SCICORD

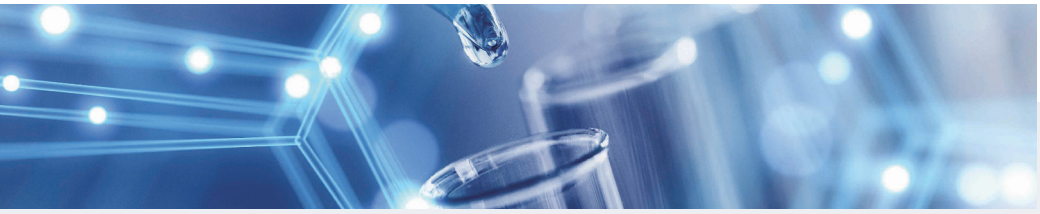
PLATFORM OVERVIEW

2024 UPDATES

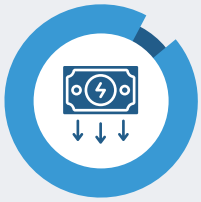
ABOUT US

SciCord strives to establish and sustain a versatile informatics platform that allows scientists to efficiently document and managing their lab data, thereby increasing efficiency, reducing errors and guarantying return on investment.

By enhancing laboratory productivity and ensuring FDA compliance, SciCord provides a data management platform that transforms spreadsheets into a powerful resource for organizing, controlling, structuring, and sharing information



OUR STORY



90%
REDUCED COST OF OWNERSHIP

75%
REDUCED IMPLEMENTATION TIME

30%
EFFICIENCY GAIN

The SciCord story begins when David Strauss, our CEO and founder, was still at GSK. There, he had created an ELN application that increased productivity by 30%.

By introducing a rapid iteration methodology, David gained valuable process insights that led to enhanced efficiency and compliance. Unlike many ELN/LIMS systems, the implementation of these top-quality work process solutions was well-received, resulting in high satisfaction among scientists and strong business retention.

David played a pivotal role in the development of LabWare ELN by defining user requirements, conducting tests, and creating the initial LabWare ELN templates. His career began at Merck, where he implemented LIMS in manufacturing testing labs and devised robotic analytical solutions.

ABOUT OUR PLATFORM

LIMS

Essential data management, tracking, and workflows for compliant pharmaceutical organizations

ELN

Laboratory data management, security, collaboration, compliance, and efficiency

SAMPLE MANAGEMENT

Maintain the integrity, traceability, and accuracy of laboratory sample

INVENTORY MANAGEMENT

Manage chemical & supply inventories for efficiency, integrity, chain of custody and full traceability

EQUIPMENT MANAGEMENT

Ensure a complete record of equipment events and a usage log of where and when the equipment was used

ABOUT OUR SOLUTIONS

The SciCord platform provides labs with a wide range of features and capabilities meant to make their work easier AND more efficient. Each of these solutions is built by a team of experienced scientists and software developers who understand the unique challenges faced by laboratories.

Unlike other offerings, all of these solutions are provided using a single application that ensures consistency, improves productivity and reduce training requirements.

By combining scientific expertise with technological innovation, SciCord creates tailored solutions that streamline lab processes, improve data management, and enhance overall productivity. From Electronic Lab Notebooks to data visualization tools, SciCord is dedicated to supporting labs in their quest for groundbreaking discoveries.

With a commitment to excellence and a passion for scientific advancement, SciCord is the trusted partner for labs seeking to optimize their operations and achieve their research goals.

