LIMS – reducing cost and improving efficiencies

Standard LIMS often require costly customisation and maintenance, which is why **Thermo Fisher Scientific** has developed purpose-built solutions for each area of the pharmaceutical value chain, writes Dave Champagne, the company's vice president and general manager, Informatics.

With drug development times of approximately 15 years and subsequent costs approaching $2 billion, 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. Enterprise level laboratory information management systems (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.

Thermo Fisher Scientific is in the informatics business and has developed a portfolio of LIMS that meet the specific needs of its customers. This is particularly true in the life sciences market where laboratory requirements are unique in research and development, discovery and manufacturing. There is no single system that could answer the unique needs of these laboratories so the company has developed, with the help of its customers, purpose-built LIMS for each area of the pharmaceutical value chain.

Standard systems

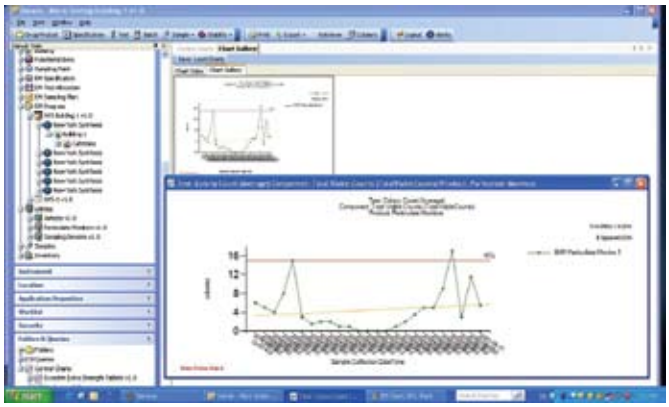
Historically, standard LIMS have only delivered 30-40% of specific functionality targeted to each user's needs, requiring extensive customisation to make that LIMS function in that particular setting. Such customisation is commonly only possible through the use of proprietary programming languages that are developed and provided by the LIMS vendor. The combination of minimal industry-specific functionality and often outdated and/or costly proprietary languages has been particularly troublesome in the pharmaceutical industry. In addition, pharmaceutical laboratories normally 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.

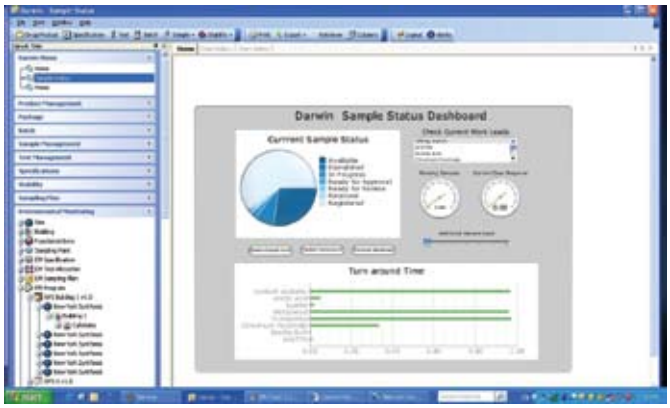
A clear example of the benefits of purpose-built informatics solutions can be found in pharmaceutical manufacturing. The growing mandates of global regulatory compliance and long-term data traceability, as well as the complexity of laboratory testing and emphasis on batch versus sample management, have 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. However, with the increasingly higher costs of bringing a new drug to market, pharmaceutical manufacturers cannot afford delaying the implementation of next-generation tools that will make them more productive. And the more an organisation needs to deviate from an 'out of the box' LIMS solution, the greater the investment is for custom software, implementation and validation.

