

Too Many LIMS?

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Laboratory information management systems are reaching toward different uses, trying to be more things to more people.

The information technology revolution planted its seeds in analytical labs long ago, resulting in the development of laboratory information management systems (LIMS). The use of information systems to provide efficient methods of recording and tracking samples, reagents, and equipment helped laboratories operate more efficiently.

The efficiency gains from implementing LIMS have led to their widespread use in laboratories. LIMS makers, many of them instrument companies, generated products to handle sample tracking and many other functions for analytical and production labs. The LIMS market has matured and changed from many products with similar capabilities to many unique products for niche markets. Many of these systems share a common ancestry and common core, that of the traditional LIMS. As a result of this specialization, a company can no longer just ask for a LIMS. Today, a company needs to know what it requires in a LIMS and the manufacturers that specialize in products for its industry.

Integration with corporate information technology (IT) functions, seamless control of laboratory instruments, enterprise-wide computing, forensics, health care, and R&D are all areas of specialization. Douglas Perry, associate dean for graduate studies and research at Indiana University School of Informatics said, "R&D used to be peripheral to LIMS if at all. Now R&D is demanding LIMS. They are demanding some sort of data management system." This need for LIMS by everyone from the R&D researcher to the pharmaceutical industry plant operator is forcing a significant change in LIMS. It may even transform LIMS so that sample tracking is no longer its most important function. If so, should it still be called LIMS?

Improvement at the Core

The core of the LIMS market is still analytical testing. While this market has gradually become more specialized, the major players are still producing very



welcome innovations in new versions of their time-honored systems.

Many manufacturers are providing increased interaction with instrumentation and other programs. One major standout in integration with instruments is Lims-Link, which provides a layer connecting instruments with LIMS programs. Other companies have signed deals with instrument makers to interact with their software. An example is StarLIMS (LIMS USA), which signed a deal with Waters Corp. to build closer interaction between Waters' Millennium chromatography data system. Interactions between LIMS and instrument software is not a new trend, but LIMS interacting with other corporate software is new.

Corporations are taking a more unified look at information systems and are demanding that programs work across the entire organization and not just in an isolated lab. In addition, some organiza-

tions are tying a LIMS to customer resource management (CRM) and/or enterprise resource planning (ERP) software to provide testing data to management or a client directly through the computer systems.

Some LIMS vendors have responded with "enterprise software" that links analytical information with corporate inventory management software at manufacturing plants. Systems such as Thermo

Labsystems' Sample Manager provide data management software to integrate lab data with other corporate IT software. PerkinElmer's Labworks LIMS provides a connection to geographical information systems to graphically display and validate sample collection dates and locations. LABlynx LIMS offers modules that can be installed with its LIMS that cover enterprise functions like accounting, human resources, and ERP. LIMS programs, like CCLAS ELL from Comlabs, are compatible with ERP programs like SAP, whereas other systems, like Blaze System's Enterprise LIMS, export information to ERP software. Other vendors are considering different solutions to the same problem. Telecation's Aspen LIMS v5.0 is one of many IT systems using XML to allow the data to be understood by a wide array of programs and platforms.

Roots and Limbs

Several LIMS companies are focused on small labs, which are an important niche area that is often ignored by large LIMS vendors. Lab-2000 LIMS (Genesis Microsystems) focuses on sample processing with wizards for sample login, analysis, and reports. Lablite Evolution (Lablite, LLC) is extensively connected to Microsoft Office applications like Word and Excel, enabling small businesses to use this software to do some of the work. Other companies provide LIMS for small labs—one clue to finding appropriate products is to look for software, like Tropical Software's LabPartner, that can be implemented on Microsoft Access.

This database program comes with Microsoft Office, and while it cannot handle very large amounts of data, it is inexpensive compared with Oracle, IBM, or other Microsoft database products. Some large LIMS vendors are now targeting the small lab. Beckman Coulter (producer of Labmanager iLIMS) introduced Polaris LIMS at this year's Pittcon. The program is designed for a maximum of 20 users but incorporates important

functions, such as electronic signatures and data locking, required by FDA and possible EPA regulations.

