When Is a LIMS a Pharma LIMS?

Generic LIMS rely on too much customization to meet the needs of today's pharmaceutical research environment.

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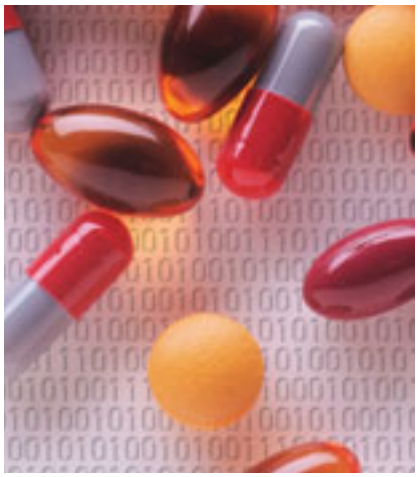
Too often, companies believe they have to purchase a laboratory information management system (LIMS) from a selection of generic systems and then spend many years and significant additional money to install the system, customize it to address critical functions that are unique to their industry, and then validate the system.

In the pharmaceutical environment, this approach has been particularly difficult. Under the governing eye of the Food and Drug Administration (FDA) or in GxP environments, the criticality of a pharmaceutical company's data cannot be overstated. Because each step in the drug discovery and development phase must be captured and recorded, the functionality of the LIMS that handles and stores all this data must be documented, tested, and validated. Custom code, therefore, requires custom validation scripts, which have to be created and validated in their own right. With each upgrade or new release of a generic LIMS, these scripts have to be retested and revalidated to ensure the upgrade is successful. Clearing the implementation and validation hurdles with a generic LIMS, therefore, can take years.

After some painful, even career-ending experiences, the marketplace acceptance of generic information technology (IT) solutions has declined. Even major companies realize this. In a recent publication, IBM stated that it was "shaking up the way it develops and sells software." The computing and services company said it plans to move away from producing generic business software and will soon begin tailoring virtually all of its offerings and sales efforts to meet the needs of users in specific industries.

IBM's software shift is driven by changes in customers' buying behavior. The company says that business customers are increasingly looking to buy software that is already configured for their specific industrial needs.



CAPSULE IMAGE: PHOTODISC

Purpose-Built

Filling the void created by generics are purpose-built solutions that deliver LIMS with a core functionality that is both unique and critical to the specific industry. This is especially important to pharmaceutical customers, but it is proving to be essential in other industries as well.

Unlike generic systems, for which implementation demands the deployment of a host of implementation specialists and consultants who often first must learn the customers' business in order to develop the custom code, the purpose-built LIMS solution has been designed with industry knowledge.

Because LIMS handle the workflow of the laboratory, and different industries have different laboratory processes, it stands to reason that a single product cannot meet the needs of all laboratories. Generic solutions traditionally have required far too much effort, expense, risk, and time; customers are demanding a better, less risky way.

Purpose-built pharmaceutical LIMS provide the pharmaceutical user with as much as 90% of the required functionality as part of the base system, thereby significantly reducing the time and money spent on its implementation and validation. To achieve this, these solutions are built from strong knowledge of the user industry and its requirements and regulations.

A pharmaceutical LIMS solution should come with standard functionality that supports the complex testing, workflow, reporting, and regulatory requirements inherent in the drug development and manufacturing process. However, until specifically coded and validated, this functionality is absent from generic LIMS.

The Pharma Process

Drug discovery has many starting points, but overall it can be regarded as a supply chain. Within the supply chain, there are many fundamental stages and studies that must be performed. The details of the supply chain are governed by the needs of the drug company to adhere to regula-

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tory guidelines and to enable the research teams to quickly isolate and identify compounds with desired pharmaceutical properties. Examples of the key stages include in vitro studies, preclinical and clinical studies, stability determination, and dissolution testing.

For a generic system to address the needs of all of these vertical applications is practically impossible. Much of what the end user requires from a generic LIMS has to be heavily customized. Even then, time, resources, and financial constraints force the user to prioritize mandatory features to ensure that "go live" dates are met. It can leave them without all the features that they need.

