Building the interconnected laboratory: data mobility to support digital transformation

WHITEPAPER:
SCIENTIFIC INTEGRATION PLATFORM

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Connectivity is the cornerstone

The digitalization of the life science industry promises streamlined operations, revolutionized business models, enhanced customer experience, and significant cost savings.

The guiding principle, defined and adopted by the International Society for Pharmaceutical Engineering (ISPE), is Pharma 4.0™, a trademarked concept that aims to bring the pharmaceutical industry in line with Industry 4.0. Specifically, Pharma 4.0 provides practical guidance and regulatory best practices for enabling a greater degree of digitization, integration, and transparency based on the Pharmaceutical Quality System, ICH Q10.[1,2]

Moving to Pharma 4.0 will enable better operational and quality control and support faster decision-making for process improvements throughout the product life cycle. There is interest within the industry for digital transformation, but according to experts,[3] the growing investment in an array of IT lighthouse projects across the industry is not yet reaping the anticipated rewards. A survey by Accenture of senior executives in 190 US companies[4] revealed that 81% of organizations lack an enterprise data strategy to enable full capitalization of their data assets, while 84% do not have the right data platform in place.

Part of the problem lies in legacy IT systems and instrumentation with proprietary data formats, which has resulted in a build-up of technical debt characterized by data trapped in siloes, business operation systems tied to transactional data management platforms, and laboratory resources that cannot support the data connectivity and interoperability required to enable advanced functionality.

Supporting data connectivity

Data produced by the typical suite of laboratory instrumentation varies widely from source to source, with no interoperability or connectivity. As a result, a substantial proportion of lab time and resources is wasted on cleaning and curating data sets before they can be accessed and put to use, via data modeling techniques such as artificial intelligence (AI) and machine learning (ML), to identify valuable scientific insights.

A survey by the International Data Corporation on the barriers to AI adoption in the industry[5] indicates that data quality, quantity, and access are among the top challenges to scaling and operationalizing approaches. In some cases, up to 50% of research time can be spent on data preparation and deployment.

The lack of access to data—characterized by lost or inaccurate data and an infrastructure that cannot gather, connect, curate, or share data from the diversity of instruments across the lab—is a significant issue. In the absence of an enterprise-wide solution, this problem will continue to impede progress toward achieving Pharma 4.0.

The challenge, therefore, is to bring together the vast amount of data generated by scientific research in a way that connects the fragmented ecosystem of instruments, informatics, software, and other laboratory resources to enable the true data mobility that underpins a successful digital transformation strategy.

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Breaking the legacy of technical debt

The lack of connectivity in the fragmented laboratory ecosystem has undermined progress toward digitization for decades.

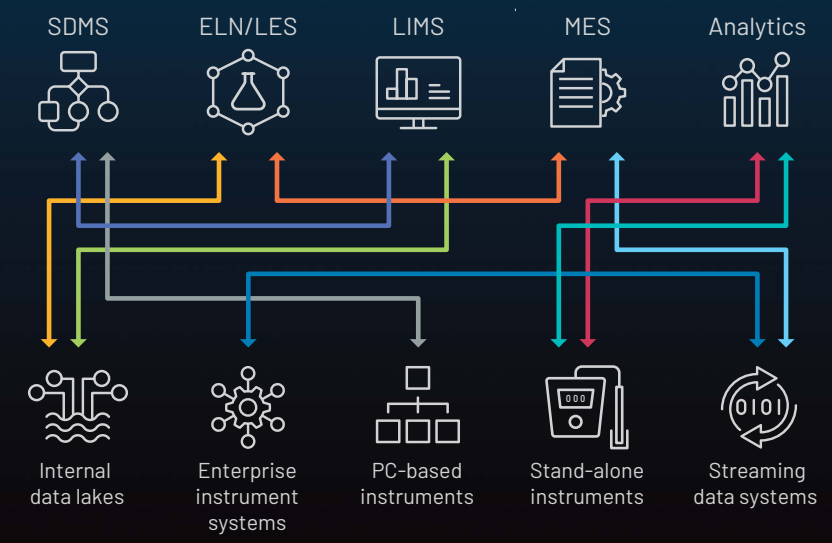
Taken in the context of a global laboratory information management system (LIMS) deployment for a global top-tier pharmaceutical company, the timeline is typically 5-7 years to deploy across a network of manufacturing and quality sites throughout the organization. By then, the software version is already obsolete.

