



MEDLINE INDUSTRIES INC. TRANSITIONS FROM PAPER-BASED DATA MANAGEMENT TO STARLIMS QM SOLUTION AND SEES IMMEDIATE RESULTS

Medline Industries Inc. is a global manufacturer and distributor of medical supplies and clinical solutions for healthcare industry customers in more than 90 countries. Founded in 1966, and with global sales of \$13.9 billion, Medline has more than 18,000 employees, dedicated operations in 25+ countries, and 45 distribution centers in North America alone.

Having operated completely paper-based laboratory testing and manufacturing facilities for more than 50 years, Medline selected STARLIMS Quality Manufacturing (QM) laboratory informatics management system (LIMS) as a highly configurable informatics infrastructure that would allow the company to digitize and automate key functionality, data management and instrument calibration recording across laboratories carrying out microbiology testing of medical device, drug and cosmetic samples.

Paper-based data management is unsustainable

Medline realized the need to move away from paper-based data management to enable significant time and cost savings, reduce manual errors, and more seamlessly achieve and maintain regulatory compliance. Complete, automated data management also helps to ensure data integrity and security, enabling more in depth, and insightful comparative data and trend analysis to make critical business decisions. To achieve all this the firm looked for an easily configurable, modular solution that could be shaped for use within different departments.

Not all LIMS are created equal

Medline's search for a laboratory informatics management solution that would meet all its needs, followed on from a previous failed experience with a LIMS that had been implemented to manage stability testing workflows. Unfortunately, within months of installing that solution, Medline realized that the package had many drawbacks. Not least of these, the LIMS didn't achieve regulatory compliance, it was not readily configurable, and any modifications or customizations that were requested took too long to implement and cost too much.

The taskforce established to find a new, more effective LIMS platform for their multi-organization requirements identified STARLIMS as the best solution that would satisfy both long-term expectations, and Medline's immediate requirements for a LIMS that could be implemented across departments, for use by management, analysts, reviewers and administrative personnel.

Key expectations were that in the short term the solution would:

- facilitate regulatory compliance and audit
- save analyst and operator time
- minimize the likelihood of errors in data entry and document handling
- automate data management and storage
- improve data access, searchability and analysis
- ensure data security, integrity and traceability
- enable data trending
- manage inventory

Having selected STARLIMS, Medline’s goal has been to roll out the platform across its testing sites over the course of several months.

Initially implemented for automation of microbiology QC and instrument calibration at four locations – Medline Lab (Mundelein, IL), Hartland (Hartland, WI), Aplicare (Meriden, CT), Excelsior (Neptune, NJ) – STARLIMS has also been implemented at four data user locations: SPT (Waukegan, IL), NPS (Waukegan, IL), ReadyCare (Waukegan, IL), Corporate (Northfield, IL).

Additional sites will be added as rollout continues. Medline expects to start employing the STARLIMS solution for chemistry testing and for batch records management at selected manufacturing facilities in the US, starting during mid-2020.

Immediate benefits from early implementation

Early implementation of STARLIMS for microbiology QC and instrument calibration immediately addressed many of the operational hurdles, and regulatory compliance issues associated with manual, paper-based data management.

“Using STARLIMS instead of paper-based processes has immediately resulted in significantly faster turnaround time to results release for microbiology QC testing.”

Cecil Runyon, Associate Director of Laboratory Operations

Medline sample throughput by key locations

Location	No of samples - 2017	2018	2019
Medline Laboratories (Mundelein, IL)	126,213	158,498	1194,856
Hartland (Hartland, WI)	9,416	15,808	15,816
ReadyCare (Waukegan, IL)	10,444	13,944	28,904
Excelsior (Neptune, NJ)	6,648	7,052	2,188
Aplicare (Meriden, CT)	2,192	1,676	232

