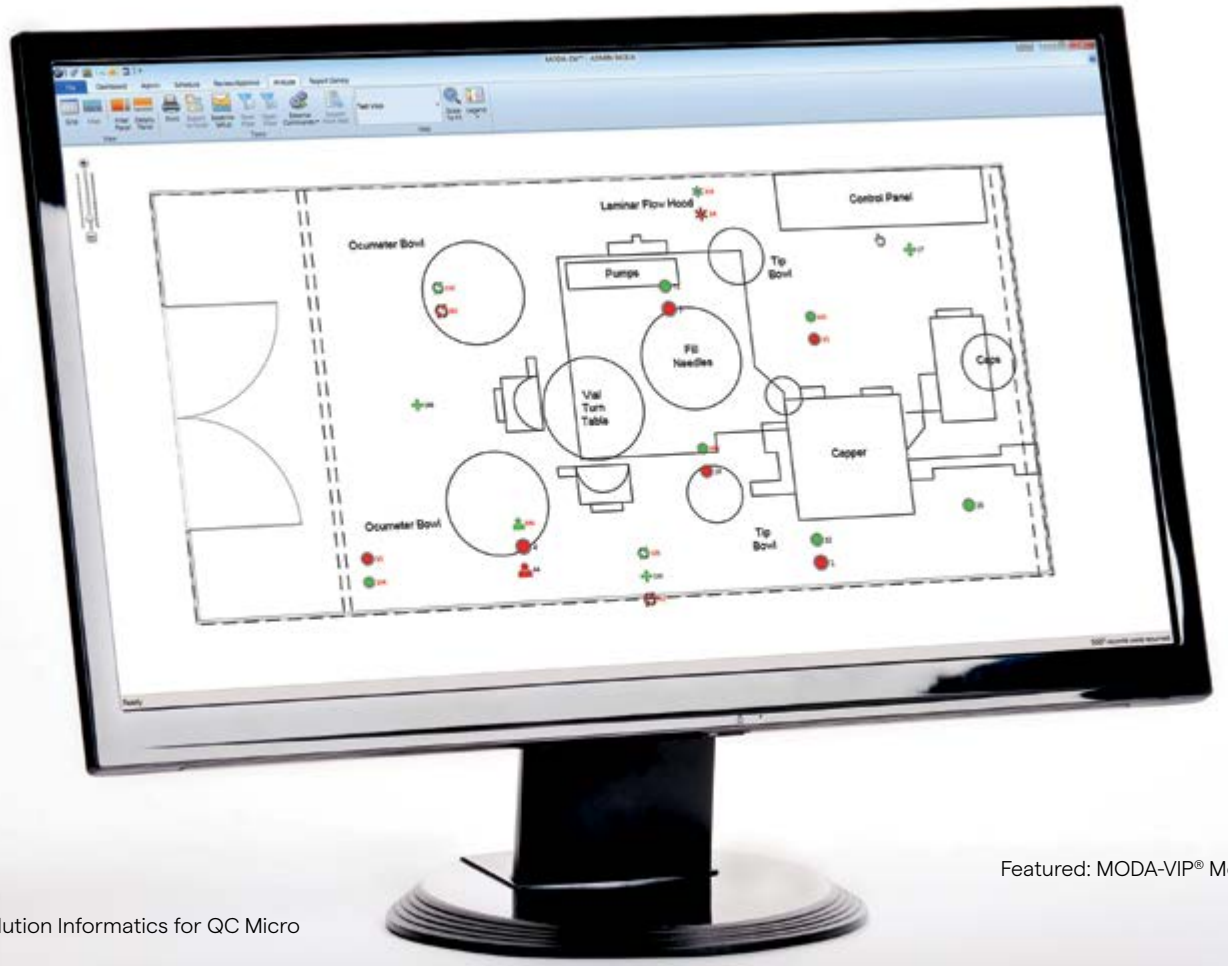
QC Departments are able to:

- Automate data collection from devices and people
- Eliminate redundant data entry and transcription errors
- Gain direct traceability of QC Micro programs
- Increase worker efficiency
- Improve regulatory compliance
- Make sound product quality and release decisions
- Quickly advance Green initiatives

Measurable benefits:

- QC Technicians quickly and accurately collect data in critical areas
- Lab Managers improve process efficiency for scheduling and tracking.
- Supervisors gain immediate, detailed reporting on the production area to enable sound product release decisions, effective investigations, and quick response to audits.
- Executive Management can access longer term trend reports to assess overall program effectiveness.

Visualize »



Featured: MODA-VIP® Module

Without MODA® Solution

Manual, paper-based process steps burden QC Micro programs with paper scheduling, marker labeling of sample media, manual reconciliation, paper log book entry, and manual notification of deviations. Test results are stored in shelves of paper binders – a challenge to quickly navigate during an audit.

For Corrective and Preventative Action (CAPA) purposes, building a set of trend reports can require more than eight weeks. By the time a trend of activity is developed and recognized, the condition causing the trend is likely to have changed – making it difficult to support corrective action activities – and nearly impossible to perform meaningful preventative actions.

A Life Sciences Focus

Across the pharmaceutical industry, problems with product safety and efficacy due to contamination issues make the front page headlines all too often. The cost of a recall due to real or even a suspected contamination event is incalculable when one factors in the risk to consumers and the loss of brand confidence. Lonza is dedicated to helping our clients prevent incidents like this from ever occurring.

Regulating agencies require comprehensive QC Micro programs to demonstrate that processing areas are under control for potential viable and non-viable contamination. However, the traditional paper-based QC Micro processes can be expensive, error-prone, and time and labor-intensive regardless if they are managed by small biotech companies or large pharmaceutical manufacturers.

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