sapio sciences

Cutting Through the Hyperbole:

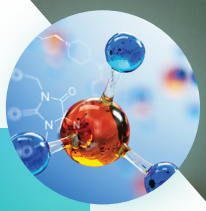
Understanding the DNA of a Unified Laboratory Informatics Platform

PRODUCT

Inflexible | Inefficient | Siloed

PLATFORM

Flexible | Scalable | Open



Introduction

Knowing the difference between a platform and a product is essential to ensuring the capability, flexibility, and extensibility for best-in-class laboratory operations now and in the future.

The term ‘platform’ is often misused in scientific software, especially when a vendor implies that its ‘product’ has greater capability, flexibility, and extensibility than it possesses. Mistaking a product for a platform can severely limit anticipated useability and extensibility, resulting in wasted time, additional cost, and extreme disappointment. This paper describes the **difference** in a laboratory application (i.e., product) and a laboratory informatics platform; the **benefits, advantages, and capabilities** of the latter; and poses **ten questions** you should answer to determine and select a genuine informatics platform for your laboratory operation.

What We’ll Cover

The Difference Between a Product and a Platform

A software product is a collection of features designed to meet a specific scientific application with limited extensibility (i.e., easy modification by changing or adding features). A platform is more extensible and much broader in scope. It serves as a foundation for multiple scientific software applications (products) to operate in a coordinated manner, and it provides a unified user experience and greater ability for real-time modification by scientists — without IT assistance — to meet the evolving, dynamic activities of a scientific laboratory.

Laboratory informatics — technology hardware (i.e., tools) and software employed for data collection, management, and analysis in a laboratory environment — is an area where platform is often confused with product and thereby misconstrued. For example, a Laboratory Information Management System (LIMS) and an Electronic Laboratory Notebook (ELN) are scientific software products. While they may share a few overlapping features, each serves a different, specific laboratory application.

The ELN was initially developed as a software application to replace the paper notebook used by laboratory scientists. As with a paper notebook, a scientist can use it to enter protocols, make notes, and record observations.

Advantages of an ELN, over a paper lab notebook, include better data management and security, collaboration, and auditing. ELNs were initially application specific (e.g., analytical chemistry, synthetic chemistry, biology, etc.). Capabilities have evolved to multi-discipline, enterprise scope, but extensibility is limited and performance across disciplines can be uneven and erratic.

As the name implies, a LIMS serves primarily to manage the collection and analysis of information (i.e., data), from laboratory tests. In a modern laboratory, the LIMS serves several core functions which include workflow automation, sample management, instrument integration, data management, and reporting. As with an ELN, the functional scope of the LIMS has expanded beyond its initial core, but extensibility is still limited.

While both an ELN and LIMS are powerful products, neither is, in and of itself, a laboratory informatics platform. Furthermore, simply connecting a disparate collection of product applications together doesn't transform them into a platform. Rather, a laboratory informatics platform and the associated product applications must be developed from a common vision and architectural foundation. This is the DNA of a unified laboratory informatics platform.

The Benefits and Advantages of a Laboratory Informatics Platform

A unified informatics platform provides multiple benefits to laboratory scientists with significant advantages over application-specific products, such as:

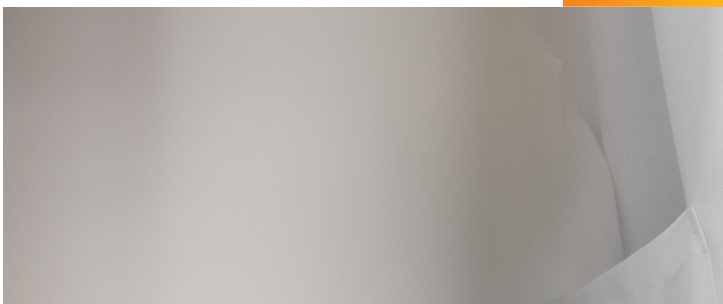
A foundation to seamlessly unify the functionality of essential product applications — ELN, LIMS, and Scientific Data Management System (SDMS) — across the laboratory test enterprise.

Access to the functionality of application-specific products with a unified user experience across all laboratory test activities — from request and initiation through all aspects of test operations to reporting.

A single, unified view of and access to all test information (i.e., a single source of truth) by every scientist in the laboratory to foster collaboration, avoid miscommunication, and accelerate the delivery of complete, accurate test results.

Quick and easy modification of laboratory workflows by scientists without the need to learn a coding language or wait for assistance from IT.

Timely availability and easy accommodation and integration of new, cutting-edge tools and techniques driving today's rapid advances in diagnostics and therapeutics, such as multimodal discovery, CRISPR editing, and artificial intelligence (AI) — just to name a few.



The Essential Capabilities of a Laboratory Informatics Platform

To achieve the benefits and advantages listed above, a unified laboratory informatics platform must integrate the following capabilities:

A common platform for end-to-end laboratory applications

The ELN, LIMS, and SDMS should be developed on a common software platform to ensure seamless, unified functionality across all laboratory activities — from request and initiation through all aspects of test operations to reporting. Without a common platform, 'seamless' functional integration may be difficult, problematic, or even unobtainable.

