LabVantage®

A CASE FOR THE PURPOSE-BUILT LABORATORY INFORMATICS SYSTEM

Positioning Your Pharmaceutical Lab for Success

FROM THE EXPERTS

According to Michael Shanler, Analyst, Gartner, "If the situation presents itself, take the opportunity to reduce the footprint of legacy ELN and LIMS systems, consolidate them into one system that is more suitable for expansion with the enterprise, and extend it to collaborators and supply chain partners."[1]

– Gartner

WHY A PURPOSE-BUILT LIMS?

The Data Management Challenge

A successful lab is more than a scientific hub. In today's age, it's a digital data enterprise. An oil and gas lab managing hundreds of concurrent tests, a food and beverage lab tracking incubation in real time, a cannabis lab with a vast and complex inventory of samples – it's all data. And it grows exponentially day by day, week by week, creating an urgent need for an integrated informatics platform where that data can be securely and efficiently stored, retrieved, and analyzed.

But should that platform be one-size-fits-all across industries? A pharma lab needs regulatory documentation, while a diagnostics lab requires advanced tracking of biospecimens. Traditionally, each would begin with the same basic building blocks: a Laboratory Information Management System (LIMS) with standalone point solutions such as an Electronic Laboratory Notebook (ELN) or a Laboratory Execution System (LES) daisy-chained together to approximate an end-to-end solution. Then, through a complex à-la-carte development and validation process, each of these labs would customize their platform in response to their divergent needs. Repeated for every organization, across every industry, this bulky deployment process represents an enormous amount of cost and effort, and a considerable degree of risk.

Until now.

The Case for a Pre-Configured, Fully Integrated Solution

A purpose-built LIMS, with the option to embed ELN, LES, and other modules, leapfrogs the lengthy customization process. Because your industry's best-established workflows and operating procedures determine its functionality, your platform is configured to meet your needs before you've even begun. The advantages of this accelerated start are numerous and notable.

1. Save Time

A pre-configured LIMS can deploy up to 75% faster than a more typical LIMS system. Its purposeful functionality reinforces a consistent, industry-standard workflow to help your lab achieve greater efficiency and productivity.

2. Save Money

Faster deployment and improved functional efficiencies translate to significant cost savings. Abandoning stand-alone ELN and LES products and other point solutions in favor of pre-packaged, fully embedded modular capabilities in one streamlined platform will help you maximize your return over time.

3. Reduce Risk

A purpose-built LIMS reflects industry best practices and the latest regulatory and compliance developments within your industry. As a result, it eliminates the need for custom code and reduces the overall configuration effort, thereby lowering the risk inherent with other LIMS projects.

4. Stay Focused

Lab managers can conceal or disable non-essential functionality in the purpose-built LIMS. The result is a user experience that's responsive not just to your industry, but also to the specific needs and use cases of your front-line staff. That means less training time, greater productivity, and better quality overall.

5. Future-Proof Your Business

Industry regulations and conditions change over time, and your lab will likely change too – you may add new service areas, new tests, or new users as you grow. A modular, purpose-built LIMS that makes use of industry-standard web technology can expand with you, from startup labs through global operations, without the prohibitive time, cost, and compliance issues of specialized coding.

Built Better for Pharmaceutical Labs

In an industry under intense scrutiny, compliance begins and ends with the right technology.

Traceability and compliance guidelines are more stringent for labs in the pharmaceutical space than in many other industries. This is particularly true as regulators turn their focus to the question of temporary memory. In 2014, the WHO updated its position on data integrity within its Guidance on Good Data and Record Management Practices report; before long, the FDA and the MHRA followed suit with draft guidance that calls for the permanent capture of all data generated to satisfy a CGMP requirement, including data in temporary memory.

For drug manufacturers reacting to these changes, the writing is on the wall: tighter data integrity standards are here, requiring new tools, training, and SOPs. LabVantage Pharma is the first and only informatics platform specifically configured to meet this need.

The web-based platform's new data auditing functionality joins a suite of built-in features already optimized for pharmaceutical labs. And because it's pre-validated following GAMP 5 guidelines and pre-configured for industry-standard testing activities, its implementation time is significantly less than that of traditional systems.

The result is a compliant-ready pharmaceutical LIMS that labs can implement in as few as three months, providing accelerated access to advantages like:

Data Auditing Functionality Compliant With Emerging Data Integrity Standards

LabVantage Pharma includes Dynamic Auditing, a tool purpose-built to help drug manufacturers adhere to existing and proposed data integrity guidelines from the FDA, the MHRA, and the WHO. Labs can use the tool to capture a clean, complete, GxP-compliant audit trail that includes:

- All changes in data
- Changes in temporary memory (entries made before saving data)
- Identity of person entering the data
- Date and time of data entry
- Electronic signatures and mandatory reason for changes

Built-In Documentation to Help You Validate Your System – and Keep It Validated

LabVantage Pharma is the only pharmaceutical LIMS solution on the market that provides complete documented evidence of previous validation execution, from user requirements to IQ/OQ/PQ and final system release.

And because it comes pre-packaged with pharmaceutical-specific functionality, labs save time and money in two ways: they don't need to apply heavy configurations to a generalized system, and they don't need to write and execute validation scripts to match those configurations. The testing and quality team behind LabVantage Pharma has already done that work using GAMP 5 guidelines. That means labs can easily and smoothly continue the validation exercise as needed, according to their own processes.

