CLARKSTON CONSULTING

INSIGHTS

Reaching the LIMS Promise

The Reality of Application Convergence and What it Means to the Future of Laboratory Automation

In the classic Aesop fable, The Fox and the Grapes, a fox desires some grapes hanging high overhead. When he is unable to come up with a way to reach them, he convinces himself that the grapes are probably sour and therefore not desirable anyway. “Sour grapes” has become an idiomatic expression, used for hundreds of years, to convey simply the universal human condition of feeling disdain for something that one could not attain.

Over the past decade, in our experience working with Life Sciences companies, we have seen our fair share of ‘sour grapes’ applied to Quality Systems and more specifically, laboratory automation. Though most Life Sciences and Consumer Healthcare companies are in a position to reap significant benefits through process improvements coupled with automation of their laboratories, the cost, resource requirements, and limited flexibility of their systems have remained largely unreachable and therefore, perceived as ‘sour’.

Our perspective remains that cost reductions, efficiency gains and increased compliance position should not be so unattainable as to call to mind the unreachable fruit. As Life Sciences and Consumer Healthcare companies embrace the concepts of laboratory automation they can reap benefits including:

- Efficiency gains in sample throughput time
- Reduction in calculation and transcription errors
- Reduced costs to staff and manage the laboratories
- Limited reliance on paper and record retention
- Increased overall compliance position
- Increased capability to perform data analytics
- Enabled review by exception

Over the past several years, changes in the Quality System technology landscape are driving convergence of tools and capabilities. Now more than ever, firms are in a position to leverage their existing system landscape and achieve this vision with significantly less investment.

Unmet Expectations

In less than a decade, the industry has shifted significantly regarding spend on Compliance and Quality System technologies. Gone are the days of 'compliance at any cost', as firms have experienced a significant increase in scrutiny related to technology spend. Risk-based approaches to solving compliance and quality needs coupled with an increased focus on return on investment (ROI) and total cost of ownership (TCO) have severely impacted funding requests and project support.

Through this new lens, the technology that has seen the most significant scrutiny is traditional Laboratory Information Management Systems (LIMS). Starting off as a way to capture results and perform calculations, LIMS gained significant momentum in the early part of the last decade due to substantial improvements in their Quality Assurance (QA) and Quality Control (QC) work flow functions. In recent years LIMS providers have taken integration to the next level, allowing for data capture directly from laboratory instruments.

While this was a significant step forward for management and control within the laboratories, it came at quite a price. Excessive customization was required, resulting in exorbitantly high implementation and support costs. Further, these systems were often created with management in mind, rather than lab analysts. The functionality needed to automate the laboratory existed within LIMS; however, it was more of a forced fit, prohibiting full-utilization within the lab.

Over time, both Quality and IT leadership began to see traditional LIMS as a costly tool that did not deliver true value for their money. It did little in terms of truly creating opportunities to reduce work and proved very costly to implement and support.

The appetite for lengthy LIMS implementations, which require significant investments of time, capital, customization, and validation, has virtually disappeared for some segments of the Life Sciences and Consumer Healthcare markets. Additionally, companies have realized the TCO for traditional LIMS, including maintenance and required support headcount, is much higher than anticipated, which has further decreased an already hard to justify ROI.

The result is simply that many companies with stalled or slow-going LIMS implementations are choosing to stop or re-scope their projects short of realizing the benefits that would come from a true laboratory automation solution. The future of laboratory automation is shifting away from traditional LIMS solutions.

The Traditional LIMS Solution

The original goal for the traditional LIMS solution was to remove paper and achieve compliance gains. Organizations were willing to invest in LIMS with the promise of the following core benefits: sample management, automated calculations, direct capture of instrument results, and reporting.

For several early adopters, LIMS delivered and the stories spread. At the same time, the focus for LIMS began to shift as organizations realized that LIMS was capable of more than sample management, results capture, and reporting. After the original benefits were realized, many companies began to look at LIMS as a possible solution to some of their other gaps. The goals for many LIMS solutions changed and became more focused on compliance and comprehensive management. The traditional LIMS solution finally took form as a laboratory automation solution - from lot creation to closure with everything in between - and could handle most of the components represented in Figure 1.