Configurable, extensible instrument integration

The scope and ability of instruments are continually evolving and expanding to deliver more advanced test capabilities. A laboratory informatics platform should provide up-to-date, standardized workflows out-of-the-box that can be deployed quickly and easily for bioanalysis, stability testing, NGS, and other specialized needs. Additionally, a lab scientist should be able to make modifications rapidly to define unique data concepts, design custom experiments, orchestrate complex workflows, and more. And the vendor should have a reputation of timely, continual upgrades to quickly utilize instrument advancements.

Self-service modification and customization without code

A scientist should be able to modify or customize laboratory processes and workflows without writing a single line of code or requesting assistance from IT. A native-language, rules-based engine using simple if-then statements can be used to define a wide range of actions including field settings, process tracking, instrument file generation, and user or group notifications. This allows lab scientists to efficiently configure processes and workflows in real-time, improve day-to-day operations, and enhance data analysis and reporting.

Open framework for seamless integration with existing systems

Integrating external systems and applications beyond the informatics platform can be essential to synchronize data, automate processes, and achieve smooth cross-platform interoperability. The informatics platform should include several interface and communications options including a RESTful application programming interface (API) — the de facto standard for life sciences software, Webhooks to enable real-time communications with web applications, and, ideally, a range of pre-built plugins to streamline common integration tasks and enhance customization capabilities.

Multimodal discovery workflows and registration

Over the past few years, revenues from new-modality products increased by $60 billion, while revenues from conventional products declined by $10 billion, according to BCG. Furthermore, the percentage value of new modalities in the five-year forward pipeline between 2019 and 2023 are projected to increase from 41% to 56%, far outpacing conventional ones. New modalities, such as recombinant proteins, peptides, and engineered antibodies are key drivers of biopharmaceutical industry growth, requiring small-molecule, large-molecule, and multimodal discovery workflows, including entity registration, on a single, unified platform.

Built-in advanced technology

Generative AI holds great promise to transform and accelerate drug discovery. The McKinsey Global Institute (MGI) has estimated that the technology could generate $60 billion to $100 billion a year in economic value by accelerating the process of identifying compounds for potential new drugs and speeding their development and approval. Generative AI accessed through a simple chat interface built into a unified laboratory informatics platform can leverage large language models (LLM) to rapidly create experiments, search and visualize data, and generate code as requested. Other advanced capabilities that should be accessible from the platform include CRISPR editing, plasmid design, and flow cytometry.

Security

Today, data is global. As such, it must be provided the highest level of protection in accordance with comprehensive global information security and data privacy standards. SOC 2 Type II certification, ISO 27001, HIPAA, EU-US Data Privacy Framework (DPF), and EU General Data Protection Regulation are safeguards required to assure data confidentiality, integrity, and availability.

Regulatory compliance

A laboratory informatics platform should be certified for Good Laboratory Practices (GLP) for basic research and Good Clinical Practices (GCP) for clinical research to ensure that data generated is of the highest quality leading to better and more effective research outcomes. GxP certifications may vary depending on the regulatory body, although efforts have been made by many of them to harmonize requirements. Applicable regulatory bodies and certifications include ISO/IEC 17025, FDA GLP compliance, OECD principles of GLP compliance, EPA GLP compliance, MHRA GLP compliance, CFDA GLP compliance, and TGA GLP compliance.

Documentation, training, and service

Beyond the software, a unified laboratory informatics platform should be supported with documentation, training, and service. Documentation and training should address both laboratory operations for scientists and technical support for deployment. Professional services should be available to assist with deployment and customization when required.

Ten Questions to Answer Before You Select a Laboratory Informatics Platform

Beyond capabilities, selecting a laboratory informatics platform is about entering into a long-term relationship with a partner whose performance and reliability will greatly affect your lab's operations now and in the future. Following are key questions to determine if you are truly selecting a platform, not just products, from a partner you can depend on for years to come.

1 One, Unified Platform

What is the company's reputation for a unified laboratory informatics platform?

- The company is acknowledged as a best-in-class producer of a unified laboratory informatics platform, not just products.
- The company developed the platform with the same architecture as its products (as opposed to connecting disparate products and calling it a platform) and delivers seamless, end-to-end functionality across all laboratory activities.
- The company can provide specific customer case studies and references from laboratories such as yours that confirm platform performance, reliability, and support.

2 Many Applications, One Experience

Unified User Experience Across All Solutions:

- Regardless of which solution is selected from the platform, every user benefits from the same intuitive interface and seamless workflow, ensuring minimal learning curves and consistent performance across applications.
- Shared Data Access Across Applications: Each solution on the platform is built on a singular, integrated data architecture, meaning all users can access and leverage the same comprehensive data set, whether they are working in LIMS, ELN, or another specialized application.
- Extensible, Modular Solutions: With a wide range of applications available, users can start with one solution and easily add more as their needs grow, all without compromising the cohesive experience or requiring disruptive re-integrations.

3 Out-of-the-box & Configurable

Does the platform provide 'flexible standardization' — i.e., an appropriate balance of out-of-the box standardized workflows and quick and easy configurability, modification, and customization?

