

Transformations

QUARTERLY NEWSLETTER

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OF SPECIAL INTEREST:

- **Information consolidation takes precedence over specialized systems**
- **Access to data and tools is not enough if you want to ensure better decisions**
- **It's not about technology, it's about behavior**
- **Create a roadmap which lays out key business, informatics and systems activities in a prioritized fashion that will achieve your business goals**

ENTERPRISE LIMS CONSOLIDATION ALIGN LIMS WITH THE BUSINESS STRATEGY

The LIMS industry has gone through many evolutions over the last 20 years from very generic systems targeted for a broad cross-section of the industry to niche LIMS developed and evolved to meet very specific needs out of the box. Customers' decisions about LIMS have evolved the same way. Generic LIMS with customization have been tailored to different application areas or multiple niche LIMS have been acquired targeted to specific needs. The latter strategy has won out in Life

Sciences over the last decade. But many large Pharma are rethinking that strategy as the greater need for information consolidation and knowledge management takes precedence over specialized systems. This article explores the rationale for LIMS consolidation and a strategy for a successful implementation.

Why Consolidate LIMS in the First Place

You might ask the same question of the industry as a whole

but the reality is that it is happening. In many companies LIMS have been proliferating unchecked. Not long ago, a senior IT executive was asked to sign off on LIMS number thirty-plus which subsequently started a consolidation effort. Certainly there are benefits in simplification. There are inherent cost reductions in licenses, integration, maintenance, and training. The other key elements from a business perspective are data standardization and sharing. It is much easier to share data

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Implementing large, enterprise-wide technology solutions is never about just the software, it's about the business first. Senior executives who allocate funds for a large enterprise system know they are signing off on a host of changes to the business processes, other systems, and the organization. Likewise implementing laboratory informatics solutions provides an opportunity to change the culture of R&D organizations, to formalize processes which were loosely dependent on individuals, and to improve the overall conduct of R&D activities.

Major technology implementations may be viewed as tactical point solutions or as a strategic

change opportunity to dramatically improve the current R&D operation. Many companies look at informatics solutions as tools for scientists to marginally auto-

*"Revolution doesn't happen when society adopts new technology - it happens when society adopts new behaviors."
Clay Shirky*

mate their work. This type of passive support for these solutions keeps expectations low but also guarantees only minimal benefits from the investment. In his book *Here Comes Everybody:*

The Power of Organizing Without Organizations, Clay Shirky offers that "Revolution doesn't happen when society adopts new technology - it happens when society adopts new behaviors." This certainly rings true in Life Sciences organizations. R&D executives and leaders looking to shift paradigms within their respective organizations can leverage an enterprise informatics system implementation to enhance the way work is performed, to increase productivity, and to free scientists up to focus on those parts of their work that drive competitive advantage.

The process used in implementing these solutions enables the R&D organization to take a

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ENTERPRISE LIMS CONSOLIDATION (CONTINUED FROM PAGE 1)

across departments when the same system is being used. Different systems promulgate data differences. Same systems lend themselves to standardization although it is not automatic.

There are also likely benefits in transfer of knowledge, know-how, system usage experience, and more. Building information about a compound and adding value to that information as compounds progress through the drug discovery, development, and even manufacturing cycle is certainly a focus these days. It is no longer about optimizing each silo – for which a niche LIMS works well; it is about optimizing the entire R&D process. Common systems, nomenclature, and data are all critical to making that happen.

Information consolidation and knowledge management are taking precedence over specialized systems.

Challenges exist

Systems developed for a purpose are hard to overlook and even harder to give up in favor of a generic system for consolidation purposes. For example, a LIMS developed for managing toxicology studies is going to be harder to realize in a generic offering. Yet having a different LIMS for discovery chemistry, biology, toxicology, pathology, ADME, DMPK, clinical, etc. also makes it very difficult to keep systems, departments, and the overall process flowing in an optimal way.