Optional LES to Enforce Consistency and Avoid Expensive Mistakes

The enterprise-level LabVantage LIMS solution is at the foundation of LabVantage Pharma; many of its functions are turned off or concealed to focus the user experience on activities that are pharmaceutical-specific, but those functions can be reactivated or added on as needed.

One example is the LabVantage Laboratory Execution System (LES). It's embedded right inside the platform, giving lab managers a streamlined tool for defining, documenting, and enforcing method work steps. With support from the LES, analysts are able to perform tests consistently and according to internal SOPs, avoiding wasted effort or costly do-overs.

The Accelerated Implementation Experience

Choosing a purpose-built LIMS is like strapping a rocket booster to the implementation process. It means much of the background work is complete before you even begin, giving you a head start without sacrificing consistency, compliance, or performance.

IF IT'S DONE IN A PHARMA LAB, IT'S INSIDE LABVANTAGE PHARMA.

The system leapfrogs time-consuming configuration activities by including pre-packaged, pharma-specific features and functions. A sampling of these features includes:

- Lot and batch management (complete lot genealogy and quality dispositioning)
- Stability testing and inventory management
- Full sample life cycle management
- End-to-end workflow with reporting and charting
- Management by exception using automated calculations and specification checking
- Consumables inventory tracking including reagents and standards
- Scheduling of environmental monitoring samples
- GLP

Here's how the LabVantage implementation process compares to a typical implementation experience.

A Typical LIMS Implementation	LabVantage LIMS Implementation
Minimum 12 months to deploy	*Deploys in as few as three months*
A massive up-front investment drives this deployment process, which begins with a detailed discovery and documentation of user needs and progresses through multiple design iterations and testing phases. Heavily customized and configured systems introduce risk and its corresponding compliance requirements, necessitating a significant investment in validation and test planning. Once fully customized and compliant, the system is ready for use – but only after a significant investment in training for all users and administrators. Training timelines are contingent on the complexity of customization and are often a significant factor in typical deployment costs. When updates are required after deployment, the vendor must be involved for specialized customization and/or installation, further adding to the costs and time required to maintain performance.	Because this system is already configured for your industry using established industry best practices, the implementation process is much more efficient. Data templates are integrated and the products and functions most commonly relied upon by industry-specific users are engaged and ready. If further configuration is required, the system's modular design is easily adaptable without code; ongoing updates and enhancements require no specialized skill or outside management.

Run Your Digital Enterprise with LabVantage

Across industries, every successful laboratory functions at the nexus of talent and technology: the right people using the best, most streamlined tools. And as the market's leader in modern and efficient LIMS solutions, LabVantage is essential to that winning formula. Here's why.

The Best and Most Secure Technology in the Industry

Our feature-rich LIMS is completely web-hosted, giving networked users access to the same information from one secure, easy-to-use system – whether they are in the same lab or across the world. Hosted on-premise or in the cloud, the system also connects labs with third-party contributors outside of their firewall, like manufacturing partners or research organizations, allowing for harmonized data input through a single platform.

A System that Adapts to Your Needs – Without Code

Our purpose-built LIMS features a modular design that invites further configuration and adaptation without specialized coding skills. Users can configure their platform themselves or rely on our global professional services team to do it; both scenarios reduce the cost, effort, and complexity of additional testing and compliance.

A Fully Interoperable Experience From Start to Finish

No more siloed informatics systems for individual use cases within a product life cycle. Our system interconnects your processes within a single, central hub, meaning that documentation generated during early R&D explorations is consistent throughout manufacturing and final quality assurance testing. The result is a more efficient lab with fewer opportunities for risk, leading to a stronger business performance overall.

A Professional Support Team in Lockstep With Your Needs

From deployment through validation and ongoing monitoring, our global professional services team of solution engineers, business analysts, and project managers offer consistent and top-rated support services. We seek to become more *partner* than *vendor* through our managed services offering; for example, our team will regularly monitor, optimize, administrate, and enhance your system, giving you greater confidence and more control over your IT and labor costs.

Conclusion

LabVantage Pharma helps pharmaceutical labs maintain data integrity standards while operating consistently and efficiently.

Enhance your pharma lab with the full-featured, entirely web-based informatics platform designed specifically for success in your industry.

TAKE ADVANTAGE of LabVantage Pharma at LabVantage.com/pharma

REFERENCES

[1] Gartner, "Hype Cycle for Life Sciences, 2018", Published 25 July 2018, Analyst(s): Stephen Davies, Michael Shanler, Jeff Smith

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ABOUT LABVANTAGE SOLUTIONS

LabVantage is the recognized leader of enterprise laboratory software solutions with over 35 years of experience. We deliver an integrated laboratory informatics platform including laboratory information management systems (LIMS), electronic laboratory notebooks (ELN), and laboratory execution systems (LES). We support more than 1500 customer sites in the life science, pharmaceutical, medical device, biobank, food & beverage, consumer packaged goods, oil & gas, genetics/diagnostics, and healthcare industries. Headquartered in Somerset, N.J., LabVantage offers a comprehensive portfolio of products and services that enable companies to innovate faster in the R&D cycle, improve manufactured product quality, achieve accurate record-keeping, and comply with regulatory requirements. The LabVantage integrated LIMS/ELN/LES platform is highly configurable, purpose-built, and 100% web browser-based to support hundreds of concurrent users and seamlessly interface with instruments and other enterprise systems.

For more information, visit www.labvantage.com.