



Transformations

QUARTERLY NEWSLETTER

VOLUME 10, ISSUE 2

OF SPECIAL INTEREST:

- **Critical success factors for change management initiatives**
- **Define and select informatics solutions—ELN, LIMS, SDMS — based on your business needs**
- **Create a roadmap which lays out key business, informatics and systems activities in a prioritized fashion that will achieve your business goals**

MANAGING CULTURE & ORGANIZATION IS CRITICAL TO CHANGE

There are many factors to consider for successful change. When planning for and implementing change, consider what should the change involve, how will the change impact workflow and technology, who will be impacted by the change, how fast should/can the change occur, what are the costs of change, how will the success of the change be measured, etc. These factors are all important to the process. However, none is more critical than those fac-

tors that surround the cultural and organizational change - those changes that impact each and every employee on a personal basis.

Ensure that people make the required changes in mindset and focus.

It is critical to the success of any transformational project to en-

sure that people make the required changes in mindset and focus. Those involved in projects tend to forget that for the change around them to be successful they must change as well. Similarly, those managing projects tend to overlook personal change factors and focus on the more technical and tangible aspects of the project.

While the project manager and the project team cannot really plan when the personal change

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BUSINESS NEEDS DRIVE DECISION FOR ELN, LIMS, OR SDMS

In the beginning there was paper; then along came Laboratory Information Management Systems (LIMS) to solve all your result data capture and sample management needs. Next the plethora of instrumentation (particularly in analytical labs) drove the emergence of Scientific Data Management Systems to be able to collect and view all that instrument data in one place. Finally the drive over the last five years has been to eliminate the scientist's paper lab notebook and capture that information in electronic form in an Electronic Lab Notebook (ELN) system.

So what are the basic differences among these systems and where should you focus your limited financial and human

resources? It comes down to clear understanding of your business objectives and a definition of your needs to support those objectives. This article clarifies the technologies and provides a high level approach to selecting the right solutions for your business.

What are SDMS, LIMS, & ELNs?

SDMS – The primary focus of these systems is to collect and store raw data files and report files (usually from instrumentation). These systems typically feature mechanisms to parse out data from files to facilitate searching of the data and viewing tools are often integrated to allow specific formats like chromatograms and spectra files to be viewed without the native application. In regulatory envi-

ronments an SDMS, if implemented correctly, may form part of an electronic data archiving solution for instrument data. Many providers of SDMS are beginning to encroach on the ELN space by incorporating direct data, report generation, and workflow tools into their products.

LIMS – There are a large number of LIMS on the market covering a wide range of disciplines. We can't focus on all of them here but we can take an analytical LIMS as an example. The main purpose of the LIMS is sample management; the collection, processing, and storage of result data collected during the execution of a defined analytical method on such samples; and the comparison and reporting of

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CHANGE MANAGEMENT (CONTINUED FROM PAGE 1)

will take effect, there are specific factors that help to drive the change throughout the organization. Based on prior experience, ResultWorks has identified five critical success factors (CSFs) that are predictors of how successful a change initiative will be.

Strong executive leadership & commitment

The executives who are serving as the initiative's champions and are driving the change must communicate the reasons behind the change to the organizations involved and to the teams that will be doing the planning and work surrounding the change. It is important to foster the impacted employees' understanding of the company's strategic direction, the competitive environment, and the business needs driving the change.

The initiative's sponsors and leadership team must be visible from the beginning and should provide regular reinforcement around the tenets and reasons for change throughout the program implementation. Further, the leadership team must develop clearly defined program objectives and convey a sense of urgency along with the business justification for why it is needed.

Aligned and measurable goals

The goals and objectives for the change initiative must be aligned with the overall organizational strategy and it must be clearly articulated and communicated to the organization. The goals must be measurable and executive leadership and the project team must define the criteria for measuring progress toward program objectives.