So once consolidation is decided, hard choices are required. Do you find the least common denominator for a system? Do you select a generic system and customize it to meet all of the individual needs? Do you migrate data from legacy systems? Looking across systems will enable visibility of differences in nomenclature, data, processes, and interfaces. It is a necessary starting point to determine issues and gaps, but also similarities that might yield the required synergy for consolidation.

Develop a LIMS Consolidation Strategy

Begin with the end in mind. The first thing to determine is the scope of the consolidation effort – research, development, manufactur-

Figure 1: Existing LIMS Matrix by Function and Site

	Site 1	Site 2	Site 3
Discovery chemistry	LIMS A	LIMS B	LIMS B
Discovery biology	LIMS C	LIMS C	LIMS B
Proteomics/Genomics			
Toxicology	LIMS D	LIMS D	LIMS D
Clinical Pathology	LIMS D	LIMS C	LIMS D
ADME	LIMS E	LIMS E	LIMS F
Drug Metabolism		LIMS G	LIMS F
Animal Pharmacokinetics	LIMS H	LIMS J	
Bioanalytics	LIMS H	LIMS J	
Clinical	LIMS H		

ing – all three or a level below these. What systems and modules are in place in all of these areas already? What needs are these systems satisfying and what needs are unmet. What systems are integrated? Where is data-entry duplicated indicating a need for better integration? How committed is business management to participating in this major initiative and looking to consolidate business processes, systems, and even organizational functions? Looking across functions and across sites may yield a matrix as shown in Figure 1. Clearly, having the same systems within a site, or within a function across sites lends itself to easier consolidation. Certainly, the more colors/boxes on the matrix, the bigger the consolidation challenge.

Developing a comprehensive strategy is a critical success factor for this kind of program. Investment in time and planning should not be underestimated; nor should it be undervalued. Figure 2 shows a possible LIMS consolidation strategy or an interim solution on the path towards a final objective.

Of course there are implications beyond the LIMS itself. Looking at the LIMS requires looking at what the LIMS supports, the organizational need, alternatives to sample management at any given site and for any given domain. Figure 2 shows several sites/domains where the LIMS was actually removed and not replaced due to organizational realignment. So once this consolidation box is opened, the business strategy needs to be considered first, then the LIMS strategy—and every other informatics strategy for that matter.

Conclusions

A LIMS consolidation program challenges the entire organization to rethink the business.

Figure 2: Potential LIMS Consolidation Strategy

	Site 1	Site 2	Site 3
Discovery chemistry	No LIMS	LIMS B	LIMS B
Discovery biology	No LIMS	LIMS B	LIMS B
Proteomics/Genomics	LIMS K	LIMS K	LIMS K
Toxicology	LIMS D	LIMS D	LIMS D
Clinical Pathology	LIMS D	LIMS D	LIMS D
ADME	LIMS F	LIMS F	LIMS F
Drug Metabolism		LIMS F	LIMS F
Animal Pharmacokinetics	LIMS H	No LIMS	
Bioanalytics	LIMS H	No LIMS	
Clinical	LIMS H		

LIMS that were originally tailored to specific scientific areas likely optimized the way data gets entered or collected into that system. Consolidation has a broader focus on data access and usage across research, development, and into manufacturing. It requires some tradeoffs among the highly specialized departmental systems, and solutions which are more consistent across the enterprise.

Like any enterprise system implementation, the LIMS Consolidation program needs thorough planning, project management, business analysis, stakeholder participation, and executive support. Departments with specialized needs and existing tailored systems need subproject teams dedicated to change management starting with planning, decommissioning of the legacy LIMS, and deployment of the new enterprise LIMS. Development and manufacturing areas also need to address GxP needs throughout the implementation effort.

LIMS consolidation projects are not to be taken lightly. They demand top-down leadership and bottoms-up participation to be successful. Changes to work flow, data flow, and systems are unavoidable and necessary. However this enables access, usage, and sharing of information across the enterprise. If organizations are serious about optimizing the entire R&D process, these are certainly some of the results to expect, or rather demand from an investment in LIMS consolidation.