Our solutions include:

1. Batch records for error prevention
2. Environmental monitoring
3. Stability program management
4. Next generation sequencing
5. Chromatopgraphy
6. Mass Spec
7. Inhalation development
8. Formulation

AUROBINDO CASE STUDY #1

AUROBINDO UTILIZES THE SCICORD PLATFORM FOR SUCCESSFUL GENERIC FILING

Fast-Tracking Regulatory Approval: Aurobindo's Journey with SciCord's Lab Digitization

BENEFITS

Using SciCord Informatics Platform, Aurobindo lab information was digitized to facilitate compliance

1. Data integrity measures for data entry, review, audit trails, data backup, data security, and electronic records management.
2. Controlled document (notebook/experiment) lifecycles guarantee that laboratory records are authored, reviewed, and approved as required.
3. Minimum 30% increase in reviewer efficiency results in timely document reviews.
4. Process execution modules ensure strict adherence to step-by-step processes and comprehensive recording of all required information.
5. Efficient management of instruments, equipment, and chemical inventory.
6. Streamlined training management (curriculums and records) for teams with variable skill levels.
7. User-friendly interface with scalability for large and small teams.
8. Analytical Execution Systems (DDU, NGI, Moisture, Leak Rate)
9. Quality Documentation (Change Control, Test Methods, protocols, investigations, deviations)
10. Validation Materials (Requirements, Risk Assessments, IQ, OQ, PQ, Validation Plans and Reports)

SITUATION

Aurobindo, a multinational pharmaceutical manufacturing company headquartered in India, operates across 15 locations spanning 5 countries, with a focus on pharmaceutical manufacturing and R&D. With a workforce of over 1,560 scientists, Aurobindo boasts in-house expertise in product development areas including API, peptides, custom synthesis, and formulations for oral, injectable/parenteral, and ophthalmic delivery systems

In 2016, Aurobindo embarked on a significant endeavor, establishing a new department dedicated to developing generic inhaled formulations. This move positioned Aurobindo to compete in the competitive generic inhaled formulations market, challenging established brands. However, the venture came with its unique set of challenges. Regulatory hurdles loomed large, requiring Aurobindo to demonstrate bioequivalence, in vitro-in vivo correlation, and navigate complex intellectual property laws and stringent quality standards. Moreover, ensuring therapeutic interchangeability and addressing patient usability added further complexity to the competitive landscape, necessitating speed and cost-effectiveness.

Overcoming these obstacles demanded strategic investment in scientific research, regulatory expertise, and market differentiation strategies, all while maintaining stringent regulatory compliance and quality assurance standards.

> We have been audited by FDA twice and they had no concerns about the system nor any findings
>
> **Deb Carr**
> Director, IPD

CHALLENGES

Prior to SciCord implementation, Aurobindo relied entirely on manual processes, leading to:

1. Increased risk of errors and compromised data integrity.
2. Inefficient paper-based document management, hindering control over document lifecycles.
3. Anticipated influx of new scientists requiring extensive training, posing potential sources of error and non-compliance.
4. Limited scalability of manual systems for growing operations.
5. Crucial need for quality data generation "right the first time," vital for analyzing clinical material, ensuring stability, and supporting regulatory filings.

IMPACT

The ability to develop and gain regulatory approval for an inhaled product would positively impact the company's bottom line and would likely determine the future of the new development group.

Digitized data was easily identified and produced for audits.

Controlled review and approval of notebooks guaranteed adherence to defined process.

Implementation of lab execution processes ensured all required information was recorded and minimized the training required for new staff.

Pearl CASE STUDY #2

PEARL THERAPEUTICS LEVERAGES THE SCICORD INFORMATICS PLATFORM FOR REGULATORY FILING

Unveiling 3x Efficiency Gains at a Fraction of the Cost with SciCord Informatics Platform

BENEFITS

Through the implementation of the SciCord Informatics Platform, Pearl Therapeutics' teams realized significant advantages:

1. Enhanced review process efficiency by over 30%
2. Achieved a 3x increase in efficiency compared to previous solutions
3. Successfully navigated FDA filings and audits
4. Fostered collaborative review processes across multiple sites
5. Enabled seamless remote work capabilities during the challenges posed by COVID-19 and other life events

SITUATION

In 2015, Pearl Therapeutics was a small company developing novel inhaled formulations. As a small company, Pearl was resource constrained and needed to increase laboratory throughput and then perform trending and visualizations on the data to guide development.

