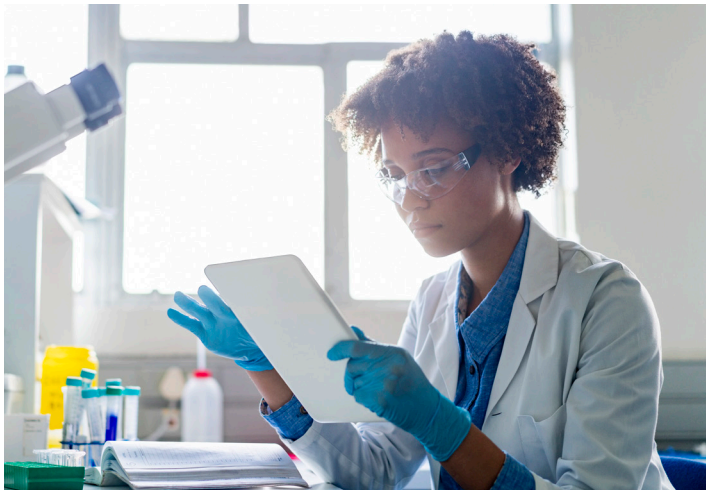
Connecting the scientific ecosystem at a top 20 global pharmaceutical organization

To standardize processes and to ensure FAIR (Findable, Accessible, Interoperable and Reusable) data, a global pharmaceutical company looked to harmonize and integrate existing tools, systems, and technologies across their chemical and pharmaceutical development organization. The department is responsible for the development, manufacture, and supply of new active ingredients from late research throughout all phases of product development until launch. They also supply investigational products for phase I to phase IV clinical trials and manage the development and characterization of pharmaceutical formulations.

Like many organizations, the Chemical and Pharmaceutical Development (CPD) department was using six disconnected systems and over 1,000 disconnected instruments. Importantly, there were large differences between sites and departments, with heterogeneous IT landscapes and inconsistent LIMS usage, which meant the project required significant conceptualization to create one strategy incorporating every system. The goal was not to replace hardware and systems, but to drive integration across existing instruments and software, enabling the department to leverage established investments.

Formulation Development was not adequately supported by IT applications, relying mostly on paper documentation with limited electronic support, which led to challenges around sharing, comparing and reusing data, as well as issues with the amount of paper being processed.



Analysts would often spend time repeating work that they later discovered had been done previously. With the same information being presented often in very different ways, the company was being held back by its inconsistency as there was no way to effectively use the data to advance their work.

The project leaders determined a set of desired outcomes, which encompassed the needs of both the business and its employees. From a people perspective it was critical to deliver a system which would ease the job of analysts, to eliminate rework and make everyday tasks easier to complete. This would also provide analysts more time to focus on science and drive tangible gains through faster development.

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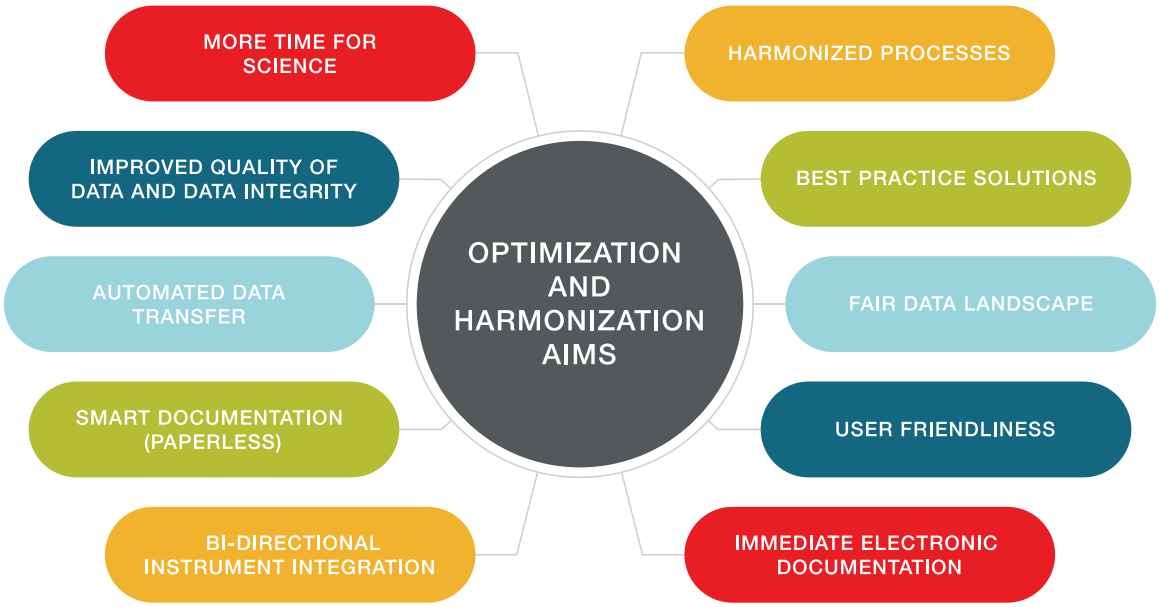
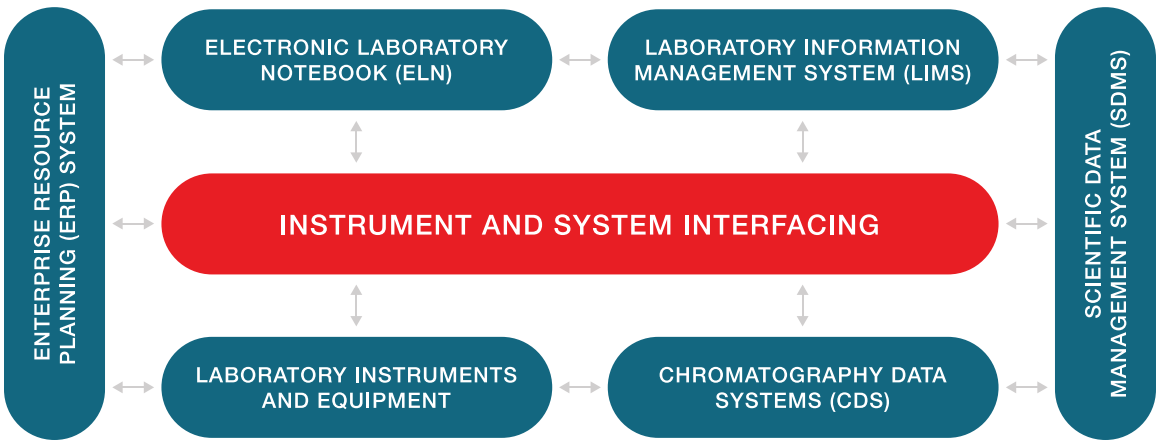