This is set to change with the launch of a new industry category that connects the final dots. The Scientific Integration Platform, SIP creates a flexible ecosystem where integrations, APIs, and automations are delivered on-demand as business needs change, provides a platform that decouples transactional data from an organization's monolithic business management system, and breaks the long-embedded cycle of upgrade-deploy-repeat that is stifling innovation at the enterprise level.

The potential business benefits associated with breaking this cycle are substantial.

Using the SIP to establish an independent connectivity layer to support the concept of digital decoupling shortens the cycle, potentially freeing up the associated substantial annual spend—often tens of millions of dollars—that can be reallocated to research and innovation in the lab.

THE ANALYTICAL LAB'S CURRENT STATE



THE ANALYTICAL LAB WITH SCITARA DLX

Data integrity

Scientific data management must follow consistent protocols, particularly when undertaken in the life sciences sector, where any data error could result in grave consequences.

One such set of principles is ALCOA, defined by US FDA guidelines[6] and used by regulated industries since the 1990s as a framework for ensuring data integrity. ALCOA stands for attributable, legible, contemporaneously recorded, original, and accurate.

- **Attributable** means that all data generated or collected must be accountable to the person generating the data and state who performed an action and when it was made.
- **Legible** specifies that all data recorded must be comprehensible and permanent. This includes the storage of human-readable meta-data that may be recorded to support an electronic record.
- **Contemporaneously recorded** requires that the data, result, or measurement must be recorded at the time the work is performed. Date and time stamps are mandatory, meaning data may never be back-dated.
- **Original** refers to the medium in which the data point is recorded for the first time.
- **Accurate** means that data should be complete, truthful, error-free, and reflective of any observations. Editing should not be performed without documenting and annotating the amendments.

Implementing a transformative digital strategy that ensures data interconnectivity, interoperability, integrity, and security requires a digital data exchange infrastructure that follows the ALCOA scientific data management principles.

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The advantages of a digital lab exchange infrastructure

Scitara is a fast-growing software company that uses digital laboratory exchange technology to redefine digital transformation in the pharmaceutical industry. Its new SIP connects laboratory informatics systems, data, instruments, and applications to enable universal data mobility. The SIP is powered by Scitara's Digital Lab Exchange™ DLX™ technology, which supports automated data transfer between multiple endpoints and the on-demand delivery of APIs, integrations, and automation. DLX offers three core pillars:

Connect

Overcoming the challenge of a fragmented digital ecosystem requires a secure data exchange infrastructure that connects the universe of lab instruments, applications, and services. This infrastructure includes multiple connection technologies that support hundreds of legacy and modern instruments and applications by means of flexible configuration tools. It also supports the easy addition of new devices and applications, and provides an open framework to add new connectors with no need to write and test new code. Establishing this data connectivity highway ensures that no instrument, application, or resource is left behind.

Orchestrate

Orchestration allows the creation of a configurable set of business rules that enable out-of-the-box workflows, which, critically, can be edited without the need to write and test new code. It also supports event-driven notifications, the application of business models to data in flight, and the automation of data curation and transfer. Once an instrument or application is connected to Scitara DLX, it has access to any other instrument or application on the platform This enables the unrivaled automation of laboratory workflows and tasks, intelligent user notifications, and remote working capabilities.