CHALLENGES

1. The delivery mechanism would be a metered dose inhaler (MDIs) and would involve multiple physical constituents, an aerosol propellant, and the active drug(s).

2. Each constituent represents a variable to be characterized in the development process and would require many formulation batches and stability trials.

3. Sample preparation for some analysis is complex with test results potentially influenced by analysis bias.

4. Simulating the lung entails complex calculations. To perform these calculations, data would need to be transcribed from instrument reports to bespoke software.

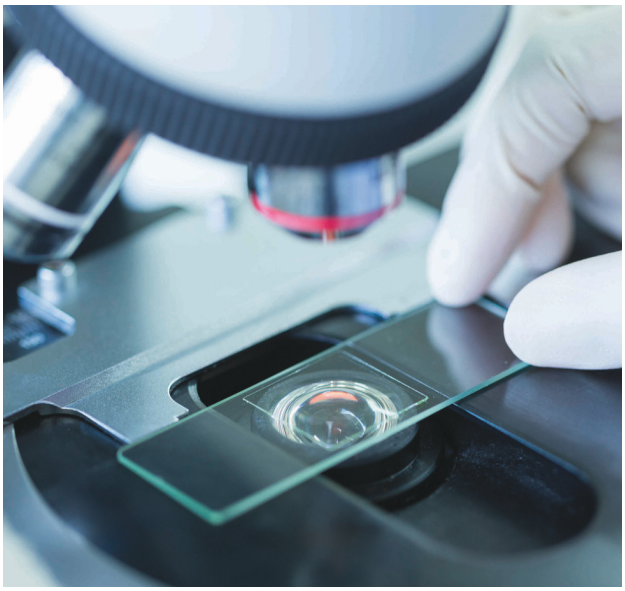
5. Trending and visualizations are key to understanding the impact of formulation and stability data. The data would need to be searchable and available for SQL query by Spotfire & JMP.

SciCord was contacted based on a previously successful inhaled data management solution at GSK by SciCord's founder.

IMPACT

The success of Pearl Therapeutics pivoted on a seamless regulatory filing process. The adoption of SciCord brought forth profound effects:

1. Validated solution integration across all operational functions.
2. Structured data and custom reports enabled robust trending and visualization capabilities.
3. Streamlined instrument interface for enhanced data management.
4. The review process saw a remarkable efficiency improvement of over 30%.
5. Efficiently managed operations across two geographical sites on the East and West coasts of the USA.



01 Formulation Support → **02 Analytical** → **03 Clinical Manufacture** → **04 Quality Control**

ELN
- Sample Prep
- Standards
- Instruments Interface
- Calculations
- Formulation Support

LIMS
- Sample Management
- Structured Results
- Reports
- Visualization

SDMS
- Instrument Reports
- Raw Data
- Misc.

eBR
- Clinical Manufacture
- Raw Materials

LES
- QC Work Process
- QMS Interface

CASE STUDY #3

TRANSFORMING EXISTING SPREADSHEETS INTO A PRODUCTION-GRADE SYSTEM

A Case Study in the SciCord No-Code Method
Transform Existing Spreadsheets into a Production-Grade System

BENEFITS

1. Quick implementation and Ease-of-Use for lab personnel.
2. Use of existing spreadsheets and processes.
3. Enhancements/Upgrades and testing performed quickly.
4. Compliance and Validation Materials (Requirements, Risk Assessments, Validation Plans and Reports)

