Lodestone

Excellence in integrating LIMS and Life Sciences Supply Chain Management

by Michael Schmidt and Stefan Kubick

Operational integration within the supply chain requires more than just state-of-the-art IT systems

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One of the key demands for the future is to enable laboratories to work seamlessly with the internal and external supply chain process

“State-of-the-art” LIMS solutions have become commonplace in the quality control laboratories of Life Science companies. Almost all major companies have implemented new systems and have gained significant operational experience. However, even with a modern LIMS system seamless integration with the company’s supply chain remains a challenge for most organizations.

Supply chain integration of quality control laboratories and LIMS to MES and ERP systems is often limited to a few technical point-to-point interfaces. Lack of integration has resulted in process, data and technology gaps requiring workaround solutions. Significant opportunities exist to improve operational business process excellence through integration.

There are many factors that are driving life sciences companies to dramatically change their way of working including, Process Analytical Technologies (PAT), Real-Time Product Release, ePedigree and Track & Trace. These factors and other influences will require companies to investigate ways of better integrating and harmonizing quality control with supply chain.

In this paper we will examine the typical state of the integration of laboratories and their LIMS with the rest of the supply chain. We will highlight some of the reasons that led to the current issues and outline Lodestone Management Consultants approach that will help companies achieve full integration of their quality control operations with their supply chain.

Current State of Integration

Most large pharmaceutical organizations have implemented “State-of-the-art” ERP, MES and LIMS solutions.

But few organizations have achieved full supply chain integration between these applications. The typical level of integration is depicted in Figure 1, which shows how today laboratories and their LIMS integrate with other key functions:

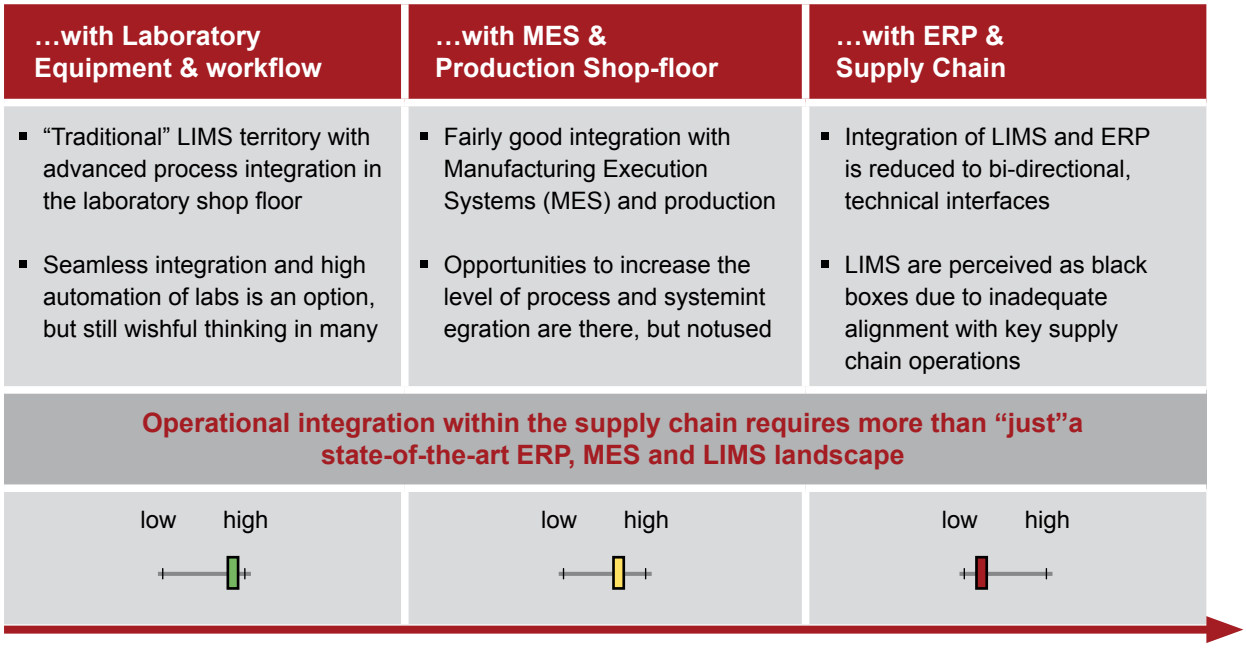

Figure 1: Level of LIMS Integration

There are a number of factors that have led to the varying degrees of integration that we find with many organizations. Figure 2 highlights some of the key reasons. Understanding these reasons will help organizations avoid these issues in the future and provide the foundation addressing the problem and achieving better supply chain integration.

