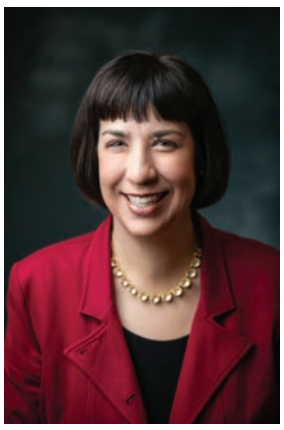
SPOTLIGHT feature

LIMS & Lab Automation



Time to integrate: how advanced informatics enables automation, optimisation and compliance

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In the pharmaceutical industry, data is everything. Collecting and maintaining accurate, reliable data allows drug developers and manufacturers to ensure operations are robust and reliable, analyses are accurate, and products are of appropriately high quality. Intelligent data management is essential for organisations wanting to increase their productivity or create new opportunities for innovation - and, as the regulations overseeing a product's journey to market become increasingly stringent, data quality and integrity are more important than ever.

To this end, advanced laboratory information management systems (LIMS) are playing an instrumental role in achieving the robust, integrated informatics essential for market success. Such systems enable workflows to become more automated, while also integrating and connecting data from multiple sources to drive fast, informed decision-making. Connectivity and integration are even more crucial for distributed laboratory networks, where they can bring operational efficiency and productivity gains which, in turn, facilitate the faster delivery of new therapies to patients in need. Furthermore, connected, integrated information management is essential to maintain a safe, steady, reliable global supply chain - the value of which is evident especially in the current landscape, given the disruption and rapidly evolving healthcare needs associated with the COVID-19 pandemic.

The challenges of laboratory and data integration

Data is continuously generated and stored throughout the stages of research, development, clinical testing, commercialisation and manufacturing of drug products, making informatics a key consideration for the pharmaceutical industry. Everything from equipment operation, calibration and validation to the use of various reagents and standards must be logged and tracked - and for this, organisations rely upon well-managed records. However, traditional systems for information management are typically quite disparate and require extensive manual input. Many organisations use digital systems that are not integrated across different locations, instruments or datasets, making connectivity a real issue.

Meanwhile, pressure is increasing to accelerate pharmaceutical pipelines, and global regulations are growing more stringent and complex. To keep pace and remain competitive, drug developers and manufacturers are seeking verifiably robust, integrated informatics systems - solutions that capture data and both monitor and manage operations by applying greater automation. Such systems can perform a whole host of activities that are usually completed manually: they can automatically keep track of stock levels, produce certificates of analysis, block processes if the correct approvals have not been attained, alert to instruments requiring maintenance, and much more. By tracking stock and alerting when levels are low, automated workflows enable supplies to be ordered as needed, while also decrementing and adjusting inventory records to reflect up-to-date usage – without the need for manual input.

Automation not only improves process efficiencies, but also frees up laboratory technicians so they can focus on valuable research rather than needing to manually gather, log and manage data. Auto-captured data is subsequently standardised and centralised by automated informatics systems, and stored in a single central database with a clear chain of custody. By storing data centrally, rather than in numerous individual silos, integrated solutions connect and collate various data sources in one repository. This enables a better understanding of wider-scale trends - from tracking seasonal production patterns to estimating likely resource requirements - and, therefore, helps organisations make fast, well informed decisions.

However, complete system integration can be a challenge to achieve without the right planning and support. Any such project is likely to require input from various stakeholders across the organisation to ensure all considerations are taken into account and also to secure buy-in and approval. Since many people and operations will be affected by system updates, there is a need for well-planned change management. Sites may have multiple different legacy systems, potentially making transition an even more complex endeavour if undertaken without support. To bridge the gaps between different facilities and informatics systems, an integrated platform must be able to bring together numerous existing data sources on to a single compliant solution.

Considering these and other challenges, it is essential that pharmaceutical developers and manufacturers are provided with the right solution to meet their needs - and that they select a partner that can offer suitable direction and support.