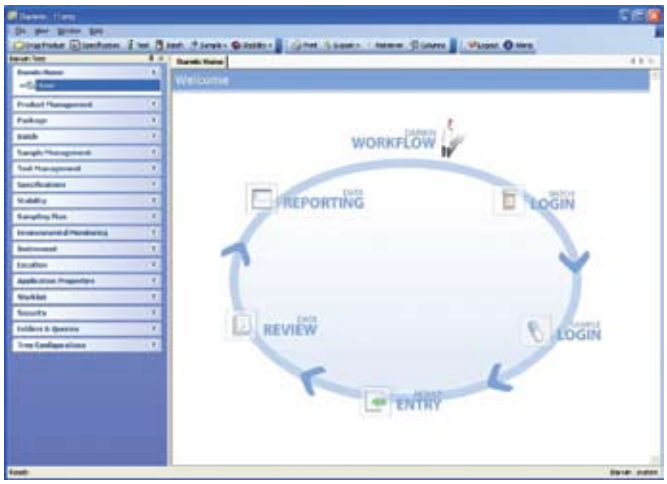
Contract manufacturing

As the cost of doing business continues to rise for pharmaceutical companies, with increases in raw materials, more stringent R&D and regulatory requirements and extended time to market, the pressure to contain costs is at an all-time high. The growth in contract manufacturing organisations (CMOs) is directly related to the need within the pharmaceutical community to continue to find more efficient and cost-effective methods of delivering a finished product. CMOs provide a time- and cost-effective way for pharmaceutical companies to outsource manufacturing, allowing for their activities to be more focused on developing new drug therapies or discovering new compounds. By outsourcing some of their manufacturing requirements, pharmaceutical firms are able to have more flexibility in their production and realise cost savings, and just as they are required to comply with US Food and Drug Administration (FDA) and other regulations, so too must outsourced suppliers, throughout the entire process or production line. Despite CMOs delivering on compliance promises, however, more and more pharmaceutical businesses are dictating the software and data management resources that are employed on their behalf.

Similarly, active pharmaceutical ingredient manufacturers (APIs) have faced the same regulatory requirements in delivering the active components used in the manufacture of drug therapies. And since the sponsor pharmaceutical company is ultimately responsible for the quality and safety of the drug that is developed, it is often dictated to APIs that methods and processes, as well as software, are in sync with the company and with their CMO partners. In this way, a reliable audit trail of data







Darwin LIMS™ provides intuitive user interfaces and workflows that are designed to be recognisable to pharmaceutical manufacturing and QA/QC laboratory users. The Darwin Dashboard shows real-time status of key parameters (above – the system's entry screen is left); the Environmental Monitoring screen shows data and trends throughout the manufacturing cycle (above left).

management can be traced from R&D to raw materials production and through to manufacturing.

To meet the specific needs of pharmaceutical manufacturing R&D and QA/QC labs as well as CMOs and APIs, Thermo Fisher Scientific has built extensive functionality into its Darwin LIMS to facilitate rapid deployment, validation and training in a fraction of the time generic LIMS systems require. For FDA and International Conference on Harmonisation (ICH) regulatory compliance, Darwin LIMS includes activity and event-based system privileges that better correspond with users' work responsibilities. It can also be delivered with the flexibility to be used in non-GMP mode for analytical development, allowing researchers greater flexibility during exploratory work, or GMP mode, to enforce adherence to company standard operating procedures (SOPs) and regulatory guidelines. Darwin LIMS also features a comprehensive test library that includes complex pharmaceutical testing methods for dissolution, dosage unit uniformity, product assays and a stability module that simplifies the process of designing, implementing and managing stability studies.

Integrating Darwin

Until recently, environmental monitoring and LIMS have typically been disparate systems, requiring users to monitor and aggregate data from multiple environmental locations for product and batch traceability. Darwin LIMS fully integrates environmental monitoring data into the batch record and its built-in charting tools allow users to visualise each location independent of the samples. This ensures that any failure is apparent at the batch level and allows the laboratory to quickly determine whether the source of the contamination is in the laboratory or the production environment.

This built-in functionality enables laboratory managers to react to non-conforming product before it reaches the consumer. By linking this data to the LIMS directly, pharmaceutical companies can have greater confidence in the quality of their results and ultimately in the quality of the product they bring to the consumer.

In order to meet the critical needs of the pharmaceutical manufacturing laboratory, Darwin LIMS has been designed to be familiar to users. By delivering an intuitive user interface and a logical layout that includes common objects such as batches, drug products, drug substances and market-based specifications, as well as standard testing methods such as assays and dissolution testing, Darwin LIMS addresses more of the critical needs of the pharmaceutical manufacturing lab while delivering the increased functionality that multi-site/multi-user labs are looking for. Darwin is developed on the Microsoft .NET framework, supporting open development standards so that in cases where specialised functionality is required, users can easily extend the system using standard commercial development tools and languages. For example, users can modify screens and develop reports to meet their unique needs without custom coding or IT involvement. Darwin LIMS is completely extensible for integration with complex in-house systems using industry standard Microsoft Visual Studio tools and skill sets that are readily available in the marketplace or within an internal IT department.

Conclusion

Pharmaceutical companies and their associated CMOs and APIs employing Darwin LIMS as part of a comprehensive informatics solution can expect to lower costs, risk and time associated with implementation, training, validation, maintenance and upgrades compared to generic LIMS that require costly customisation and maintenance. Since a LIMS is one of the most important tools in the pharmaceutical laboratory, Thermo Fisher Scientific believes that by providing purpose-built solutions, it enables its customers at every level of the delivery chain to be more productive in their business, and ultimately lower the total cost of ownership for their LIMS investment. ■

Further information
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