Integration of SAP into the Laboratory Workflow

A laboratory management solution optimizes workflow and leverages technology to improve various aspects of the lab, including improving sample throughput time, reducing errors in calculations and transcriptions, reducing overall costs, and improving the ability for an organization to have a solid compliance position.

Traditionally, a LIMS has played the central role in the lab. However, there is a growing interest in improving the integration of the lab into the rest of the manufacturing process controlled by SAP. Through this deeper level of integration, organizations see a golden opportunity to better extend the reach of SAP into the lab while realizing the benefits associated with improved integration and automation over the entire manufacturing process. Recent advances in technology have made this level of integration not only feasible and cost effective, but also flexible enough to not comprise a lab's operational requirements.

We can break the types of laboratory to SAP integration into three categories – the first category is where a traditional LIMS manages all aspects of the lab and reports final results to SAP. The second is where

SAP QM plays the role of the LIMS and analysts interact directly with SAP QM. The third is an in-between scenario, where functionality of SAP QM is augmented by software such as an ELN, SDMS, and perhaps even a light LIMS – just enough to give the lab analysts control over their day-to-day operations without the need to realize the cost and complexity generally associated with the deployment of a full-blown LIMS.

A middleware software solution such as Labtronics' LimsLink ™ and the Connector for SAP module is the backbone to any laboratory SAP integration scenario. LimsLink ™ is instrument and LIMS independent, so it can be used to interface virtually anything in the lab with SAP – so long as there is a means of getting the information from it, or reporting information to it.

In order to improve the level of integration of the lab into the manufacturing process, the middleware software solution should also be capable of receiving notifications or requests from SAP that trigger information retrieval or initiate work to be completed by the lab. Examples include the automated creation of samples and scheduling of tests

within the LIMS when inspection lots are created within SAP, the pushing of an updated work list to a CDS, the execution of custom calculations whose results get reported back to SAP, or pre-populating an Electronic Laboratory Notebook (ELN) with information provided by SAP in order to prepare it to accept results of tests to be performed.

Another capability that some laboratory-centric middleware solutions provide is the ability for analysts to define calculations within the middleware application that are executed automatically as part of an inspection process within SAP. A common scenario is where statistical calculations are incorporated as part of an inspection plan and reported back to SAP as characteristics with associated usage decisions.

With a flexible middleware solution such as LimsLink ™in place, we can now focus on the type of procedural control that we want to have within the lab. One of the criticisms of SAP QM and traditional LIMS is that they lack the flexibility to control the analytical testing process. Whether or not a LIMS is involved, an Electronic Laboratory Notebook (ELN) such as Nexxis ELN ™ can be used to satisfy the need for procedural control at the bench top. For example, Nexxis ELN ™ can step the analyst through testing SOPs while automating as much of the process as possible, including steps involving sample preparation, data collection, calculations, review, approvals and reporting of results to SAP, LIMS, SDMS or any other system. An ELN now becomes the primary tool used by the analyst, providing significant levels of automation.
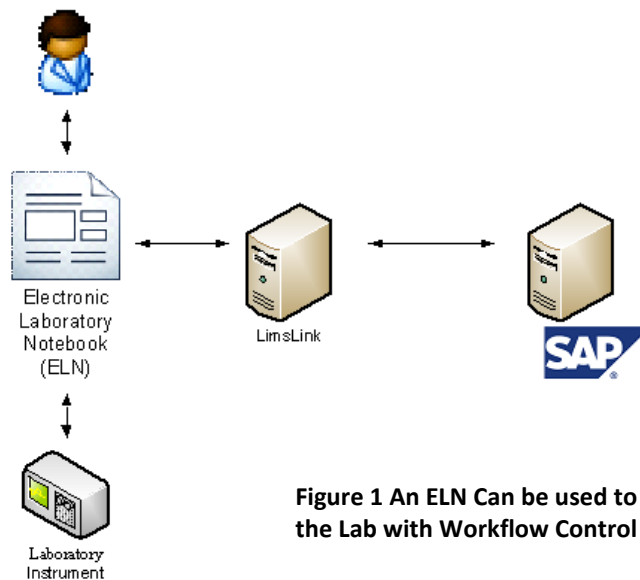