The right change team must be in place

A change initiative's success is directly related to the level of employee involvement in the transformation from inception through implementation and beyond. It is crucial to create an approach to the project organization and communication plans that allows for high employee involvement either directly or through communication channels.

It is also essential to identify the right team for the project. Those involved have to have the authority to make decisions around the changes to take place, have insight into the overall workflow that will be affected as well as the larger impacts organizationally. They should also have the respect of the organization from the bench to the leadership team. Typically, ResultWorks looks for change agents, early adopters and organizational influencers to participate in the project. This is particularly important during the definition and engagement phase of the project as this team will set the direction and lay the foundation for the overall project.

Clear roles and responsibilities

Key stakeholders, internal and external, must be identified early in the program. In the absence of other direction, people will continue to operate in the same old way—performing old processes, using old systems, taking on old ownership of issues, etc. New roles and responsibilities must be clearly defined and understood across the organization. The alignment and metrics described above will help to support this. It is likewise important to ensure everyone understands their accountability for their new responsibilities within the changing organization.

Effective communications and visibility

Communication is one of the most critical elements to build buy-in to the change initiative. Successful change projects evaluate the current communications channels, make use of effective communications approaches, and create new channels as appropriate. It is also imperative to ensure consistency in communications so that conflicting messages are not conveyed to those impacted by the change, either directly or indirectly.

Towards that end, it is useful to build formal and informal feedback channels into the project to allow for employees to share their views and perceptions of the planned changes at strategic times. This feedback must be assessed and responsive so that employees see that their input is considered and valued.

Additionally, the communications plan must be sensitive to corporate culture and the diversity within the organization and should be tailored to different sites, groups, and functions as needed.

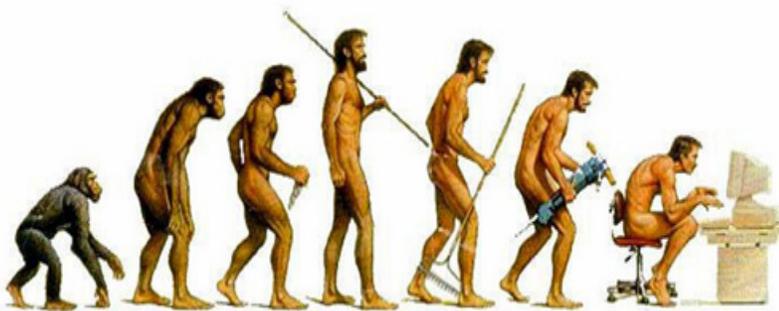
Change Management Critical Success Factors

1. *Strong Executive Leadership*
2. *Aligned & Measureable Goals*
3. *Right Change Team*
4. *Clear Roles & Responsibilities*
5. *Effective Communications & Visibility*

Summary

Culture and organizational issues are among the greatest challenges in managing change. In order to deal with them effectively, there are five critical success factors: strong leadership, aligned and measureable goals, the right change team, clear roles and responsibilities, and effective communications and visibility. Paying attention to these factors are not necessarily guarantees of success, but neglecting any one of these will surely contribute to falling short of objectives.

As Life Sciences companies work to reinvent themselves today, they are spending significant resources to be more effective in bringing new drugs and devices to market. Managing the change process across the organization is fundamental to ensuring that investments in change yield sustainable results.



DECIDING ELN, LIMS, OR SDMS (CONTINUED FROM PAGE 1)