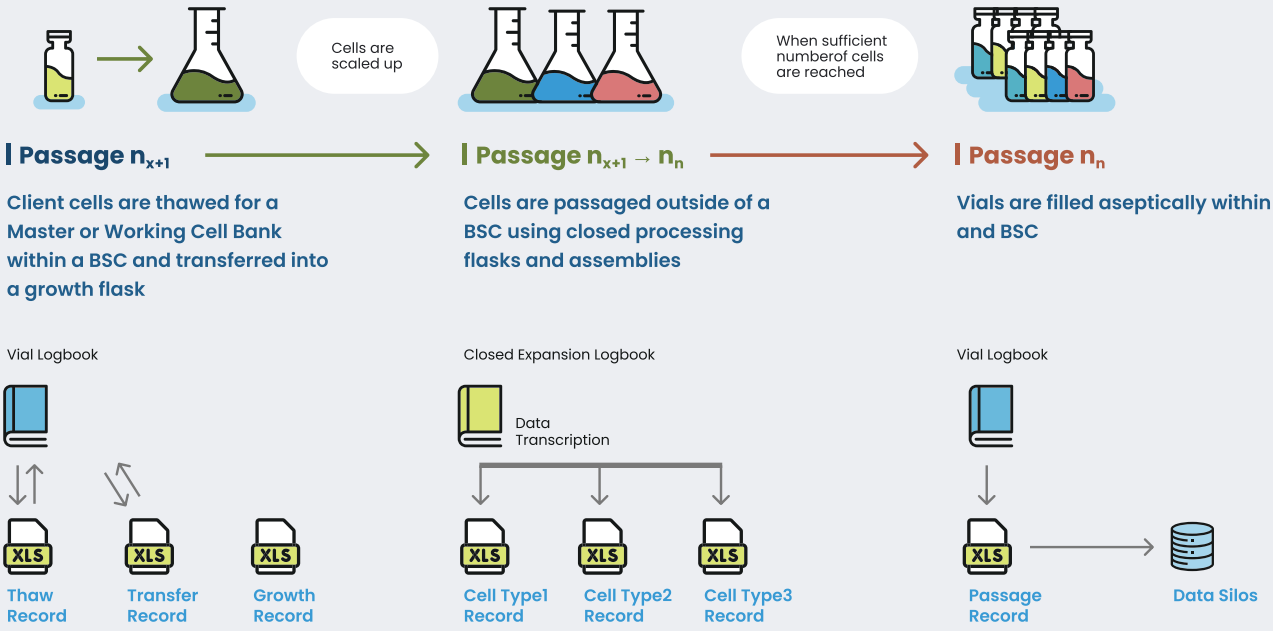
SITUATION

In May 2022, a customer embarked on plans to optimize their operations, implementing a closed expansion process.

The aim of the closed expansion protocol was to enable the simultaneous expansion of multiple products within a single facility, eliminating concerns about cross-contamination through airborne particles.

The new process introduced the risk of inadvertent contamination when similar flasks containing different products were present in the same room.

To address this issue, the scientists devised a spreadsheet-based batch record system. This solution not only managed the expansion process but also ensured proper segregation of products. However, it fell short of compliance standards.

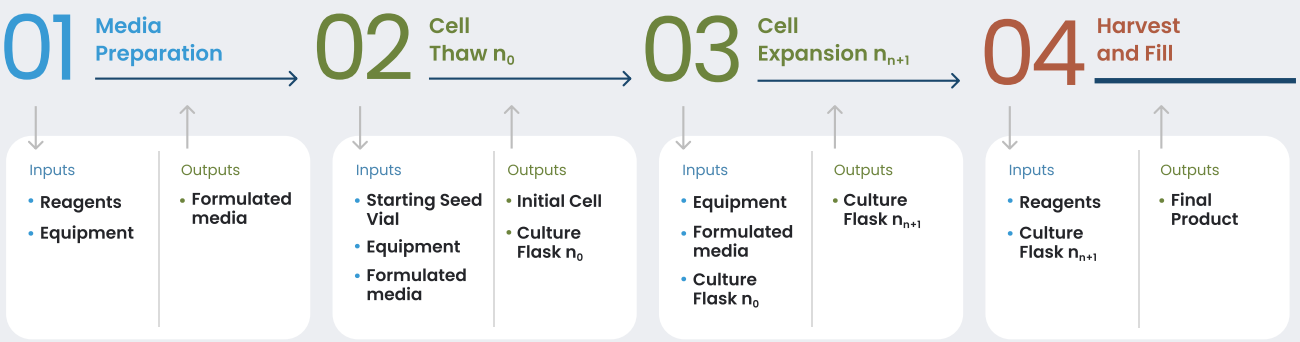


IMPACT

The closed expansion process was scheduled to be implemented for production in 2023, necessitating a compliant and robust flask management process.

