

LIMS Solutions: Getting a Balance Between Off the Shelf or Custom-Built

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INTRODUCTION

Purpose-built software is a hot topic because many companies are hoping to significantly reduce the risk of laboratory information management system (LIMS) implementations, and subsequent validation processes. Companies are also looking for reduced maintenance and training costs, simplified upgrades, and much greater user acceptance. There is confusion, however, about what a purpose-built solution really is, and what the true validation requirements of such a solution would be.

A LIMS PRIMER

Traditionally, LIMS solutions have been designed to be as generic as possible in order to suit the requirements of as wide a market as possible across multiple industries. These systems offered basic sample- and test-management capabilities, but they required lengthy and costly customisation so as to meet industry- or application-specific needs. For this reason, vendors provided tools that allowed the customer, the vendor, or third-party consultants to modify and extend the system and the database to suit their purposes.

In some industries, this approach was not too problematic, as the basic functionality of conventional LIMS solutions was close enough to the principal industry requirements, thus requiring only minimal customisation. For the pharmaceutical industry, as well as biotechnology and contract research organisations, however, the situation was much more complicated.

Pharmaceutical researchers work in labs ranging from early-stage drug discovery to bioanalytical testing of drug candidates, to manufacturing development and quality control. Application of a LIMS solution to those varying labs requires extensive customisation. Customisation is also required due to the batch- versus sample-oriented production processes, complex specifications and test methods, and tight global regulatory requirements. Like a snowball, each

additional requirement generated an avalanche of additional work: specifications, design, development, testing and validation, documentation, and more. Customers also ran the risk of breaking their customisations when upgrading to new releases.

Productivity was further decreased due to the increased system complexity resulting from extensive customisation

As a consequence, the risk of failed or significantly delayed deployments increased considerably. Pharmaceutical customers often found they needed to build via customisation as much as 60 per cent to 70 per cent of their desired functionality. Productivity was further decreased due to the increased system complexity resulting from extensive customisation.

Today, flexible purpose-built LIMS solutions are designed to deliver as much as 85 per cent of the required functionality right out of the box, while enabling users to tailor the system to their exact needs. From a timeframe perspective, past experience with generic solutions has seen LIMS implementations taking as long as 36 months and, in some cases, dragging on for so long that the projects were cancelled. It is no wonder, then, that application-specific solutions have generated such great interest in the pharmaceutical industry.

WHAT IS A PURPOSE-BUILT SOLUTION?

There are several interpretations for whether a software system is purpose-built or not. The war of words often revolves around 'customisation' versus 'configuration'. Customisation is defined as ANY manually written code that modifies the system behaviour. Whether the LIMS embeds a scripting language or requires custom functionality to be

written in an external tool or environment, any written instructions to create functionality represent customisation – at additional cost in time, money and resources to the customer. This would include manually creating XML or HTML for web-based user interfaces, or stored procedures to automate workflow processes. Configuration, on the other hand, offers control over the software without requiring any additional code.

Take the example of automatically printing sample labels at the time of registration. In a configurable scenario, a purpose-built LIMS may include a checkbox in the set-up options that activates label printing at the time of sample registration. In the customisation scenario, systems that do not offer such an option would require the system administrator to write code that triggers sample label printing at registration time. In the first scenario, the customer relies on vendor testing as evidence that the label printing capabilities are functioning as designed; in the second, there is no such vendor testing. The functionality has been implemented at the customer site in a specific instance, and requires complete lifecycle management and validation, at additional expense to the customer.

That is a small and simplistic demonstration of the differences between configuration and customisation. A more complex example can be found in dissolution testing for oral dosage forms, which represents a complex, multi-stage test that is typically not supported by generic LIMS. The majority of LIMS solutions available require extensive customisation to handle the stage-to-stage evaluation of results, as well as the cumulative results review that is necessary to assess whether or not the dissolution testing meets specifications.

Customisation to build this functionality, as noted in the previous example, requires extensive testing, validation, documentation, training and maintenance. Many LIMS administrators have actually had to build dissolution-testing functionality from scratch more than once, as their companies have moved from one LIMS platform to another.

CAN A PHARMACEUTICAL LIMS REALLY BE PURPOSE-BUILT?

For years, pharmaceutical customers have been asking in frustration why they must rebuild what they consider should be standard functionality in their LIMS. Dissolution-testing procedures, for example, have been clearly defined in the USP and other pharmacopoeia for many years. Yet, vendors have resisted incorporating industry-specific functionality. The most commonly cited reason is that they cannot incorporate industry-specific features into a product that is designed to be generic enough to be sold across multiple industries.