Accelerating pharmaceutical pipelines with integration

In any organisation, the presence and prevalence of a 'silo mentality' is damaging to productivity and can stymie innovation. Pharmaceutical organisations often comprise multiple departments and locations, all of which require data to be accurately captured, stored, updated and shared as needed. To increase operational efficiency and unlock new opportunities for optimisation, facilities can benefit by shifting away from disconnected systems and data sources towards a single, integrated system that allows for greater automation of manual processes. Here, fully integrated laboratory software suites offer a streamlined solution. Systems such as Thermo Scientific SampleManager LIMS software are comprised of LIMS, laboratory execution system (LES), scientific data management system (SDMS) and electronic lab notebook (ELN) capabilities. The complete solution helps to manage laboratory processes and procedures, connects different laboratories and sites together to manage samples, resources, instruments, equipment, stocks and suppliers, drives quality and process integrity through repeatable procedures - and captures and manages the data generated so it can be used to its full potential.

Whether an organisation is comprised of a single smaller laboratory or a global multi-site network of laboratories and manufacturing plants, a complete laboratory software solution offers essential benefits as a result of increased connectivity, such as gains in productivity and efficiency. As data is archived in a central repository and can be retrieved and visualised on demand, staff can easily track the progress of a given sample from receipt to report delivery regardless of when in their data retention period the sample was acquired. Data accessibility is a key benefit. Rather than needing to chase data from across different manufacturing and development stages or from multiple facilities, decision-makers can instead access and use it on demand to reach swifter and more informed conclusions.

Standard Operating Procedures (SOPs) can also be managed through the LES and operators are guided step by step through the process execution, increasing accuracy and reducing process nonconformance. Within a distributed network, LIMS enable best practices to be shared between laboratories at different locations, creating greater opportunities for organisation-wide optimisation. Other systems in use at any laboratory site can be easily integrated with an advanced LIMS, from Chromatography Data Systems (CDS) to Enterprise Resource Planning (ERP) and Manufacturing Execution Systems (MES). Overall, this increased connectivity enables staff to improve efficiency and data integrity, spend less time on manual data management and maximise their productivity.

As all data is stored and accessible in a single central repository, LIMS provide organisations with the potential to implement innovative data analytics strategies including artificial intelligence (AI) like machine learning (ML), which can help identify trends and patterns, optimise processes for the future and more. High-quality, well-structured data stored in a 'data lake' rather than disparate silos is the foundation for all AI technologies; such innovation is becoming increasingly prevalent as more pharmaceutical organisations look to implement Pharma 4.0 and is, therefore, an important part of staying competitive in an advanced and forward-thinking industry.

Alongside integration, optimisation and innovation, a core element of any information management system is compliance. Pharmaceutical manufacturing laboratories must comply with a range of essential regulation and guidance, including ISO 17025, GLP and cGMP. Integrated LIMS bring a 'single system of truth': information is only logged once in a largely automated way, and is then fully traceable, protecting data integrity and improving accuracy (as there are fewer chances for errors and data is traceable throughout the process).

With an integrated laboratory solution, regulatory compliance is streamlined, data review and visualisation are faster, and samples that are trending out of specification are identified before a sample fails. It also provides access to comprehensive process, personnel, sample, product and system information. LIMS prevent a user from executing work when they require training or when an instrument requires calibration, ensuring compliance and minimising rework. This further accelerates the process of drug production, helping to maximise profit and productivity.