OUTCOMES

This customer joined forces with SciCord to transform their existing spreadsheets into a production-grade batch record system. This transformation involved the development of several modules to digitize all aspects of the process:



To initiate the batch record development process, the engineers provided SciCord developers with one or more workbooks. The workbooks laid out the process steps and defined the flow of materials and required calculations. The workbooks form the basis of the module and are integrated with LIMS.

In a matter of days, the first iteration of a process is implemented (plug and play) in a test environment for review by the engineers. Typically, 2-4 iterations of each module are required to finalize the process. Each module can be developed and ready for documentation and testing in just a few weeks.

CASE STUDY #4

FORMULATED SOLUTIONS ACHIEVES OPERATIONAL EXCELLENCE WITH SCICORD

A Case Study of LIMS Implementation Requiring Harmonization Across Multiple Sites and Facing a Tight Schedule

BENEFITS

1. Reduced Operational Cost:
   Transitioning from a product offering similar functionality but requiring higher operational costs resulting in savings of $360,000 per year.

2. Streamlined Operations:
   Centralized data management and automated task workflows, boosting operational efficiency for Formulated Solution leading to accelerated turnaround times and heightened productivity.

3. Regulatory Confidence:
   Built-in compliance features assure Formulated Solutions adherence to industry regulations and standards, ensuring continuous regulatory compliance. Elimination of errors associated with manual data entry.

4. Unified Performance Across Sites:
   Harmonization across production sites, ensures consistent testing procedures and data management practices, optimizing efficiency and facilitating collaboration

"

I have been involved in four stability migrations and this has been the easiest"

Jackie Linder
Supervisor, Stability Services | Formulated Solutions, LLC

SITUATION

Formulated Solutions faced challenges in their laboratory data management processes, grappling with inefficiencies and inconsistencies across their operations. The headquarters Largo site utilized spreadsheets and paper solutions while the newly acquired Cleveland lab operated a legacy LIMS.

Despite this discrepancy, both sites were responsible for conducting similar tasks in environmental and water monitoring, requiring precise data management and regulatory compliance.

An essential aspect of addressing these challenges was the harmonization of operations between the Cleveland and Largo sites.

A motivating factor for the transition was Cleveland's dependence on an expensive legacy LIMS with the lease due Jan 2024.

Substantial savings would accrue if processes and data were migrated prior to this date.

Failure to configure the new LIMS system before the lease date would result in having to renew their old LIMS system at a considerable cost, making it imperative to implement the new system before the lease renewal date.