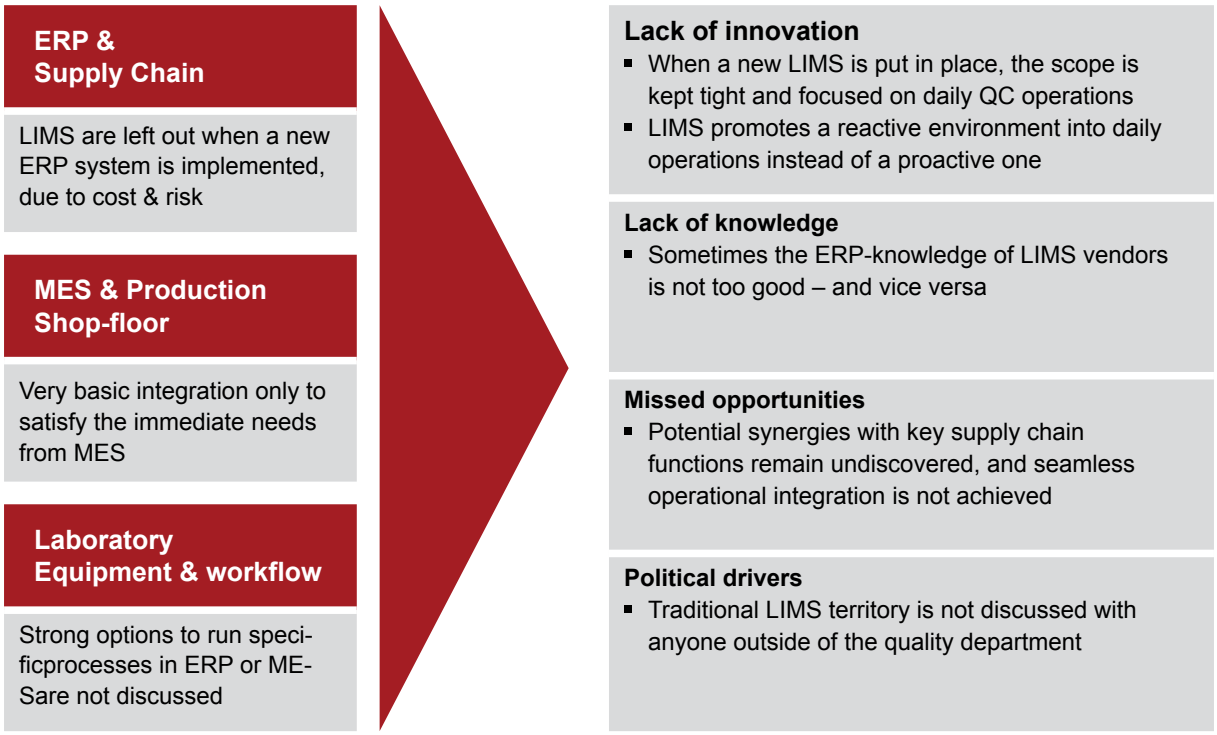

Figure 2: Reasons for Lack of Integration

When companies were implementing or updating laboratory systems, opportunities to integrate were not always considered:

- Due to the cost and risk to the business, integration to LIMS systems were not always fully considered when implementing or updating ERP systems
- In “best-of-breed” implementations, not enough attention was given to the aspect of LIMS integration
- In LIMS implementations often we only find basic integration to MES and production shop floor systems. Only the immediate integration requirements have been considered
- Options to run specific laboratory equipment and workflow processes in ERP or MES were not considered and/or implemented
- In some instances a lack of knowledge amongst vendors and their ability to understand and appreciate the need for integration
- LIMS processes and requirements are not discussed outside of the quality department and therefore integration points and opportunities are not fully considered
- Common or standardized processes for key integration points were not developed across production sites. LIMS implementations focused on site specific operations and did not consider common integration points to the global supply chain

As a result of these and other factors we find a lack of standardization and varying degrees of harmonization between LIMS systems and the supply chain. Potential synergies with key supply chain functions remain undiscovered, and seamless operational integration is not achieved.