Drawbacks of paper-based operations	The STARLIMS solution
Manual data entry on paper is time-consuming, error-prone and may not be complete.	STARLIMS automates data capture where possible, and requires users to input data in predetermined templates to ensure the required information is recorded in the correct data fields.
Spreadsheets, word files and PDFs may not be secure, and it might not be possible to identify or track unauthorized, accidental or intentional changes to or deletion of data.	STARLIMS ensures only authorized personnel can access data and modify information. All changes to data are tracked and recorded, and relevant personnel informed of changes. The system ensures full traceability of all data, and confidence in data integrity and security.
Operators may inadvertently miss essential steps in the workflow and not complete critical stages of data entry into paper forms and documents, spreadsheets or Word files.	STARLIMS ensures that SOPs are adhered to and all necessary data is acquired or entered into appropriate electronic forms and records before allowing the next stage to proceed.
Paper-based files may be lost, misplaced or destroyed.	STARLIMS does not allow unauthorized data deletion. The software automates data storage for security, and ease of access, and alerts relevant users when new documents are available to review.
Paper files, Word documents, PDFs and Excel spreadsheets are flat files that may not be easily found, searched or compared in context.	Data held in STARLIMS repository can be easily searched, retrieved and analyzed by authorized personnel. This improves traceability, for example, when performing out-of-tolerance tests.
Paper files may not be passed to appropriate personnel for checking and authorization prior to starting the next stage in the workflow	STARLIMS automatically sends completed records and files to the right personnel for checking and authorization prior to unlocking next steps in the workflow.

Following implementation of STARLIMS, Medline has witnessed immediate paybacks in terms of time- and cost-saving, and error reduction, together with confidence in data integrity, security, and meeting regulatory compliance. Additional benefits include improved access and reporting, and laboratory and inventory management.

STARLIMS Results

STARLIMS SAVES TIME AND MONEY FOR MICROBIOLOGY QC

An initial assessment of time and money saved through recording microbiology QC data directly in STARLIMS vs. reporting manually on paper data sheets showed that **STARLIMS reduced recording time by up to 17-33%**.

Across two sites processing 90 samples per week – which is a small fraction of Medline’s total sample load – the STARLIMS solution would **save potentially \$2730 per year**.

A comparison of manual typing vs. STARLIMS automation for generating certificates of analysis for microbiology QC samples also indicated that STARLIMS was about **18.5% faster**. For the same throughput of 90 samples per week, these time savings would equate to monetary **savings of \$6678 per year**.

“STARLIMS automatically generates certificate of analysis, so we don’t have to waste time on data entry, and this saves thousands of dollars per year.”

Julia Meyer – Microbiologist II

STARLIMS ENABLES DRAMATIC REDUCTIONS IN DEVIATIONS

The application of automated and SOP-compliant guided data entry directed by STARLIMS similarly enabled dramatic reductions in deviations due to improper recording of data – for example, due to removing samples from incubation late or early, not recording weights, and not logging samples in central receiving. These events can require a sample retest and delay product release by several weeks. **Before implementation of STARLIMS there would be on average 5 deviations per quarter. Following STARLIMS implementation there was just 1 deviation in the quarter evaluated, equating to an 80% reduction.**

“Using STARLIMS we have witnessed an 80% reduction in deviations due to improper data recording.”

Lauren Oesterle – Engineer

STARLIMS SIGNIFICANTLY IMPROVES MANUAL RECORDING ERRORS

STARLIMS also prevented results delays due to errors in the manual recording of information on reagents/equipment, and lot number misreporting. While at least one result would be delayed per day due to manual recording errors, **such errors were essentially reduced to zero after implementation of STARLIMS.**

STARLIMS AUTOMATES INSTRUMENT CALIBRATION DATA MANAGEMENT

Configuration of STARLIMS to automate instrument calibration data management at selected Medline sites, beginning June 2019, **saved an average of 12 minutes per calibration** when compared with manual, paper-based calibration processes:

- **5 minutes saved per calibration (dependent on equipment being calibrated)**
- **5 minutes saved per 25-minute (on average) paper-based review**
- **2 minutes saved per 10-minute paper-based data storage**

For Medline, this equated to financial **savings of \$700 per 100 calibrations.**

By mid-2020, Medline was expecting within the next couple of months to implement STARLIMS for managing the generation of certificates of analysis for instrument calibrations, which would **save an estimated 75% (15 minutes) of the 20 minutes it takes to manually generate a CoA.** The overall **time saved per calibration would then increase from 12 minutes to 27 minutes**, which for Medline would equate to a combined **\$1575 saved per 100 calibrations.**

“Our calculations suggest that we will see a positive return on our investment in STARLIMS within just 3 years.”

Megan Kocanda – QA Specialist II

As the rollout continues and additional sites begin to use STARLIMS, Medline expects to see a positive ROI within just 3 years and continuous returns and cumulative year over year savings thereafter.

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