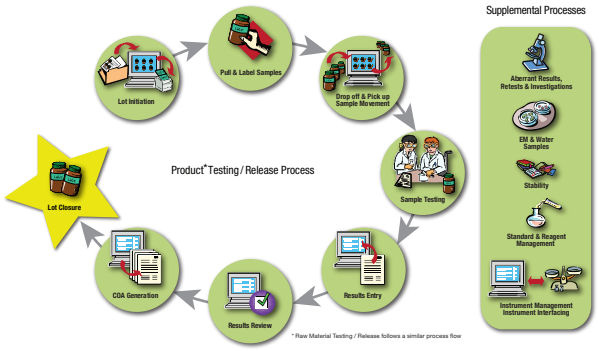

FIGURE 1: Traditional LIMS Footprint

The compliance and management drivers that led to traditional LIMS remain honorable and relevant. Unfortunately, many of these systems failed to meet organizational expectations which damaged the LIMS ROI promise. In the pursuit of achieving the right laboratory automation solution, 'Thick LIMS', a broad and deeply developed LIMS, was born.

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New Beginnings…and Application Convergence

The evolution of 'Thick LIMS' has been the result of companies seeking an ideal solution that, quite frankly, did not yet exist. Application providers in the laboratory systems space continued to augment their capabilities in order to differentiate themselves. This meant that LIMS providers continued to move vertically down into the laboratory instrument integration space and up into batch management. Many organizations followed suit, developing their LIMS systems to fill the voids not effectively addressed by other applications.

Meanwhile, in an effort to be more flexible and adapt to a user-base with different requirements, other application providers enhanced their products, blurring the distinction between their functionality and that which could have been done by LIMS. The result has been a convergence of applications in the Quality Systems laboratory automation space, which can either synergize or replace strained LIMS implementations. Convergence from instrument-centric solutions with Electronic Lab Notebooks (ELNs) and enterprise-centric ones such as SAP Quality Management (QM) are squeezing out traditional LIMS.

The convergence of ELN solutions and LIMS has continued to evolve into Laboratory Execution Systems (LES). Just as the movement toward electronic batch records drove development in the Manufacturing Execution System (MES) space, the movement towards electronic laboratory records has created the opportunity to record data and seamlessly integrate with existing systems and instruments. Many LES systems can now provide functionality previously reserved for LIMS, such as method execution, automated calculations, specification checking, sample tracking, and results review.

Further convergence has been demonstrated by LS companies with significant SAP system investments that are considering deeper utilization of Quality Management (QM) and related modules. Beginning with SAP ECC 6.0, the stability management, inspection scenario, and reporting capabilities of SAP's QM module have been significantly improved. In addition to the improvements in SAP QM, ECC 6.0 is more open and flexible for integration with external systems such as LES, and the platform is SAP's best yet at allowing for web enablement. This allows for actions like batch release decisions to be done from a browser window. Add to this scenario the reporting capabilities of SAP Business Intelligence or Business Warehouse and the quality group will be able to measure, manage, and possibly improve many everyday quality functions through better insights.

As the Quality Systems landscape continues to advance and converge, it is time to step back and re-evaluate laboratory automation solutions. Companies who have long searched for the promised benefits of laboratory automation are now privy to a new world of possibilities. The question is changing from 'if' the benefits can be achieved, to 'how' the benefits can best be achieved for an organization.

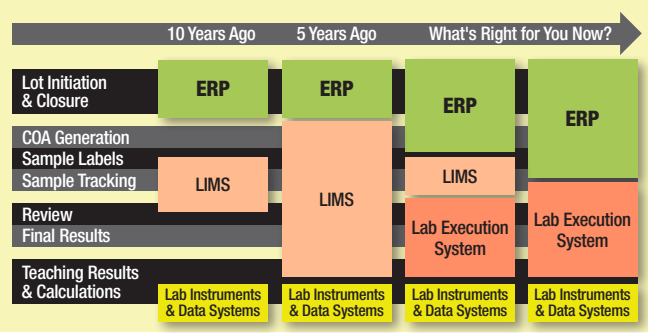

FIGURE 2: 10 Year Application Convergence Picture

Alternative Landscape Possibilities - What's Right for You?

Business issues have become more clear and technology advancements have allowed for alternative methods of sample management, analytical data build, and instrument integration. Traditional LIMS' original goals are once again in focus; only this time, there is an opportunity to use best-in-class applications to maximize ROI, minimize TCO, and achieve the ideal solution. The revolutionary landscape for laboratory automation appears to be shifting away from 'Thick LIMS' and converging towards 'LIMS Lite' – leveraging the strengths of LIMS and other leading applications to create a solution with optimized benefits and lower TCO.

