



In Perfect Harmony

Each of your labs probably has a laboratory information management system (LIMS) that it knows and loves. Chances are that each of those LIMS is functioning independent of the other labs' LIMS — but why? It's a lonely and complex industry. Introduce them to one another. Standardize.

Pharmaceutical companies that are planning or deploying a laboratory information management system (LIMS) solution face significant challenges. In the past, LIMS purchasing decisions largely focussed on meeting the needs of individual labs, with little consideration made for enterprise knowledge sharing, compatible reporting formats or business process harmonization from lab to lab. Today, companies are contending with increased LIMS adoption across more of their labs, an increasingly stringent regulatory environment (see sidebar "Regs Affecting LIMS") and a proliferation of installed LIMS solutions resulting from company mergers and acquisitions. In addition, tighter

budgets and changing economic conditions are forcing companies to curb expenses, reduce errors and improve quality. The combination of these factors is driving companies to closely examine the way in which their LIMS solutions are purchased and deployed across the organization.

Companies operating multiple LIMS solutions, resulting either from lab-level purchasing decisions or corporate-led merger and acquisitions, fail to benefit from business efficiencies that can be realized from a consistent approach to LIMS acquisition and deployment. With a decentralized LIMS strategy, laboratories wind up operating solutions that were acquired, customized and/or configured to support local

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processes, and end-users find themselves at odds with corporate initiatives to harmonize processes. In addition, incompatible file formats resulting from disparate LIMS make reporting and sharing lab data across the enterprise difficult. This can have repercussions for global management structures in making critical decisions concerning product quality, resource allocation and process optimization. A multi-LIMS strategy also poses challenges for a company's information technology (IT) department, which must be adequately staffed to support, upgrade and validate a range of solutions.

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Admittedly, the process of introducing a standardized LIMS can be challenging. Companies must first develop consistent procedures, processes and methodologies, and encourage end-users to adopt them. Convincing scientists to discard established processes and embrace centrally-dictated policies for the benefit of the organization can be a challenge. However, visible senior-level commitment to the initiative and solid project management can be crucial in ensuring a smooth and successful implementation. It is also important to involve a representative group of end-users to ensure early buy-in to the project and a full appreciation of the potential benefits of a standardized solution.

In an effort to address today's changing economic environment, the industry is witnessing growing trends toward harmonizing business processes and standardizing LIMS solutions. The case for implementing a standard solution on a global basis is clear. From a business perspective, one global

solution enables easier access to data from across the organization, facilitating better and more standardized enterprise reporting, lowers training costs and affords greater flexibility in transferring employees from one lab to another as work volumes change. With one LIMS, companies can more easily centralize training and train more users at the same time, significantly lowering the cost of training per end-user.

From an IT perspective, a standard configuration applied to all sites allows IT resources to develop expertise in one solution, making them better equipped to identify and solve problems before they occur and quicker to respond to problems when problems do occur. Standardization can also reduce vendor complexity, improve purchasing power, allow more efficient upgrades and integration to other systems, and streamline IT management. By streamlining the number of vendor relationships, for example, the challenge of managing multiple relationships, licence agreements and support contracts diminishes significantly. A single LIMS strategy lets IT departments focus on delivering end-user support on one system and developing a consistent, harmonized validation plan. In addition, standardization simplifies the integration of LIMS with other corporate applications such as an enterprise resource planning (ERP) solution. Developing, acquiring, installing and maintaining an interface between a standardized ERP and a standardized LIMS is a considerably easier undertaking than implementing 'point' solutions between the ERP and a number of different LIMS.

Standardization has a direct impact on lowering a system's total cost of ownership (TCO), a measure of the full life cycle costs of a particular IT asset. In addition to licensing fees, implementation costs and annual vendor maintenance expenses, TCO takes into account internal costs associated with implementation, hardware, IT support and upgrades. Studies have proven that the capital expense associated with any software deployment often comprises the smallest portion of a solution's TCO. For example, several research firms, including META Group, Forrester and IDC have compared the costs of Windows and Linux operating systems. These studies concluded that Linux, which is essentially free because of its limited acquisition costs, actually winds up costing more than Windows primarily as a result of IT staffing, integration and ongoing infrastructure management. One study in particular confirms that initial software acquisition costs are only one driver of TCO.¹ Despite such research and a general acknowledgement that acquisition costs do not comprise total costs, some decision makers continue to focus only on licence cost when making a LIMS decision. Non-vendor costs, such as internal system support and administration, however, comprise the largest portion of the TCO of a LIMS.

Challenges in deploying a standard solution

Although the benefits of implementing a standard LIMS solution are evident, a global LIMS implementation can be fraught with challenges. Standardizing on one LIMS requires a significant investment of time and resources. Successful deployments entail months of planning and time devoted to a review of company-wide processes, identification of best practices, system design and development, data migration and training.

REGS AFFECTING LIMS

FDA's Electronic Records and Electronic Signatures Final Rule (21 CFR Part 11) has been in force since 1997, bringing about a sea change in laboratory compliance regarding LIMS and other laboratory informatics systems. The following are a few of the predicate rules underlining Part 11 compliance:

Good Laboratory Practice (GLP)

- 21 CFR 58 GLP for Non-clinical Laboratory Studies.

Good Clinical Practice (GCP)

- 21 CFR 310 New Drugs.
- 21 CFR 510 New Animal Drugs.

- 21 CFR 514 New Animal Drug Applications.

current Good Manufacturing Practice (cGMP)

- 21 CFR 211 cGMP For Finished Pharmaceuticals.