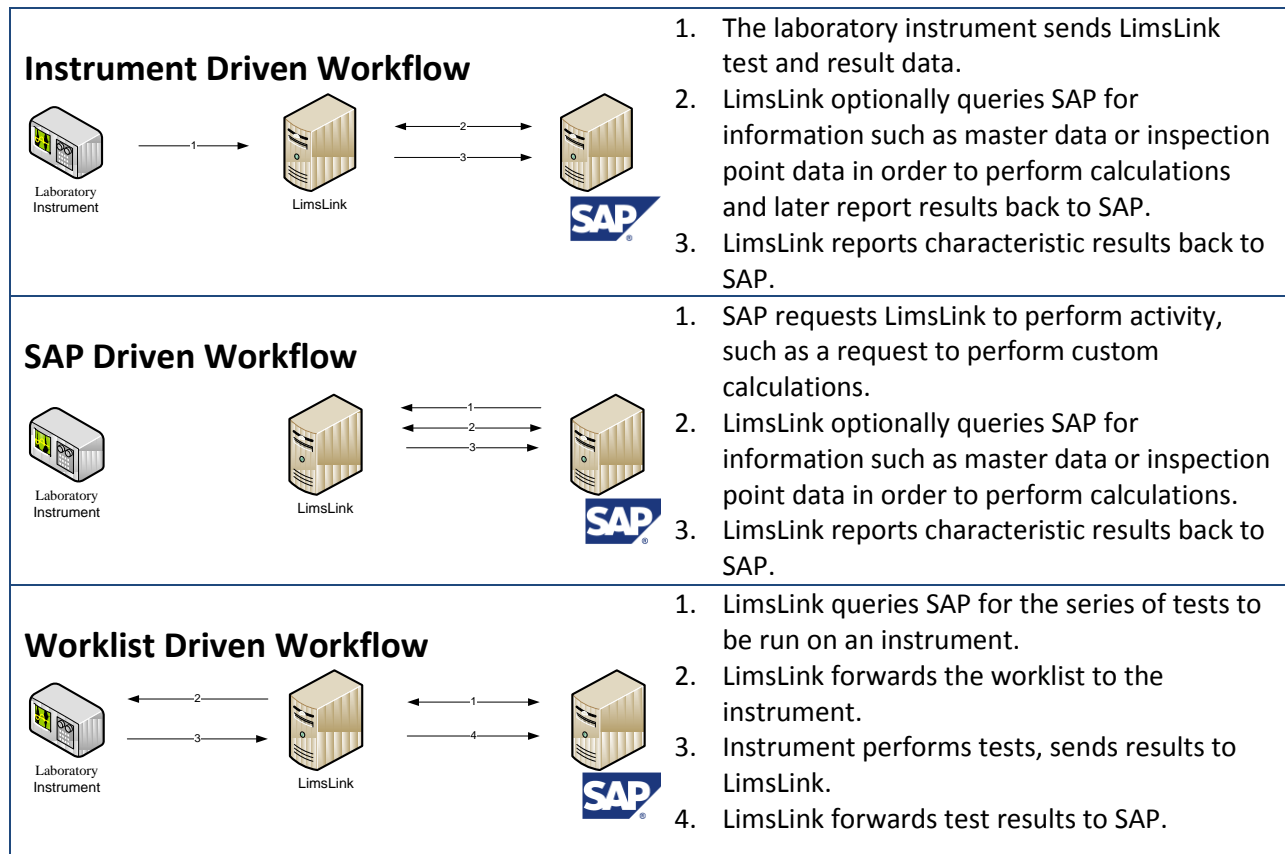**Figure 1 An ELN Can be used to Assist the Lab with Workflow Control**

An Electronic Laboratory Notebook (ELN) can provide the interface to the Analyst, providing process control, automating SOPs, managing reviews and approvals, and integration with Lab instruments. The interface to SAP occurs seamlessly in the background using a middleware solution such as Labtronics LimsLink ™ and the Connector for SAP module

In order to tie SAP into a laboratory process, it's important to understand when and where the touch points between SAP and elements of the lab exist at various points of a workflow. By reviewing the various possibilities, integration patterns begin to take shape. The following are common integration patterns associated with interfacing SAP into the lab.

1. Instrument Driven, where the instrument posts results
2. SAP Driven, where SAP initiates work to be performed
3. Worklist Driven, where the instrument performs work based on a worklist it first retrieves from SAP, then posts results

The following describes the various types of integrations in more detail –

Instrument Driven Workflow	1. The laboratory instrument sends LimsLink test and result data. 2. LimsLink optionally queries SAP for information such as master data or inspection point data in order to perform calculations and later report results back to SAP. 3. LimsLink reports characteristic results back to SAP.
SAP Driven Workflow	1. SAP requests LimsLink to perform activity, such as a request to perform custom calculations. 2. LimsLink optionally queries SAP for information such as master data or inspection point data in order to perform calculations. 3. LimsLink reports characteristic results back to SAP.
Worklist Driven Workflow	1. LimsLink queries SAP for the series of tests to be run on an instrument. 2. LimsLink forwards the worklist to the instrument. 3. Instrument performs tests, sends results to LimsLink. 4. LimsLink forwards test results to SAP.