- The company can provide many out-of-the box workflow templates to meet standard laboratory needs.
- A lab scientist can modify or customize laboratory processes and workflows to meet specific needs quickly and easily without writing a single line of code or requesting assistance from IT.
- The company has a professional services team with a track record of helping customers with more extensive customization supported by case studies.

4 Scalable Operations

Is the platform scalable to ensure long-term viability as the operational size and scope of a lab evolves?

- The company has a documented track record of platform scalability and extensibility across multiple, different laboratories with operations of varying size and scope.
- The company can provide customer case studies of scalability and extensibility from different laboratories of varying operational size and scope.

5 Multimodal Discovery

Does the platform seamlessly support the discovery of new modalities, such as recombinant proteins, peptides, and engineered antibodies?

- The platform incorporates small-molecule, large-molecule, and multimodal discovery workflows, including entity registration, in a single, unified platform.
- The platform features a single materials management system that does not distinguish between small-molecule, large-molecule, or multimodal entities — rather, they are all collected and managed as molecular materials with attributes that record the unique characteristics of each type of entity.

6 Open & Interoperable

Does the platform provide interoperability to integrate new scientific methodologies and technologies beyond its own platform?

- The platform provides multiple interface and communications options including a RESTful API, Webhooks, and a range of pre-built plugins.
- The company has a documented track record of providing cross-platform interoperability including customer case studies.

7 AI Built-in

Does the platform incorporate advanced AI tools to help transform and accelerate drug discovery?

- Machine learning (ML) has been an integral part of the platform since inception.
- Generative AI is easily accessed and utilized through a simple chat interface built into the platform.
- Large language models (LLM) are leveraged to enable scientists to rapidly create experiments, generate code, and search and visualize data.

8 Security & Privacy

Does the platform meet global information security and data privacy standards to assure data confidentiality, integrity, and availability?

- The company has documented certification by SOC 2 Type II, ISO 27001, HIPAA, EU-US Data Privacy Framework (DPF), and EU General Data Protection Regulation.

9 GxP Compliance

Does the platform meet global GxP certification and compliance?

- The company has documented GxP compliance certification including ISO/IEC 17025, FDA GLP compliance, OECD principles of GLP compliance, EPA GLP compliance, and other applicable regulatory bodies.

10 Robust Roadmap

Does the company deliver timely, reliable updates to continually keep pace with and utilize new, advanced capabilities?

- The platform is cloud-based to provide fast, robust, and automatic updates.
- Review new platform features and capabilities that have been delivered to users over the past 12 months as proof points.

The Importance of Customer Case Studies as Proof Points

A good deal of information can be obtained directly from a company during evaluation of its laboratory informatics platform. This includes architecture, features, configurability, extensibility, interoperability, customization, modification, and built-in advanced technology. The company should also provide verification of third-party certification regarding GxP regulatory compliance and information security and data privacy standards.

In addition, an extremely important proof point regarding platform implementation, performance, service, and support is best obtained from customer case studies. The experiences of present customers can provide prospective customers with similar responsibilities — lab director, scientist, quality control, IT director, etc. — in a similar laboratory environment — academic or commercial basic, clinical, and/or translational research — a user's view and assessment of the platform and the company. An established company with a history of developing and delivering a unified laboratory informatics platform should be able to provide customer case studies to help inform your critical purchase decision.

Conclusion

Evaluating and selecting an informatics platform for your laboratory is a decision with far-reaching consequences. The right platform will include the capability, flexibility, and extensibility to enable best-in-class laboratory operations now and in the future. But too often a product is mistaken for a platform, either through a misunderstanding or misrepresentation, and the unfortunate outcome is wasted time, additional cost, and extreme disappointment.

Fortunately, there are guidelines to help one differentiate a platform from a product and select a platform that best meets a laboratory's specific requirements. This paper first describes the difference in a laboratory informatics platform and a product. It then details the benefits, advantages, and capabilities of a unified laboratory informatics platform. And, finally, it provides a list of specific questions that can help you determine and select a genuine laboratory informatics platform. Following these guidelines can help you evaluate and select a platform from a dependable company to meet the needs of your laboratory now and for years to come.

Sapio Sciences Unified Laboratory Informatics Platform

For 20 years, Sapio Sciences has been developing and delivering informatics software to make laboratory research easier for scientists and to accelerate scientific progress for everyone. Sapio has always recognized the fundamental role of a proper platform, a scalable data architecture, and a unified user experience to empower scientists. The Sapio Platform combines essential products, such as ELN, LIMS, and SDMS, and critical capabilities, including configurability, extensibility, interoperability, customization, and built-in advanced technology, into a unified laboratory informatics platform that delivers a seamless end-to-end user experience.

1. Brochu, Mike, Lu Chen, and Brian Bush, New Drug Modalities 2023, BCG, June 30, 2023.

2. Shah, Bhavik, Joachim Bleys, Chaitanya Adabala Viswa, Delphine Zurkiya, and Eoin Leydon, Generative AI in the pharmaceutical industry: Moving from hype to reality, McKinsey & Company, January 9, 2024.