Currently, however, some vendors are recognising that solutions which satisfy the pharmaceutical industry's unique needs can be mutually beneficial. After all, the pharmaceutical industry is the LIMS industry's predominant market. Newly developed purpose-built solutions meet specific industry and application needs from scratch. While formal data are not available, anecdotal evidence indicates that the majority of pharmaceutical customers would pay a higher licence fee for software with more application- or industry-specific functionality.

This may seem improbable, but the advantages are numerous. Every feature that eliminates the need for custom development work provides significant savings during implementation and production use. Equally important, the reduced customisation allows a pharmaceutical company to have a better grasp on actual deployment costs and timelines, since there are far fewer opportunities for delay when customisation is minimised.

Newly developed purpose-built solutions meet specific industry and application needs from scratch

To reduce risk and customisation further, Thermo Fisher Scientific provides four distinct LIMS solutions for the pharmaceutical industry. Each one of these systems is purpose-built to support a specific application, such as early-stage R&D, particularly in biotechnology (Nautilus LIMS™), in vitro ADME/Tox research (Galileo LIMS™), bioanalysis (Watson LIMS™), and manufacturing R&D and quality control (Darwin LIMS™).

This may raise a seeming contradiction between the trend towards more granular out-of-the-box functionality and the global trend toward standardisation. However, this is not a contradiction at all when viewed at the right level of standardisation in an organisation.

The fact is, one should standardise only where it is advantageous to do so. If a company has 25 manufacturing facilities worldwide, with a quality control lab in each, standardisation can have great benefit in harmonising processes, and in reducing deployment and validation costs across those 25 sites. It would not make sense, however, to try and apply a tool designed for QC testing to a protocol-driven clinical bioanalysis laboratory, nor would it make sense

to use an MRP/ERP (manufacturing resource planning/enterprise resource planning) system to manage complex testing and sample management.

Pharmaceutical companies are competing for sales in the same markets, they must satisfy the same regulatory agencies, and they face regulatory trends towards standardisation, as evidenced by the success of the International Conference on Harmonisation. Given this situation, built-for-purpose solutions do offer multi-faceted benefits. Not only do they greatly reduce customisation, but they place the burden of following and implementing new regulatory and industry developments and trends on the shoulders of purpose-built LIMS providers. Domain expertise on the part of the vendor is therefore critical.

100 PER CENT IS NEITHER POSSIBLE NOR DESIRABLE

There are several challenges that make a 100 per cent purpose-built solution impossible to attain. The sheer volume of tests and results that need to be supported, the extensive calculations, and the wide variety of reporting requirements are all areas of high variability that seemingly do not mesh well with the built-for-purpose philosophy. The wide variation in requirements and workflow between companies working on small molecules or in biotech, different routes of administration, differences between research and development and the production world make it virtually impossible to design a one-size-fits-all solution.

But, anyway, a 100 per cent application-specific functionality is not desirable. Pharmaceutical companies do not wish for fixed, rigid off-the-shelf solutions that users could not modify at all to suit their specific purposes. The real objective is to minimise customisation to the maximum extent possible while allowing for enough flexibility to enable users to tailor the system to their exact needs.

When examining a LIMS to assess the extent to which the system may meet your requirements, you should always identify some areas which represent gaps between user requirements and out-of-the-box functionality available from the system. The important thing, after reducing the gap as much as possible by selecting a purpose-built solution, is to have a complete understanding of the vendor's strategy for closing the remaining functional gaps.

Tools to extend the software must be available; the vendor should be able to provide experienced analysts to assist in the deployment, and the technology platform should use modern architecture and open standards to facilitate the required extensions. In addition, an application-specific solution does not

eliminate the burden of responsibility on the part of the user. While the validation effort may be greatly reduced, there will still be some effort required to provide reassurance that the system, as configured, is functioning according to expectations.

It is also important to assess the levels of compliance and flexibility inherent in the solution. Historically, despite extensively customising generic systems, pharmaceutical companies have been unable to implement one solution to concurrently meet the needs of the less-regulated users, such as in analytical R&D labs, and those working in tightly monitored production laboratories. The configuration of the system should include the definition of compliance rules based on the type of data being manipulated.

CONCLUSIONS

The built-for-purpose philosophy has great appeal and provides tangible benefits in the pharmaceutical world. While pharmaceutical LIMS buyers should not seek out a 100 per cent off-the-shelf solution, a system that can provide as much as 85 per cent of industry- or application-specific functionality out-of-the-box will be a great boon to LIMS administrators, users, and their pharmaceutical companies. The significant reduction in deployment time and costs, as well as the reduced risk associated with clearly defined pre-existing functionality can change the nature of a LIMS from an overhead expense implemented to provide regulatory compliance, to a truly effective business solution with measurable gains in efficiency and timeliness. ■

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