

The importance of integration

DAVE CHAMPAGNE evaluates the integration benefits of enterprise-level laboratory information management systems.

Enterprise-level integration is particularly relevant in today's business climate where near instantaneous response is required by pharmaceutical companies to protect the public and the environment. Seamless enterprise-wide integration is a necessity because it enables key knowledge originating in the laboratory to be available to management in real time. As such, the world of laboratory informatics is changing to meet the needs of pharmaceutical companies, which are continually searching for ways to reduce costs, accelerate time-to-market and respond to increasing regulatory requirements.

Enterprise-level laboratory information management systems (LIMS) can help to streamline the flow of information successfully, providing companies with the information they need in today's business climate to make critical business decisions.

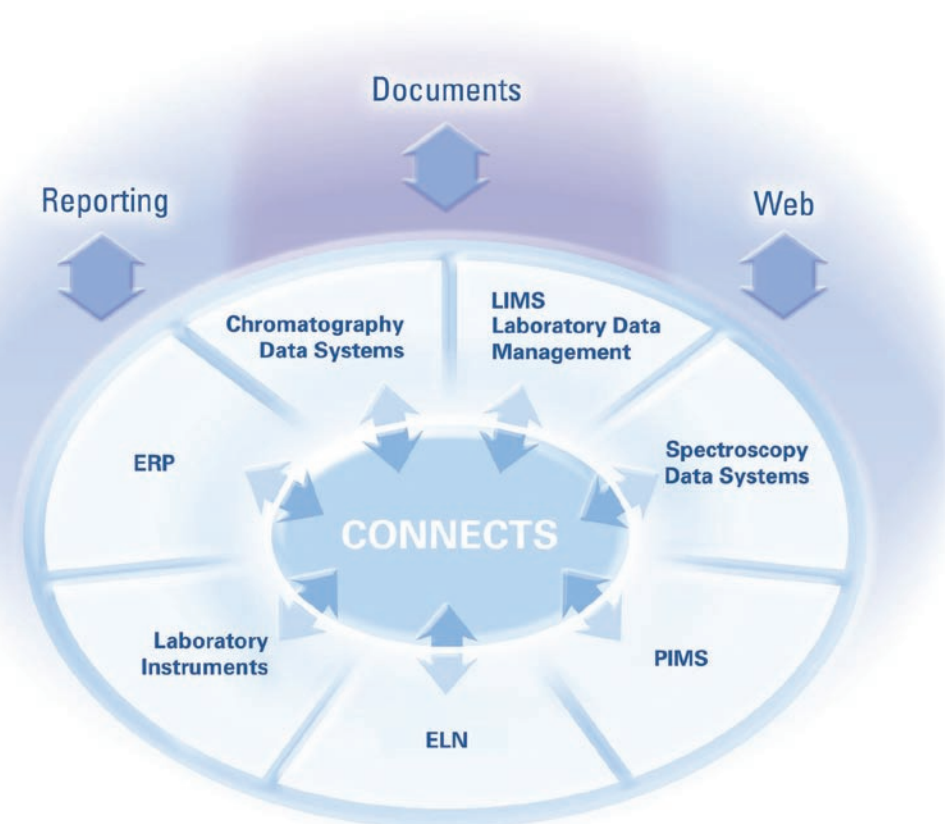
Historically, industry standard LIMS have only delivered 30-40 percent of specific functionality targeted to each user's needs, requiring extensive customisation to make that LIMS function in that particular setting. Such customisation is commonly only possible through the use of proprietary programming languages that are developed and provided by the LIMS vendor. The combination of minimal industry-specific functionality and often out-dated and/or costly proprietary languages has been particularly troublesome in the pharmaceutical industry. In addition, pharmaceutical laboratories often create their own user documentation, design documentation, validation scripts and help files. As a consequence, the implementation of LIMS in various laboratory settings has been, almost without exception, a long, costly and painful process not only during installation, but also in operating and maintaining the system over the years.

With pressure to cut costs, shorten the pipeline lifecycle and maximise return on investment, pharmaceutical companies need tools that help them improve enterprise-wide communications, reach critical decisions faster and produce timely, accurate reports on how compounds are progressing. Working with multiple disparate systems with minimal to no integration is no longer an option.

The growing mandates of global regulatory compliance and long-term data traceability, as well as the complexity of laboratory testing and emphasis on batch versus sample management, have forced pharmaceutical manufacturers into lengthy, expensive adaptations of generic LIMS to meet their specific

requirements. Extensive and costly customisation, validation and implementation periods, in many cases lasting 36 months or more, have become routine, resulting in decreased productivity. With the increasingly higher costs of bringing a new drug to market, pharmaceutical manufacturers cannot afford to delay the implementation of next generation tools that will make them increase productivity.