Quality Systems

- 21 CFR 820 Quality System Regulation.

Non-FDA

- EU Annex 11 to the EU guidelines of GMP for Medicinal Products.

- Australian Code of GMP for Medicinal Products, August 1990.

Organizations deploying a standardized LIMS must also harmonize business processes across the organization and ensure the solution can accommodate a diverse user group and geographically dispersed labs. This involves balancing the needs of individual labs and devoting time and effort to negotiating process changes across the organization. In early-stage research and development (R&D) environments, for example, harmonization may not be ideal and lab managers may resist corporate-led initiatives to standardize. In these situations, companies implementing a standardized LIMS will need to devote significant resources to customizing the solution to meet the needs of each lab. Manufacturing environments, however, are generally marked by clearly defined, repeatable processes. Achieving business process standardization in these environments might be easier to accomplish, but will still require effort to accommodate the needs of individual labs.

Is it all worth it?

Despite the challenges associated with a global LIMS implementation, more and more companies are actively undertaking initiatives to harmonize business processes and standardize on one LIMS solution. To date, the benefits of standardization have largely been anecdotal, with no industry data to support the notion of a global LIMS or to justify the costs associated with implementing a standardized solution.

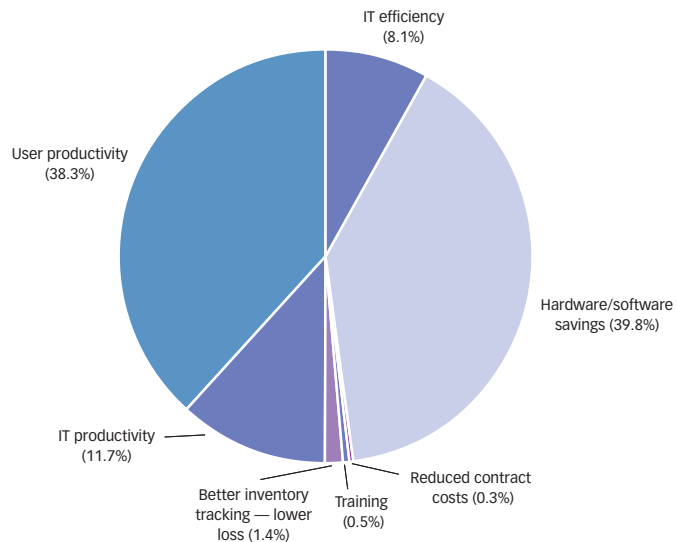
A study recently examined the issue of LIMS standardization in depth, interviewing senior LIMS and IT managers at leading companies across various industries that either have standardized or are in the process of standardizing on one LIMS solution. These companies cited the potential for reduced IT personnel, better reporting and easier access to data as key reasons for standardizing on one LIMS solution.²

All study participants experienced a significantly reduced TCO for LIMS, increased IT productivity and increased LIMS user productivity as a result of standardizing on one solution. Altogether, the companies recognized benefits of approximately \$300,000 (€250,000) per lab annually from implementing a standardized LIMS. Figure 1 shows that cost reductions such as hardware and software savings, IT efficiency and reductions in lost inventory accounted for almost half of all savings. Improvements in user productivity yielded another 38% of benefits.

TCO. In the area of TCO, 50% of the benefits of standardization were found to be in hard cost reduction, which includes expenses associated with hardware, software and IT operations. Additional savings were derived from IT staff reductions. Companies that standardized were able to grow their user base without adding staff, and others were able to reduce their LIMS IT staff. On average, companies were able to improve IT efficiency by changing their user per IT staff ratio from 50 to 86 — a 72% change, as a result of standardization. Other TCO-related benefits of standardization quantified in the study included a reduction in training costs per employee, reduced contractor costs and improved inventory tracking.

Increased IT productivity. The study confirmed that, as a result of LIMS standardization, companies could improve productivity, defined as the percentage of time IT staff devote to

Figure 1: Distribution of 3 year benefits from LIMS standardization (IDC, 2004).



productive areas. User support activities, applications management and validation, time devoted to troubleshooting activities and data management were typically reduced by more than 50%, and in some instances by as much as 90%.

Increased LIMS user productivity. A standard LIMS solution improved users' ability to access and report on data. Close to 60% of the companies credit LIMS standardization with reducing their time-to-market, while 77% felt a standardized LIMS improved product quality, which freed up on average 6.3 hours of productive time to each LIMS user per month. This number becomes significant when multiplied by the few hundred LIMS users a company may have in place.

Conclusion

Today's economic conditions require IT managers to do much more with far less, so the stakes are high on decisions regarding the procurement and implementation of solutions such as LIMS. Business process harmonization and standardization on one LIMS solution have become leading strategies for companies to not only reduce the TCO of LIMS, but also to improve time-to-market, enable more efficient reporting and improve the productivity of IT staff and end-users. Whereas standardizing on one LIMS can be a large and consuming undertaking, proper planning, devoting the right resources and partnering with an experienced vendor are all key to mitigating risk and ensuring success. Companies have already proven that the benefits of standardization clearly outweigh the costs, which will only encourage more companies to move in this direction.

References

1. "Windows 2000 Versus Linux in Enterprise Computing — An Assessment of Business Value for Selected Workloads," www.idc.com
2. "Standardizing on LIMS: TCO and ROI [return on investment] for the Multi-Lab Setting," www.idc.com ■