Although the patterns described below are instrument focused, similar patterns exist when integrating LIMS to SAP, ELN to SAP, and so on. The term *Instrument* can be used loosely to describe the system used to generate information from within the lab, including physical instruments such as a CDS, or through a process involving an ELN, or LIMS.

The integration of a Scientific Data Management System (SDMS) into the laboratory workflow provides the ability to capture and maintain metadata generated during the analytical process. Each of these artifacts can provide a reviewer with a better understanding of how a characteristic result or usage decision was obtained. Examples of these information artifacts include raw data generated by the instruments, ELN worksheets, Microsoft

Word™ and PDF documents, images and reports. Having access to this information during a review or investigation phase can provide a high degree of traceability. This is useful not only for quality assurance and regulatory compliance, but also as part of review and approval process associated with GMP and GLP.

The automated integration of laboratory processes into the manufacturing process controlled by SAP is often one of the last integration points into SAP being considered. With the advances in laboratory automation available today, there is little reason as to why a lab cannot be highly automated and integrated into the manufacturing process. The following are some considerations that can help ensure a successful integration of SAP into the lab –
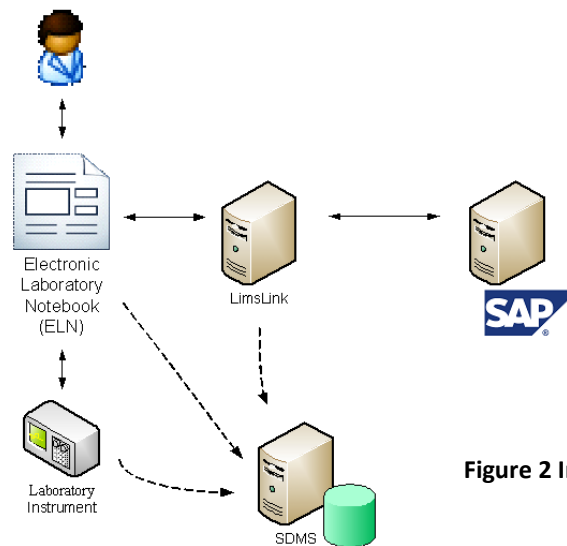

Figure 2 Incorporating SDMS

1. *Achieve Management Buy-In* – This is required at two levels. First, SAP is a corporate resource that is used across all of manufacturing so the type of buy-in and commitment required to bring the lab into the fold must be made at a higher level than perhaps the deployment of a LIMS, or an instrument interface. The second type of buy-in is required within the lab itself. Analysts and lab managers must feel confident that the solution will give them the flexibility needed to automate existing SOPs with the aim of realizing significant benefits described earlier.

2. *Get IT Support* – Integration of SAP QM into the lab requires knowledge of SAP QM and, in some cases, associated SAP RFC calls. You'll want someone with good knowledge of SAP QM to ensure that integration into SAP QM is configured properly and assist in developing a solution that is consistent for all manufacturing sites.

3. *Start Small, Build on Successes* – Use an iterative approach to deployment to ensure that lessons can be learned early on in the process and applied as soon as possible. It's advantageous to test SAP QM integration into the lab as early as possible in order to develop standards early on. Starting small is also a good way of achieving buy-in without significant up-front costs.

4. *Leverage Vendor Expertise* – Avoid learning lessons the hard way. Use the services of the software vendors who have experience to help you identify a deployment strategy that fits your needs, while leveraging the experience of previous deployments.

Conclusion

The automated integration of laboratory processes with the manufacturing process controlled by SAP is often not considered. However, laboratory integration with SAP delivers significant benefits to the organization by ensuring fast, accurate and automated delivery of data that is needed for decisions that impact the manufacturing process.

As we have seen in this article, bringing the lab into the manufacturing process managed by SAP can result in highly automated and cost effective processes.

At Labtronics we are able to provide expert guidance and assistance as you investigate and discuss the possibilities of lab automation within your organization. We can also provide the tools and the expertise to deliver a successful integration project - whether it is a full scale implementation or a pilot project that initially focuses on a small set of instruments and lab processes.

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