Today, global deployments of LIMS solutions have become more consistent and more rapid. The implementation of purpose-built LIMS across the enterprise allows for more simplified system upgrades, minimised project risks, and enhanced compliance. In addition, industry-specific solutions facilitate enter-



prise-wide application and training. These multifaceted benefits help lower the total cost of ownership of the solution, which is critical to pharmaceutical companies that are under ever-increasing pressures to contain costs and increase efficiency. This goal can be achieved by integrating the LIMS with instrumentation and enterprise systems, which can facilitate the global harmonisation of business processes, automation of operations and consolidation of data management in a single system, allowing for near-instant decision-making.

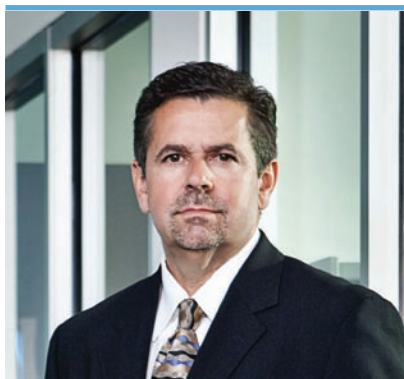
Purpose-built integration solutions

With drug development times of approximately 15 years and subsequent costs approaching US\$2 billion (€1.5 billion) by 2010, pharmaceutical companies are increasingly in search of processes that can help them consistently deliver a return on investment during the patent life of a drug. LIMS are key contributors in this effort. Delivering advanced functionality that is specific to each stage of the drug development process, sophisticated, purpose-built LIMS streamline processes and costs and present organisations with unique integration opportunities. These LIMS provide superior capabilities by delivering real-time analysis and reports, facilitating regulatory compliance and product quality, integrating with the company's broader network and providing secure access to key data throughout the organisation.

When the required functionality is built into the base system as standard, it eliminates the need for user-specific customisations during implementation. This, in turn, results in reduced validation time, shortened deployment and easier ongoing support. Purpose-built LIMS for pharmaceutical applications are particularly relevant. According to the 2008 Strategic Analysis of the US Laboratory Information Management Systems Market, by Frost & Sullivan, preconfigured solutions with test methods for specified industries, will drive growth across all markets. The more functionality included in the core product out of the box, the less risk, lower costs and less time involved in the implementation, validation and support of the applications. According to the same Frost & Sullivan report, market growth indicators for LIMS solutions providers are focused on providing customers with not only

purpose-built LIMS that are fully integrated with other laboratory equipment, but also LIMS that easily align with global enterprise solutions. At Thermo Fisher Scientific, our objective in developing purpose-built LIMS solutions is to deliver the domain-specific functionality that addresses the critical needs of the laboratory and also delivers the increased enterprise-level access that multi-site/multi-user organisations are looking for.

In response to the needs of our customers and these market growth indicators, Thermo Fisher Scientific has introduced a new informatics initiative aimed at bridging the gap between laboratory-generated data and the enterprise-level information that is required for mission critical management decisions.



Because of the breadth of our company's product offerings, and our strategic partnerships, we are uniquely positioned to offer Thermo Scientific CONNECTS, an enterprise-level solution set that allows companies to more fully integrate the work of the laboratory into the enterprise. CONNECTS enables our customers to extend the business of science from the laboratory throughout the enterprise, providing both the integration of instruments and system and the interoperability necessary to transform data into relevant business drivers.

Seamless enterprise-wide integration is a necessity because it enables key knowledge originating in the laboratory to be available to management in real time. Integrating the laboratory with the enterprise will facilitate better planning, data quality, collaboration and end-to-end report generation, all with the goal of providing management dashboard views of key business metrics, which are essential to effectively run operations. By investing in this enterprise-wide integration of systems, man-

agement will have the information they need to have early insight into how pipeline drugs or compounds are progressing on a routine basis, and they will also have the critical data they need before, not after, any point of crisis that may affect operations, shareholder value or the safety of the consumer.

A LIMS fully integrated with laboratory instruments and enterprise systems can help bring key business knowledge originating in the laboratory to management at all levels of the enterprise. By effectively integrating laboratory informatics data and providing management key with business knowledge, laboratory informatics can elevate the role the laboratory plays in day-to-day mission critical decisions. LIMS can help pharmaceutical

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companies respond with more certainty to the many unforeseen challenges that can often make or break a company.

Modern LIMS serve as common platform frameworks that other informatics solutions, instrumentation, enterprise systems and enterprise communication tools can plug into to share common functions, without having to build them from scratch for each product. As such, a coherent strategy that can integrate data from a LIMS, chromatography data system (CDS), enterprise resource planning (ERP), manufacturing enterprise system (MES), electronic laboratory notebooks (ELN), and other sources across the enterprise is a key business driver for pharmaceutical companies. ■

Dave Champagne was named Vice President and General Manager of Thermo Fisher Scientific's Informatics business in April 2005. He joined Thermo Fisher in April 2003 as Director of Global Services for Informatics, and was later promoted to commercial Director for the company's Informatics and Services division.

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