Current State of Standardization

A prerequisite to achieving full supply chain integration is the standardization of key processes within the ERP, MES and LIMS systems. Figure 3 depicts the typical levels of standardization that are found.

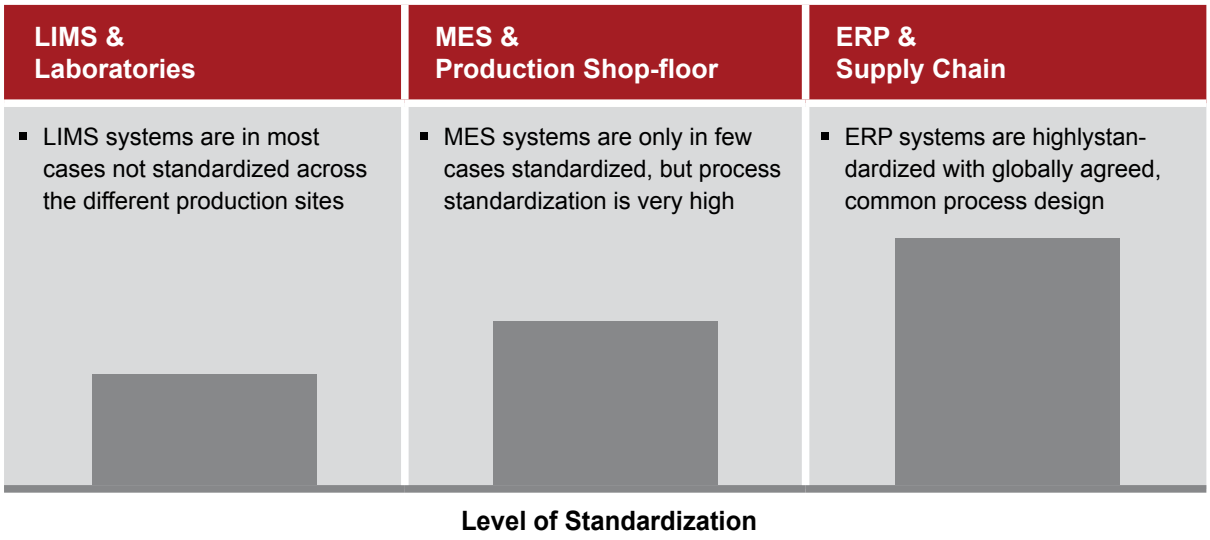

Figure 3: Process Standardization

Where ERP and supply chain processes are often highly standardized, with a globally designed process and business rules that are mandatory for all partners along the supply chain, the level of process standardization is the opposite for LIMS.

LIMS systems are in most cases not standardized across the different production sites. The basic business processes are similar, but LIMS are used discriminatively due to local, historically grown specifics. While local manufacturing sites have site specific operations to cover local requirements, all partners have common integration points with the global supply chain. For these common integration points, standardized business processes must be defined to achieve operational integration with the supply chain.

Designing a standardized model for key business processes allows the local quality departments to become a standardized unit with a high ability to work with and influence the fast changing supply chain.

Achieving full supply chain integration - Lodestone Approach

Based on the current state of integration and standardization, companies must take a systematic approach to analyze their business and look for opportunities to improve. The project should be viewed as a Business Excellence project and not an IT driven project.

Lodestone has the experience to help guide organizations through the process of standardization and assist companies in identifying opportunities to increase systems integration across the supply chain.

Experience shows that in Life Sciences around 20 key business processes managed in the ERP MES-LIMS triangle provide huge potential for improved supply chain integration.

