

MAKING THE PAPERLESS LAB A REALITY

The paperless lab concept has been around at least since the notion of the paperless office came into being. However, as long as paper scientific notebooks were the industry norm for experiment and laboratory work, paperless was not going to happen. With the rapid progress of electronic lab notebooks over the last five years, the concept of the paperless laboratory is now becoming a reality.

ResultWorks has been engaged by clients to help them dramatically increase efficiencies in their global manufacturing QC laboratories. Sandwiched between the enterprise resource planning (ERP) system and a diverse array of instruments in the lab, is the space where a significant amount of data is captured, analyzed, and used to make critical decisions in the manufacturing process. It is a terribly inefficient

space that is heavily reliant on manual data reviews, manual analysis, and manual data re-entry into systems at each level as shown in the figure below. The QC analyst is the primary integration point for data collection, analysis, and reporting. Depending on the environment and past investments, there could be a mix of systems including chromatography data systems, scientific data management systems, LIMS, manufacturing execution systems (MES), document management systems, and ERP systems. Today, QC leads want to integrate and automate the QC lab operation reducing their paperwork and increasing their overall efficiency.

The approach offered by ResultWorks is outlined as follows:

- Assess current QC lab environment
- Develop strategy for paperless lab
- Construct a gap analysis
- Build business justification

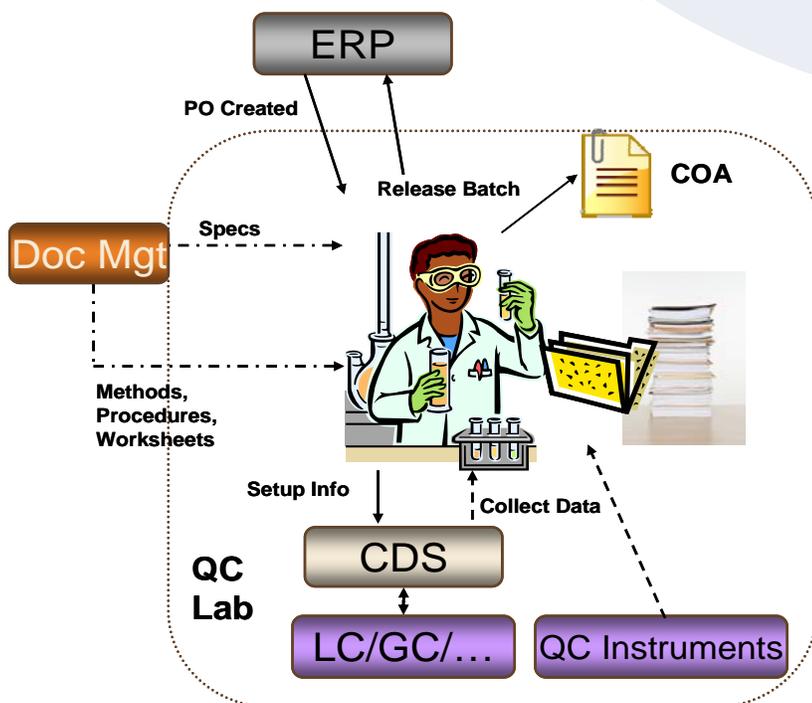
QC Lab Assessment

The assessment of the current environment consists of a review of documentation of each site QC lab, and interviews of key stakeholders from senior managers to QC scientists. This groundwork helps to establish the key work flows, primary systems in use, pain points in the process, and needs of the organization. The consistent theme that emerges from organizations looking to move ahead is a paperless or integrated electronic laboratory operation. The baseline information collected during the assessment phase is the foundation for developing the strategy.

QC leaders want to integrate and automate the QC lab operation reducing their paperwork & increasing their efficiency.

Paperless Lab Strategy

Once the needs and desires of the organization are assimilated, a strawman strategy can be developed considering the business and IT constraints. Some systems may already be in place (ERP, LIMS, CDS). Needs may span multiple systems - method management, specification management, test requesting, procedure execution, and long-term data management to name a few. To realize the strategy, a mix of systems may be required from traditional LIMS, to Scientific Data Management, to a QC Electronic Lab Notebook (ELN). Taken together we refer to these as a lab execution system (LES). The diagram



below depicts the LES concept. LES becomes central to the QC lab function.

Gap Analysis

The next step is the gap analysis to define the delta between the current state and what is required to achieve the desired future state. This effort can delve down to specific work flows in order to determine where efficiencies might be realized with an LES solution.