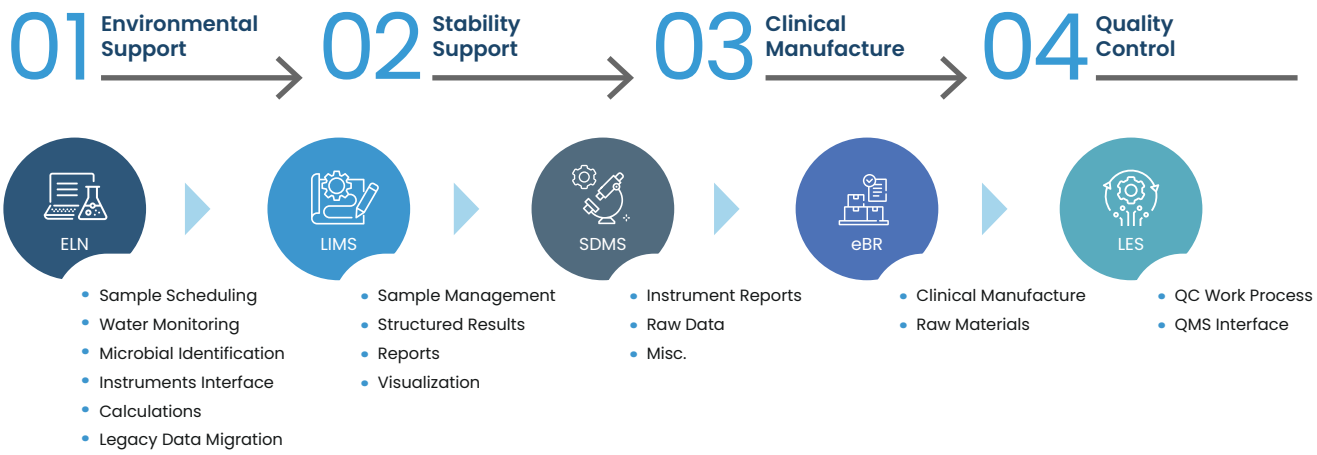
CHALLENGES

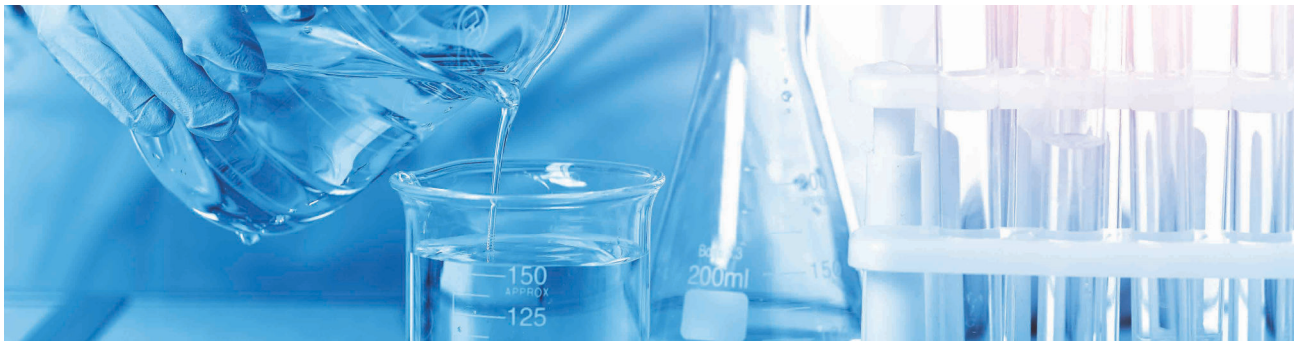
Formulated Solutions encountered and overcame several challenges in implementing SciCord LIMS across multiple sites:

1. Tight Schedule:
   The project faced a strict timeline, with the contract signed Aug 2023 and full transition for Cleveland site scheduled for January 2024 to avoid having to renew legacy LIMS.

2. Diverse Workflows:
   Processes at the Largo site used a combination of paper and spreadsheets while the Cleveland site utilized a digital approach with known inefficiencies and challenges. While reports and stability testing were consistent across sites, analysis was required to understand the "As Is" situation and define a harmonized "To Be" model for each site.

Bridging Expertise Disparities: The Cleveland and Largo sites faced a disparity regarding digital ways of working. The Largo site without any previous LIMS experience required a crash course in managing processes electronically. The Largo site had digital expertise albeit with an outmoded LIMS solution which was an advantage but also created confusion in the team due to inefficient legacy processes.