Monitor

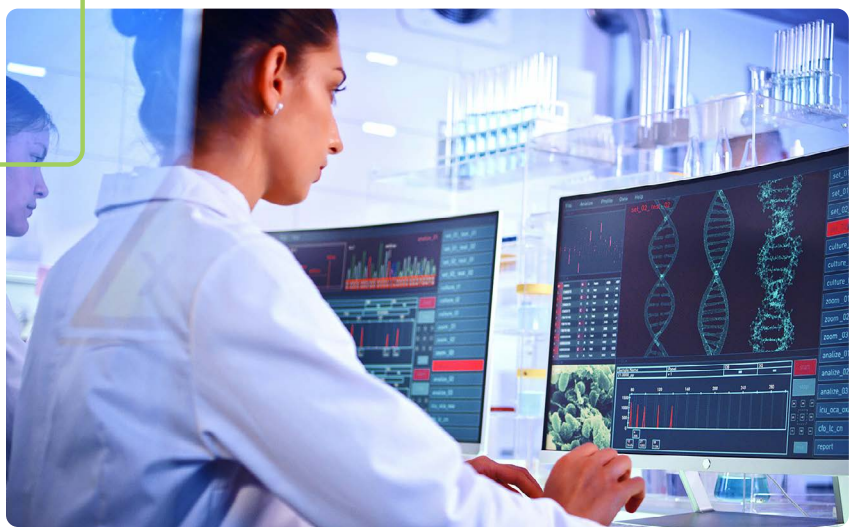
The Scitara DLX system provides automated monitoring of instrument status and connectivity. Eliminating manual transcription and creating an auditable chain of custody delivers enhanced data integrity through technology that links each laboratory instrument to the authenticated user, giving transparency to review and sign-off steps. Instrument-to-instrument communications are also supported, and event-driven notifications for required intervention reduce unnecessary investigation time, maximizing workflow progress and minimizing bottlenecks.

Use case example—SIP in practice

There are multiple use cases that an SIP technology supports, both from a practical as well as strategic point of view. From a practical standpoint, leveraging the platform allows configurable and compliant automation for common integrations such as:

- Interfacing informatics applications (such as LIMS, ELN, MES) to simple devices, such as balances, pH meters and others.
- Configuring automation across PC-based systems such as HPLC, LC/MS and other PC based analysis systems.
- Configuring a strategy to manage the large volume of file-based systems that still exist and reducing or removing the petabytes of file stores on servers.
- Creating a configurable infrastructure to manage the feeding and data curation for data lakes from a wide variety of sources.

From a strategic standpoint, the SIP gives companies a way to future-proof a lab by separating the system connectivity layer from the applications and instruments that need to be connected. This configurable approach allows a business to adopt its technologies of choice and to have high confidence that all the technologies can be integrated to support business strategies.



Pharma 4.0 becomes reality

The ISPE has identified two enablers that are essential to achieving Pharma 4.0: Digital Maturity and Data Integrity by Design. The Scitara DLX contributes toward achieving both. Built by experienced personnel with expertise in supporting the pharmaceutical and biotechnology industries as they face regulatory challenges, the system supports robust, automated systems validation and documentation, performing reliably and in line with customer requirements.

For more information on how to build a connected laboratory:

BOOK A DEMO HERE

Powering digital transformation

The Scitara Scientific Integration Platform, SIP

Scitara offers an industry-leading SIP that connects the world's scientists, data, applications, instruments, and devices. The Scitara technology drives scientific data mobility by:

- ☐ Automating the exchange of scientific data across multiple endpoints in the scientific network.
- ☐ Creating a flexible ecosystem where integrations and automations for laboratory instruments, applications, and other resources may be switched in and out, and the platform reconfigured on-demand as business needs change.
- ☐ Accelerating the delivery, accessibility, and sharing of scientific data across the enterprise.

Scitara Digital Lab Exchange DLX™

Designed for operation in a regulated environment, Scitara DLX is the foundation technology of the SIP. The Scitara DLX delivers a seamless digital data exchange experience by incorporating unparalleled connectivity and unrivalled automation, resulting in unprecedented scientific insights and on-time decision making.

Meet the Modern Lab™

For the first time, organizations in life science can close the loop in achieving a data mobility strategy. By implementing a fully connected and compliant laboratory infrastructure with data mobility as standard, the life science sector can start to embrace Pharma 4.0 as the new reality.

For more information on how to build a connected laboratory:

BOOK A DEMO HERE

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