Figure 4 below depicts Lodestone's approach to design and implement integrated business processes in an existing ERP – MES – LIMS environment.

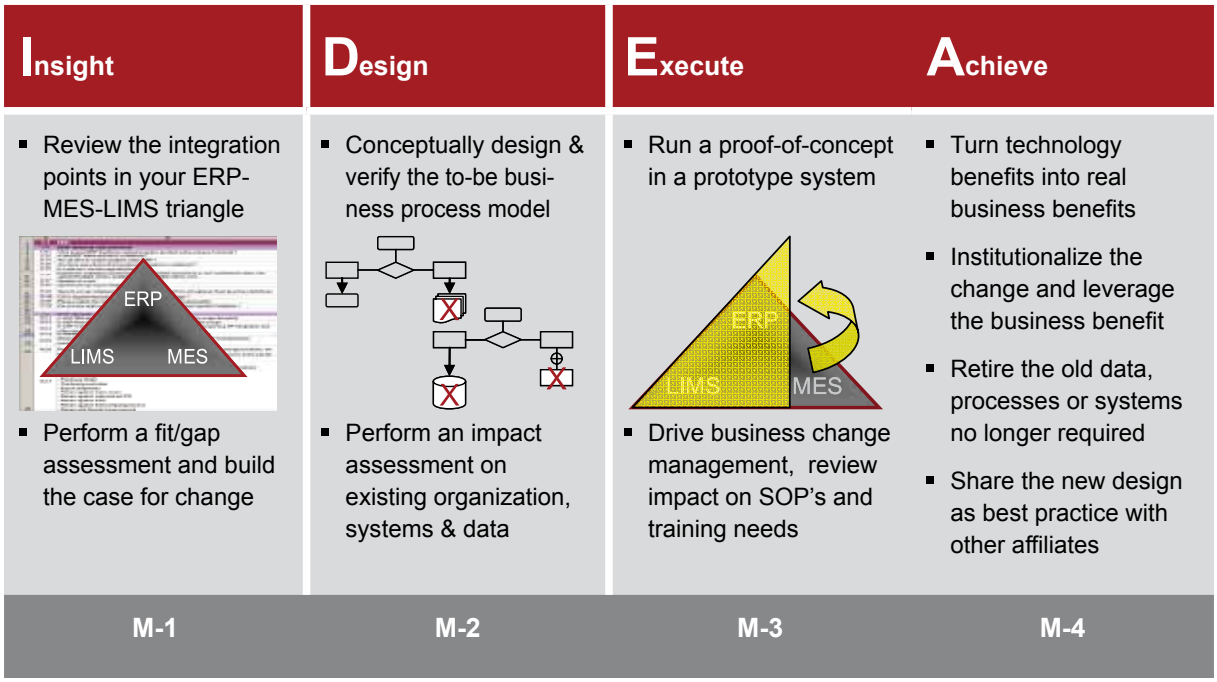

Figure 4: A typical project by phases

Following are a number of opportunities and examples of benefits that companies can anticipate as a result of better systems integration within the supply chain.

Opportunities and Benefits

Improved monitoring of internal and external quality control cost:
Most organizations do not take full advantage of available quality cost information because it is not fully accessed or not transparent enough to meet their needs. As an example, planning efforts for quality control and their associated cost information are maintained in ERP while actual cost data is collected in LIMS. Many organizations do not have a reconciliation process between planned costs and actual costs. As a result, wrong or outdated planning data is used for product cost calculations or for invoice generation of service laboratory activities. This situation also applies to the monitoring of external operations executed by 3rd party labs. Due to the missing integration with supply chain planning, yearly forecasting of projected external lab costs based on the actual manufacturing plan is not possible. Strategic decisions to outsource specific tests or to enhance internal lab capacity or resources are taken based on wrong information, or are not supported by any actual data at all.

Integrated cost monitoring between LIMS and ERP ensures visibility and transparency of quality cost information within the supply chain. Reliable cost data provides a foundation for significant cost saving potential.