Dissolution testing, for example, is a requirement of all pharmaceutical companies producing drug compounds. Even more common is the need for stability testing. The International Committee for Harmonization (ICH) has defined stability protocols for various product types on the basis of four climatic zones found around the world.

Given that these standards exist, clients should expect to see this functionality within a pharmaceutical LIMS as standard. It is disappointing that while some LIMS vendors provide stability functionality, these systems are not designed to meet global ICH standards. As for dissolution testing, such functionality is even rarer. This lack of appropriate functionality means that such systems must be described as generic rather than pharmaceutical LIMS.

For a pharmaceutical company to perform a full analysis of a drug compound, it must be able to store within the LIMS all desired information about the drug. This includes all information about the chemical properties of the compound, its formulation, excipients, and properties. While many generic LIMS can be customized to store this data, pharmaceutical LIMS solutions provide this functionality as standard.

Another benefit of a purpose-built LIMS would be its focus on organizing data in a way that is useful for the industry that the LIMS is being designed for. Typically, generic LIMS organize data according to samples. But the pharmaceutical industry generally organizes its data by studies, batches, products, or lots—as do pharmaceutical LIMS.

A Vendor's Answer

The difficulty facing pharmaceutical customers has not gone unnoticed by LIMS vendors. Many have adopted the strategy of providing, along with their generic systems, bolt-on tool kits that address the pharmaceutical industry. Yet other vendors, such as InnaPhase Corp. (*www.innaphase.com*), have gone back to the drawing board and built—from inception—LIMS specifically for vertical markets. Programmers with pharmaceutical industry experience are essential for developing LIMS that address all segments of the drug development continuum—from discovery through preclinical and clinical stages to manufacturing quality control. Pharmaceutical LIMS can also be delineated from generic LIMS even further, and although only one example, InnaPhase has introduced three LIMS for specific

LIMS on the Web

A great deal of information about LIMS can, naturally, be found on the Internet. Several prominent groups support users and those interested in LIMS, and they also hold meetings. The LIMS Institute (*www.limsconference.org*) annual meeting, now called Laboratory Informatics, has been held since 1986; and for the past two years, it has been held in conjunction with the Pittsburgh Conference (Pittcon). Another service that the LIMS Institute offers, through the servers of the LIMS consulting company Taratec, is the LIMS List. This is a list server on which numerous LIMS users post questions, answers, jobs, and comments about the LIMS industry.

A slightly different organization that has a strong interest in LIMS is the Laboratory Robotics Interest Group, sometimes better known as LRIG (*http://lab-robotics.org*). This organization of more than 7000 members is a grassroots-based group holding meetings in its 12 local chapters and is a probationary member of the American Chemical Society. Although the organization is best known for its local meetings, it also operates an e-mail discussion group and an advance meeting calendar highlighting all types of laboratory informatics meetings.

The Association for Laboratory Automation (*www.labautomation.org*) produces a journal, JALA, and hosts two yearly conferences, ALA LabFusion, which held its inaugural meeting in June 2004, and LabAutomation, which was held in February 2004.

With these conferences and resources, LIMS users and potential users have numerous opportunities each year to find a meeting that is convenient to attend and numerous places online to find additional information. If you are interested in the history of LIMS, be sure to read the article by James Ryan on page 34 in April's *Today's Chemist at Work*. That article was based on Ryan's talk on the history of LIMS given at the Laboratory Informatics 2004 conference at Pittcon.

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portions of the drug development pipeline: bioanalytical studies (Watson LIMS), in vitro studies (Galileo LIMS), and analytical development (Newton LIMS).

When faced with the choice of taking a generic LIMS and building it to suit their needs, or implementing a purpose-built system that can more quickly configure for individual needs, the bioanalytical market has spoken. One simple test to ensure that a LIMS being demonstrated is in fact a pharmaceutical LIMS is to check the documentation provided with the system. Map this documentation to the functions and features demonstrated. If such documentation is not available—and often it is not during the evaluation process—look to see if the demonstrated features are fully explained within the help file. The lack of help almost always means that the features are not validated and that the system has not been designed exclusively for a given field.

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