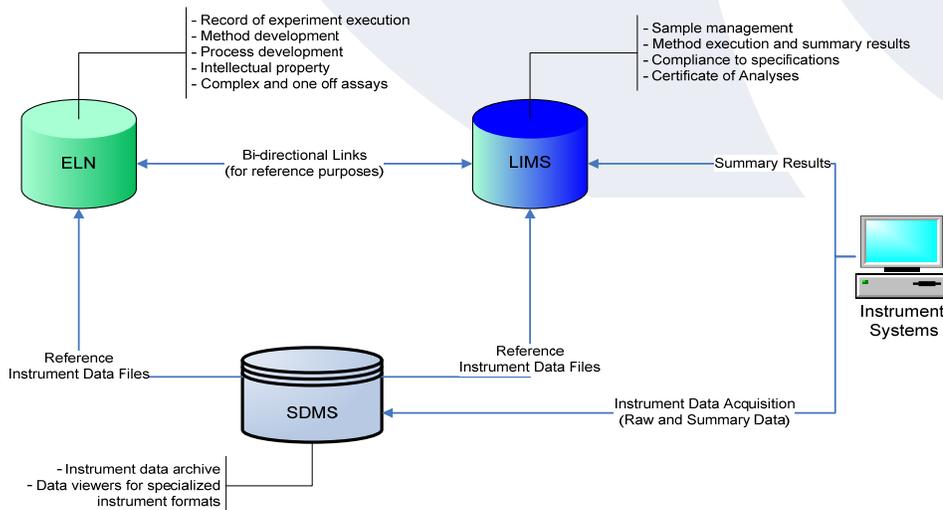
result data against standard product specifications. LIMS in this area are often deployed in GxP regulated operations and tend to be fairly structured in their workflow enforcement. Many LIMS providers are beginning to encroach into the ELN space by incorporating more flexibility for less formalized data capture.

ELN – In its simplest form the electronic lab notebook's primary function is to electronically capture the same information that is currently being recorded in paper lab notebooks. This is primarily experiment information. Hence an ELN is really recording details of the process development. The ELN becomes the main intellectual property record for an organization and the electronic records enhance collaboration and knowledge transfer by being more readily searchable and legible. From their initial data capture beginnings, ELNs have evolved to incorporate specialized functions to further support specific business processes (e.g. support for chemical structures and reaction schemes in the chemistry area). Many ELN vendors are beginning to encroach into the LIMS space by incorporating more workflow functionality (to direct the execution of work) as well as capabilities to manage samples and batches.

How are these systems deployed?

Using the Analytics laboratory example as a reference point, one way of combining these systems is illustrated in Figure 1 below. This arrangement allows best in class systems to be selected to meet specific requirements:

Figure 1: One Possible Implementation of All Three Informatics Systems



- Sample management, formal test execution, and results capture – LIMS
- Record of experiment execution and method development, as well as record of novel ideas and inventions – ELN
- Consolidation and archiving of raw data – SDMS

Sample Management, Experiment Management, or Raw Data Management

So Which Solution is Right for You?

The initial answer to that question might be all, none, or somewhere in between. The systems being discussed provide solutions to specific data capture and workflow needs of a typical laboratory but do not address the whole picture. There are typically many other ancillary business processes and associated systems that are involved running the business unit and all of these need to be considered with an understanding of how they interact. To this end ResultWorks strongly recommends that the starting point for any consideration of a new system should first be to step back and look at the overall business needs and associated information needs of the business unit. The following five step model is proposed:

1. Conduct business process analysis – this is a system independent analysis of the business imperative and needs of the business unit:
 - What is the main purpose and mission of

the business unit?

- Who are the main suppliers/customers?
- What management and regulatory structures does the unit operate under?
- What makes the unit competitive versus other internal or external groups?
- What are the primary activities?
- Which activities add the most value and which ones incur the most overhead?

2. Conduct an information flow analysis – again this should be a system independent analysis:
 - What information is needed to perform its business operations?
 - What information is produced and how is this differentiated in terms of :
 - Information used to support internal business operations
 - Information for customers/ suppliers
 - Information for management
 - Regulatory information
 - Intellectual property
 - How is the information communicated, stored, and accessed?
 - Are there any special requirements surrounding the information (e.g. regulatory data needs specific attention in terms of security and archival)?

3. Analyze the informatics needs of the business – consider the business process and information flow above what types of informatics solutions are needed to support data capture and storage, data search and retrieval, reporting, collaboration, and workflow automation.