Application convergence has given life to 'LIMS Lite' solutions that fit an organization's needs by combining the strengths of SAP, LES, and LIMS. The exact formula differs among organizations, which must consider current systems landscape, company resources, and future strategy driving the decision-making process. The following is a scenario in which SAP QM, LIMS, and LES work together to automate laboratory functionality and the associated decision-making criteria compared to 'Thick LIMS'.

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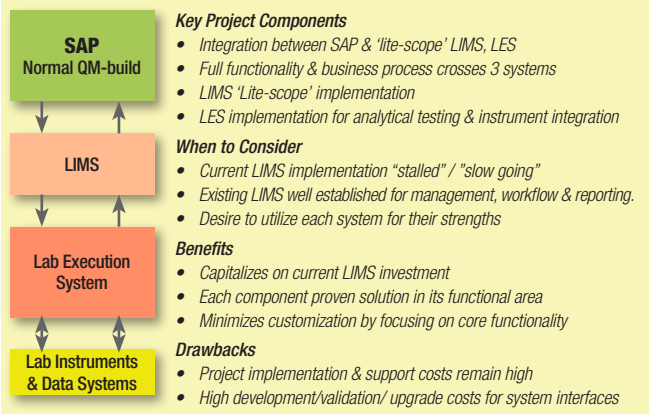
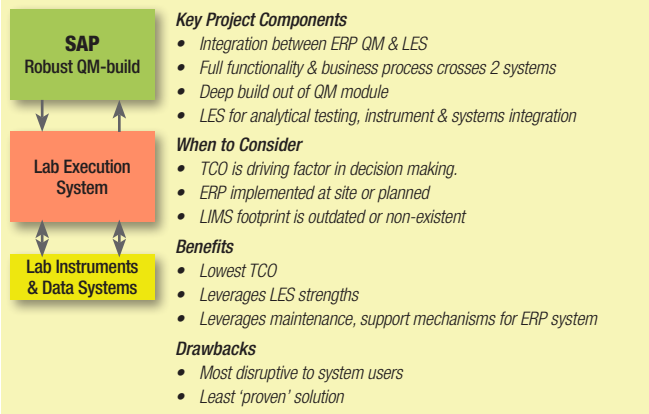


SCENARIO 1

In some cases it will prove beneficial to remove the LIMS component entirely from the equation. The functionality that the LIMS solution provides in Scenario 1 can be replaced by expanding the depth of an SAP QM implementation and extending the functionality of an LES to include more sample management. In this case, LIMS is squeezed out by converging the technologies. This can result in significant cost savings.



SCENARIO 2

Figure 3 provides an example of Scenario 2. Unlike the earlier traditional LIMS example (Figure 1), all the components are now strategically targeted at the optimal functions. SAP QM handles the lot and sample management functions while allowing an LES solution to focus on activities taking place in the lab. This design allows the scientist to focus on method execution and result entry, while capitalizing on the strong instrument interfacing capabilities found in the LES to capture instrument results.

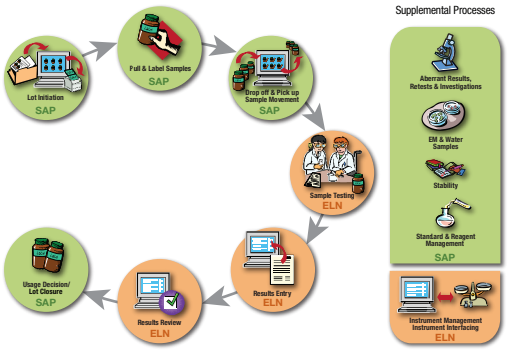


FIGURE 3: An Alternative LIMS Footprint

New opportunities are emerging in response to Life Sciences and Consumer Healthcare companies' demand for better efficiency and lower total cost. Technology providers have heard the cries and addressed them with expanded functionality packages that are driving application convergence. Companies seeking to optimize their laboratory automation systems to reap the full benefits must assess their current landscape and consider how they can leverage previous investments to build a future strategy roadmap. As the economy rebounds and organizations look for the next competitive advantage, why not start by revisiting the old quality goals and maybe…finally turn 'sour grapes' into fine wine?

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