Migration to 21 CFR 11

In 1997, the FDA finalized requirements (Title 21, part 11 of the *Code of Federal Regulations*—21 CFR 11) stating how electronic data is to be handled in industries that it regulates. The regulations produced a surge in LIMS develop-

ment. The aim of the rule was to convert the trail of information from paper to computer files, yet to retain the legal accountability of paper. In other words, electronic signatures and documents need to be as trustworthy (in court or FDA audits) as a paper document or a handwritten signature. Affected companies were required to submit proposals outlining how they were going to comply with the regulations.

Companies affected by the FDA regulations searched for ways to comply with them, and LIMS vendors responded with systems that were 21 CFR 11 compliant. The trickle of compliant programs has since turned into a deluge.

In fact, with so many LIMS becoming 21 CFR 11 compliant, the regulation has become a standard for auditable information systems. New EPA regulations are being built on the 21 CFR 11 rules. This means that almost all LIMS will need to be compliant with 21 CFR 11 and/or the EPA's version.

When a LIMS Is Not a LIMS

Perhaps the greatest change in LIMS is what is not yet being called LIMS. It is clear that this category, without a standardized name, is what LIMS is becoming—something more than sample tracking. Various acronyms could be used to describe these programs, from scientific knowledge and information management (SKIM) to enterprise electronic lab notebook and LIMS (EEL-N-LIMS), just to propose a couple.

There are several other companies pursuing the data management angle. LabVantage's Sapphire software is aimed at bringing the lab closer to the rest of the enterprise, as well as incorporating electronic lab notebook (ELN) qualities. ActivityBase, by IDBS, also targets managing scientific data at the enterprise level, but unlike LabVantage, IDBS does not call its product a LIMS.

NuGenesis' Scientific Data Management System (SDMS) and Scientific Software's CyberLAB Knowledge Engineering System (CyberLAB KES) are two of a new breed of LIMS-like programs. They embody LIMS functions as well as ELN and data management functions. The result is a new specimen, capable of more than either LIMS or ELN alone or installed together.

SDMS and CyberLAB operate by capturing data generated by instruments in their native file format. They are also

capable of capturing human-readable data from Microsoft Windows programs. In capturing data from instruments, these programs are like a LIMS in that they direct samples and results. In capturing human-readable data, they are like an ELN. However, SDMS and CyberLAB manage all of this information by putting it in a large database, which can then be accessed by other computers via a Web interface.

One of the key features of SDMS and CyberLAB is the method used to import information from instrument report files and Windows programs. The program shows the user the text file generated by an instrument or program. The user can then select which information within the document to provide metadata for. In other words, the user can show the program where to look for certain information. The information can then be lifted

from the same location in subsequent imported files from the instrument.

These steps could be accomplished using programming languages like PERL; however, it would be potentially more time consuming and would require more programming experience. SDMS and CyberLAB eliminate these problems and generate a useful, flexible way to manage data generated by labs.

The method by which SDMS and CyberLAB gather human-readable data, like a Microsoft Word document, begins by tricking Windows programs to generate a document for printing. The Windows program in question generates a file for the printer, which SDMS or CyberLAB captures and incorporates into its database. Then, metadata can be provided and information gleaned from the document.

This print trick is patented (U.S. Patent 6,260,044) and is the subject of an ongoing patent infringement case between NuGenesis and Scientific Software. The patent was granted on July 10, 2001, to NuGenesis, and the company launched its patent infringement suit on July 12, 2002, because Scientific Software's CyberLAB uses similar methods to obtain information from other programs. Scientific Software President Soheil Saadat responded by saying, "We see no basis for asserting that Scientific Software is involved in any infringement. Moreover, we also believe that this patent is invalid." Scientific Software is countersuing NuGenesis to prove that the patent is invalid.

Conclusion

LIMS vendors are shifting their weight, for the most part, from the testing labs to R&D. New classes of LIMS products are taking advantage of needs in various niche areas, such as forensics and small labs. The name of the game will continue to be customization on one side and growth into scientific information management on the other side. Whether the LIMS name is used or abandoned, new systems will benefit all areas, as new developments make their way throughout the entire scientific information technology field.

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