Aims of the optimization and harmonization project

Building a connected scientific ecosystem

Thermo Scientific™ SampleManager™ LIMS (Laboratory Information Management System), LES (Laboratory Execution System) and SDMS (Scientific Data Management System) was chosen to manage laboratory, data and procedural workflows.

At the start of the implementation, the teams analyzed the existing known pain points and, through a third party, performed a multi-moment analysis to identify any unknown bottlenecks in the process. They took a pragmatic approach to identify best practices for the new solution, and architected a workflow connecting all of the major systems in their process as shown in the diagram below.



“Providing a scalable solution with the capability to share data across and possibly extend into other business processes is a key consideration of our enterprise projects.”

– Christian Müller, Director, Services and Support, Digital Science

Thermo Fisher’s integration technology was used to enable cross-connectivity between SampleManager software and the incumbent CDS (Chromatography Data System), ELN (Electronic Lab Notebook) and across to the ERP system, as well as the instruments and equipment used in the lab.

Thermo Fisher Scientific were understanding of the need to fit their solution into the existing components to leverage established capabilities and deliver a complete, connected ecosystem. The flexibility and scalability of SampleManager software provides a clear opportunity to extend the system into other areas of the business, should the opportunity for further harmonization arise in future.

Before the implementation, each analytical development, formulation development and quality assurance site was disconnected from their peers. After the implementation, the CPD department functioned as one connected, global team. The scope of the implementation covered all of the major workflows including:

- End-to-end sample management from preparation to certification
- Management of stability studies and testing such as content uniformity and dissolution
- Control of reagents and assets including columns
- Integration of instruments and instrument logbooks
- Development of drug product formulations

Legacy data was migrated to the new system to enable the company to leverage historic data to advance future formulation development. Paper-based processes were drastically reduced. Documents like order, sample preparation and raw data sheets all became part of a fully digital process.

An important element of the project was to improve the human experience. Scientists were spending a disproportionate amount of their time on time-intensive, low value work like manually moving data between systems. The organization recognized the importance in eliminating these tasks, not just for productivity, but to ensure they were able to attract and retain top scientific talent.

Bi-directional instrument connectivity is used to drive analytical processes direct from the LIMS, sending worklists to instruments and retrieving data automatically, eliminating manual data transcription and making information instantly available to production. By connecting instruments into the new integrated landscape, the business is able to view instrument availability and status, and schedule time to use them for critical projects.

Scientists are often required to focus on operational tasks, detracting from their real focus. By establishing a holistic strategy that incorporates the people who use the systems, pharmaceutical manufacturers can ensure their data integration programs are more effective. The user experience across the laboratories is almost seamless – and scientists now have more time for what they are most passionate about: science.

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Strategic partnership was the formula for success

The success of the project was driven by the strategic partnership and common goals between the pharmaceutical company and the implementation team. Between the clear direction and vision of the laboratory and IT team and Thermo Fisher's system and integration expertise, the team was able to make the lab of the future a reality.

Today, the organization has a fully connected workflow between LIMS, ERP, ELN, CDS and over 1,000 complex and simple instruments. The higher degree of integration achieved has increased efficiency by 20%, with additional improvements to both data quality and integrity. Fewer mistakes are possible through transcription errors, while the laboratories benefit from the security of a full audit trail, including a risk-based audit system. Information isn't simply captured as "paper on glass," but intelligently linked to improve searchability.

This project also highlights the importance of cultural change to a successful data strategy. The real measure of success for any system deployment is that of the end users. When asked about the implementation, users highlighted the improved access to data, logical workflows and enhanced data management and traceability. They also highlighted the flexibility of the system. By improving on the systems they already knew through tighter connectivity, the project provided significant benefit to the users without introducing unnecessary change.

The implementation had a transformative impact on the business. At the start of this process, it was evident that the organization needed a new informatics infrastructure to enable their plans for digitalization and automation. The LIMS facilitates compliance with regulatory processes and enables significant improvements in product quality. Today, their integrated infrastructure benefits not only the laboratory but all aspects of their operations, providing a seamless flow of information throughout the development, scale-up and manufacturing process.

Find out more at **thermofisher.com/digitalscience**

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