Case study: A global roll-out of SampleManager LIMS software

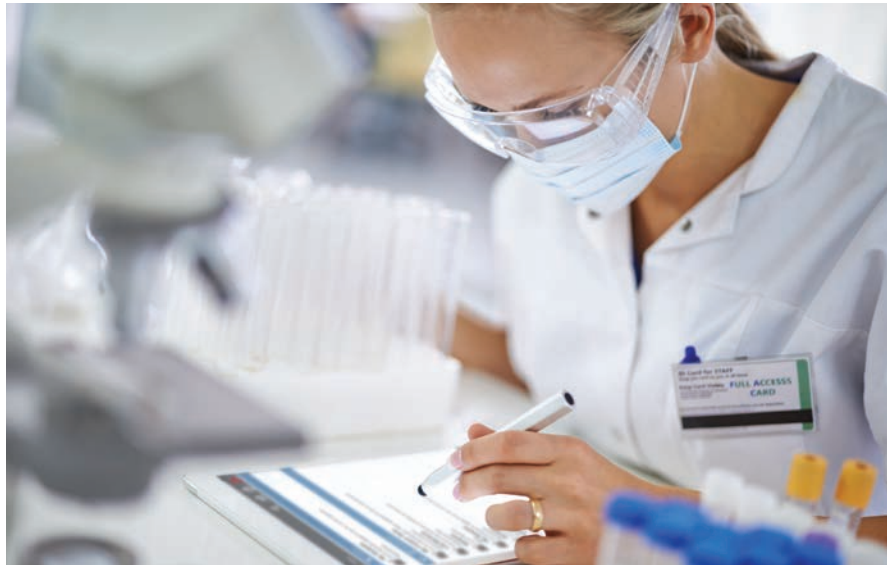
Many laboratory networks use laboratory and data management systems that are disconnected across locations and instruments, preventing them from attaining the benefits of integration and automation. Here, a fully integrated LIMS stand to bring significant benefits - as demonstrated by Thermo Fisher's Pharma Services business, a pharmaceutical contract development and manufacturing organisation (CDMO) that develops and manufactures products for customers across the industry, from development and commercial scale-up of active ingredients to final dosage forms.

Seeking synergy and efficiency, Thermo Fisher Pharma Services initially implemented SampleManager LIMS software at their Cork, Ireland location to test the system's suitability before considering a roll-out across more of their 25 sites. The CDMO grew to its current configuration as a result of multiple acquisitions, and, therefore, had an array of software and information management systems implemented at different sites worldwide. However, they needed a common system throughout their whole network to reduce the burden of running and maintaining disparate software across so many sites, and to improve data sharing. In spring of 2020, Thermo Fisher Pharma Services went live with SampleManager LIMS software at the pilot site in Cork and began to enter their static data into the digital system.

As a result of their LIMS implementation, Thermo Fisher Pharma Services were able to streamline data management and demonstrate the value of a cross-functional team in optimising operations: a team comprised of IT and laboratory subject matter experts, and quality and regulatory personnel, all of whom understand the day-to-day requirements of an efficient, compliant laboratory. The LIMS automated large parts of the data acquisition process, removing the need for manual input while also detecting errors or issues in real time for improved accuracy. As data has a single point of entry and maintains a clear chain of custody once in the system, the LIMS streamlined compliance and protected the integrity of every single data point, a crucial aspect of data management for a large global CDMO that experiences frequent regulatory audits.

After experiencing the benefits of SampleManager LIMS software at the Cork site, Thermo Fisher Pharma Services began creating a playbook with which to guide a wider roll-out and enable smooth, streamlined global integration. The organisation plans to launch SampleManager LIMS software in waves, providing more and more sites with the software until all 25 sites are connected. The implementation has brought about efficiency and process optimisation gains such as improved remote working capability, that are essential to successfully weather stochastic events, such as the COVID-19 pandemic.

After implementing an integrated LIMS across their network, Thermo Fisher Pharma Services anticipate the ability to connect, standardise and communicate across all sites, and to enhance operational efficiencies across their network using a common system. As well as integrating across sites, the organisation sees new opportunities to bring together specific projects - something with significant value in pharmaceutical development and manufacturing. By connecting systems and data across an entire project, from the development of an active pharmaceutical ingredient through to manufacturing of a final dosage form, the integrated solution can help drugs progress through the pipeline faster.



A single, standardised solution: From disconnected to optimised

Standardising and connecting different aspects of the laboratory brings numerous benefits to any pharmaceutical organisation. By utilising a single solution from development through to manufacturing, and across all locations and projects, integrated LIMS can help facilities of all sizes and functions optimise their operations. Using a LIMS, laboratories and manufacturing plants can achieve easy, streamlined compliance, realise truly informed decision-making, and prepare for future innovation.

Integrated laboratory software solutions enable data to be easily shared between sites, and standardise processes and systems for optimised performance and continual improvement. By helping drug developers and manufacturers establish globally automated, optimised process execution and data management, LIMS bring significant operational, efficiency and productivity gains - ultimately facilitating faster delivery of life-saving new therapies to patients.