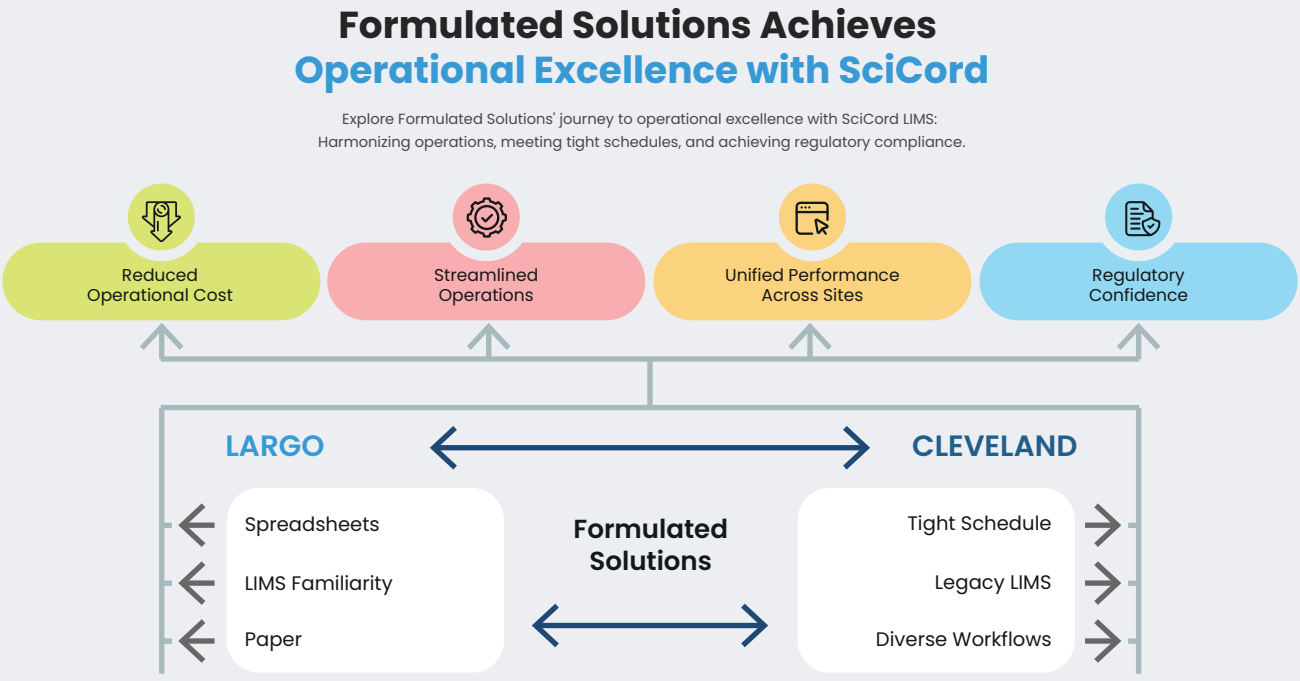
OUTCOMES

The SciCord team was able to successfully achieve timely completion of the project, aligning with Formulated Solutions' tight schedule and saving significant costs associated with renewing their legacy LIMS.
Harmonized digital processes were achieved resulting in enhanced efficiency and streamlined operations across Formulated Solutions' Cleveland and Largo sites.

Formulated Solutions previously relied on outdated LIMS systems and manual spreadsheets, which posed challenges common to many organizations dealing with legacy systems.
SciCord Informatics Platform provided flexibility to integrate with existing spreadsheets and processes. SciCord adaptability overcame constraints imposed by legacy systems while retaining the valuable aspects of their previous workflows and gaining efficiency throughout the organization.

As you evaluate your organization's needs, consider the practical benefits of the SciCord Informatics Platform in optimizing your laboratory data management processes, particularly across multiple sites. Whether you're grappling with disparate workflows, differing levels of digital experience in your team, or regulatory compliance challenges, SciCord LIMS capabilities offers tailored solutions to drive efficiency and productivity.

Contact us today to discover how SciCord LIMS capabilities can align with your organization's goals and empower your team to achieve operational excellence.



WANT TO LEARN MORE?

Contact us today and let's talk

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