4. Assess what systems are needed to fulfill the informatics needs identified in above.
 - Do existing systems support the informatics needs?
 - What gaps exist?
 - How can the gaps be filled?
 - Can existing systems be extended or enhanced?
 - Do existing systems need to be replaced?
 - Do new systems need to be put in place?

5. Create a roadmap which lays out key business, informatics and systems activities in a prioritized, time-sequenced fashion that will achieve your

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RESULTWORKS

Transforming Strategy. Delivering Success.

DECIDING ELN, LIMS, OR SDMS (CONTINUED FROM PAGE 3)

business goals.

So which lab informatics system is best for you? There is no one answer for every R&D organization. Legacy systems are different. Business processes vary. Organizational objectives and resources depend

Steps for deciding ELN, LIMS, or SDMS

1. Conduct business process analysis
2. Conduct information flow analysis
3. Analyze informatics needs
4. Assess systems that will support the needs
5. Create a roadmap to achieve results

on the business. By following the approach presented here your specific business objectives will drive your needs, leading to a strategy specific to your environment. That strategy may need to be revisited annually as business needs and directions change, but overall

TECHNOLOGY - JUST PART OF THE ANSWER

As a consulting company, ResultWorks is involved in many technology solutions from strategy to definition to implementation. As other articles drive home in this newsletter, technology projects in the absence of business needs, people, or change management may yield limited results. To make this a bit more personal, take a look at this blog in *Harvard Business Review* entitled "[Why I Returned My IPAD](#)" by Peter Bregman. In business, as in our personal life, it's all about achieving the right balance.

ABOUT RESULTWORKS

ResultWorks is a management and business process consulting company which transforms strategies for Life Science companies into successful technology and process optimization initiatives. Results are achieved through skilled facilitation and exceptional management leadership.

The ResultSessionSM is the cornerstone of our methodology, promoting collaboration and rapid decision-making while balancing people, process and technology challenges.

To request additional information, send us an email or visit our website www.resultworkslc.com.

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ELN BEST PRACTICES & PITFALLS

Best Practice: The best way to identify the highest value ELN functions is to conduct a thorough solution pilot. Start with your user requirements then take the proposed solution from the vendor selection step and refine it as a starting point for user evaluation. Configure a few experiment templates and workflows as well as the search interface. Use the vendor evaluation team plus a few more user representatives to utilize the system for a few weeks and identify what works well and what should be enhanced. Collect and manage a prioritized set of change requests from the pilot user community and consider working with the vendor to make mid-course configuration adjustments. If you plan to integrate the ELN with some of your existing systems, select the ones with the highest priority and build prototype solutions for them. Most important is to document your findings and decisions within a functional specification. Conducting a thorough solution pilot enables you to rapidly assess the most important functional requirements for your system before committing to a large implementation project.

Pitfall: Most vendors today will tout the highly configurable nature of their ELN system. This leads some organizations to move immediately from solution selection into implementation with plans to adjust the system as needed later on. While many ELNs are highly configurable, this thinking can lead to low user adoption and large cost overruns because the initially deployed system has only minimal refinement and buy-in from the stakeholder community.

RESULTWORKS NEWS

Sample client initiatives:

- Pre-clinical Development Change Management
- Formulations Business Analysis and IT Strategy
- Data Management Strategy Development
- Computer Aided Translation of Clinical Study Documents
- R&D ELN Implementation

Recent appearances:

LabAutomation 2010

- Bob O'Hara, Managing Partner presented "Use your ELN Implementation to Shift the R&D Paradigm"
- MetaStorm Global User Conference
- International Meeting on Automated Compliance Systems

Philly LIMS/Laboratory Informatics Group

A LIMS/Laboratory Informatics discussion group is getting started in the greater Philadelphia area. The group plans to structure in-person meetings quarterly on topics of significant interest in the King of Prussia area similar to the Boston LIMS/LI group. If you are interested in learning more or participating please send an email to LIM-SLI Philly@Yahoo.com, or contact Bob O'Hara directly.

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