Business Justification

The gap analysis provides the basis for the business justification. The returns on investment are primarily cost savings resulting from more efficient operations in the QC labs. Some examples of typical savings include:

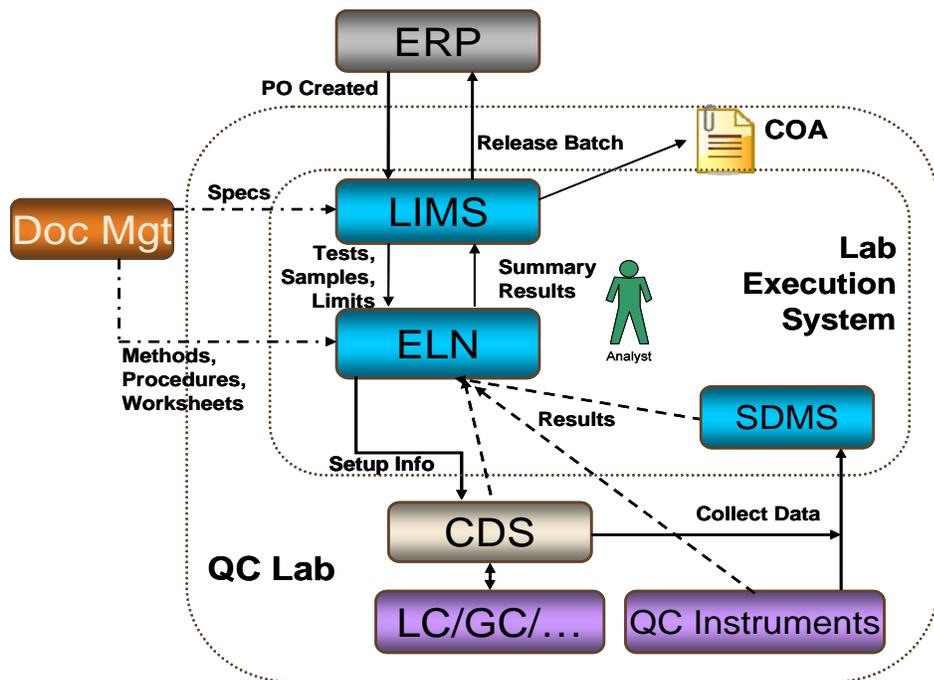
- Elimination of paper documents and handling
- Reduced time performing data transcription and manual calculations.
- Reduction in data review/checking
- Reduction in peer and supervisory review time
- Reduced deviations/investigations

It is not uncommon to see analyst and supervisor efficiencies of 25% or more by implementation of an LES solution.

The investment side of the business justification will depend on the starting point and the vendor selected. Some vendors will provide budgetary estimates incorporating licensing costs and full implementation costs inclusive of training, metrics around methods development, and integration. The full cost of

It is not uncommon to see analyst efficiencies of 25% or more with a lab execution system.

the implementation effort needs to be developed based on a complete project plan considering organizational resource



availability, external resources, the number of methods/procedures that need to be automated, and validation requirements. The business justification exercise requires a lot of detailed work, but the returns on the effort are worth the time invested.

Conclusions

The paperless lab is no longer just a gleam in the eye of QC leadership. With the latest technologies and the merging of traditional data management and lab management systems, it is a real possibility these days. However, there is no easy "one size fits all" solution.

A structured approach must be undertaken to assess the current QC lab operations. Ground work must also be done to define a strategy for a paperless lab based on organizational objectives. While the return on investment is typically much shorter, the strategy should reach out 3-4 years to give the organization adequate time to invest in new technologies and new business processes; time to assimilate the new technology; and time to achieve credible results.

The gap analysis and the business justification are critical to getting approval for the investment. They are also key for establishing metrics to track the success of the project and the return on investment.

Of course there is a significant project at this point to implement the system, but if these steps are taken to start, the paperless lab can be a reality for your organization.

Authored by Susan Cohen Butler and Bob O'Hara, Managing Partners and Co-Founders of ResultWorks, LLC based in King of Prussia, PA, and Terry Graber, a Senior Consultant at ResultWorks.

For more dialogue on paperless lab concepts and an approach to making it a reality, please contact ResultWorks.

Contact: Bob O'Hara
Phone: 610-688-5870
Email: bob.ohara@resultworksllc.com
Website: www.resultworksllc.com