Greater benefits are typically realized by organizations who utilize external laboratory services. Managing external services via operational purchasing processes in ERP provides a seamless flow of information from contract negotiations to purchase order creation and finally to invoice verification.

Integrated planning of manufacturing and quality control due dates should read:
A key issue in many organizations is that LIMS quality control planning activities are not integrated to the planning and execution activities in both ERP and MES. The planning of sample testing activities in LIMS is a black box for production planners. Sample testing is rarely aligned with planned availability dates of manufactured or purchased goods. Quality control becomes the bottleneck and has a negative impact on lead times within material availability planning.

An integrated planning approach ensures that quality control lead times are seamlessly embedded in material availability planning and bottlenecks disappear. Planning of capacities, resources and test dates for individual laboratories are fully aligned with the rest of the supply chain. Unexpected delays or a reprioritization of production shifts at short notice are immediately visible to quality control planners and allow fast reaction and higher flexibility in manufacturing planning and execution.

Integration of quality control activities has resulted in lead time reductions of 15 – 20% percent at some of Lodestone’s clients.

Provision of quality certificates across the supply chain:
In many companies the creation and provision of quality certificates is a stand-alone quality activity, detached from key supply chain processes such as physical shipments. Quality certificates are often not available when required, or customer or country-specific information is wrong or missing. Missing or incorrect quality certificate information can result in delayed shipment of product to customer. The distribution of quality certificates along the supply chain is often a manual process supported by mail and fax.

The integration of the certificate creation with key supply chain processes allows a high degree of automation ensuring that relevant documents are available at the time of shipment. Central provision of quality certificates and easy retrieval processes via web solutions ensures that relevant data is accessible at any time from anywhere, across different geographical regions, time zones and organizations.

Additional benefits are seen in the reduction of certificate templates with customer or country-specific information. At one of our clients, a multinational Pharmaceutical company, we achieved the reduction from more than 400 templates to 1.

Conclusion

Operational integration and process standardization are the key factors businesses have to embrace as they plan their Business Excellence strategies.

- Operational integration of quality control operations with the supply chain requires more than just state-of-the-art LIMS
- Changes in the way companies will work in the future will require better laboratory systems integration to the supply chain
- Process standardization is a key prerequisite to achieve operational integrity within global supply chains
- Quality departments must develop good expertise in complex supply chain processes
- LIMS implementation projects should be positioned as Business Excellence projects, not as pure IT exercises

The ability to learn and adapt from other leading edge industries on how to utilise and change existing business processes to gain the most out of your applications is essential to prepare the organization for the upcoming challenges for the lab of the 21st century.

Authors

Michael Schmidt, Director, Switzerland

Michael brings 10+ years of management consulting experience for multinational corporations and has worked as lead consultant for major clients in Life Sciences, managing complex ERP and supply chain transformation projects as well as global, large-scale LIMS implementations. Main areas of expertise are best practice implementations of enterprise LIMS solutions and the integration with supply chain systems (ERP, APS, BI, MES, and ELN).

Stefan Kubick, Senior Consultant, Germany

Stefan has several years of consulting experience for multinational companies in Life Science industries. He has worked for several Pharmaceutical companies and brings deep expertise in defining global LIMS solutions based on SAP QM, with the main focus on supply chain integration and the connection to the laboratory shop floor.

Colin Bryant, Managing Consultant, Toronto, Canada

Prior to working as a consultant Colin spent 5 years in the Pharmaceutical industry working as a Clinical Research Associate. For the last 10 years Colin has worked as an SAP and Management Consultant primarily focused in Pharmaceutical and CPG industries. Colin SAP expertise is in Sales & Distribution and Project Management.

Lodestone is a global management consultancy, committed to designing and delivering solutions that enable companies to thrive in today's complex business environment. Lodestone has developed significant experience and expertise in systems and supply chain integration and has a proven track record in delivering solutions to global Life Sciences companies.

Headquarters:
Lodestone Management Consultants AG
Obstgartenstrasse 27, Kloten | Postfach 201 | CH-8058 Zürich, www.lodestonemc.ch

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