INFORMATICS SHIFTS R&D PARADIGM (CONTINUED FROM PAGE 1)

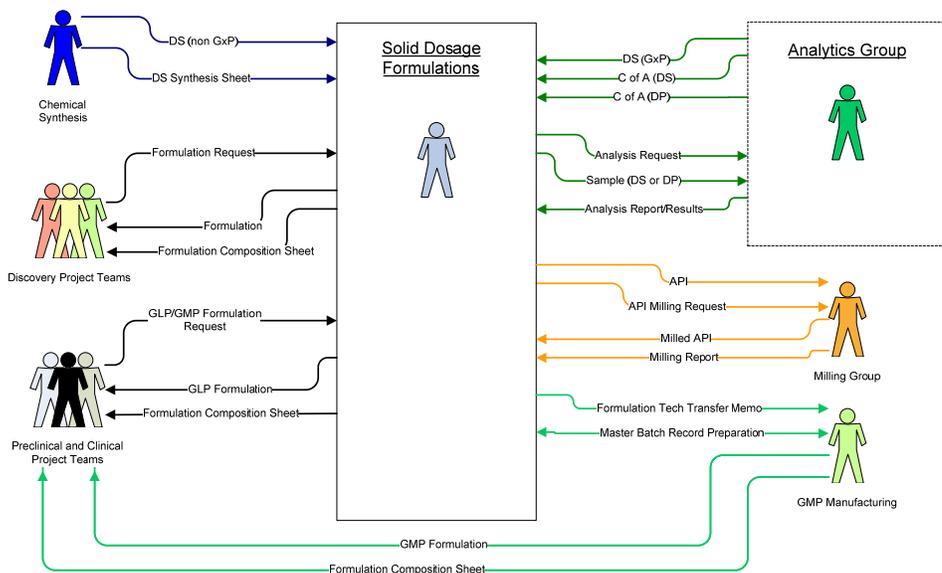


Figure 3: Workgroup Interaction Diagram shows work and information transitions

critical look at itself, its business processes, the informatics architecture, how decisions and knowledge are managed, and even the way the organization is structured. This requires a vision, a strategy for attaining it, management commitment, and a well structured approach. It also requires alignment between the business and IT leaders. If these things are not present, an informatics project which starts out with high expectations and involvement gives way to short-term demands, diminishing attention to the project, and ultimately an unsuccessful effort.

In order to get the most from informatics solutions and your investment in them, these key items below must be present.

Secure management commitment This starts with setting stretch goals for the organization such as doubling productivity or throughput, improving intellectual property management, or markedly increasing compliance. Framing that in a vision enables people to get a more visceral sense of how things might be different in the future. Assigning resources in people and funding ramps up the commitment to the project. However, management cannot then disappear. Ongoing participation even if it is only for several hours per month to keep the team on notice the effort is still vital. Planned review or checkpoint meetings are one way to engage. These sessions also facilitate key decisions that are critical to the progress of the project team.

Streamline business processes & infor-

mation flow Business process analysis is a valuable tool that is often overlooked and undervalued. Yet this analysis provides a foundation for understanding where you are and where you are targeting to be. Workgroup interaction diagrams as shown in Figure 3 provide a high level overview while summarizing key processes, information flow and transitions among groups. Swim lane diagrams can be used for further detail during implementation.

Prioritize requirements & clarify assumptions Informatics systems, like technology in general, involve tradeoffs. If people make too many assumptions and don't force explicit decisions, the stakeholders are sure to be disappointed. In defining requirements for a new informatics system, be clear. Prioritize requirements with stakeholders. Force tradeoff decisions considering funding, resources, timing, and changes required to realize the vision.

Design & implement a revised technical architecture Since systems and processes evolve and even overlap with time, a new informatics sys-

tem is an opportune time to revisit functions performed by different systems, data storage strategies (what data retained where), and integration needs (movement of data). Clear definition of a technical architecture promotes explicit decisions about each informatics system, their purpose, and their functions. It removes ambiguity that often creeps into legacy system use over time.

Apply project management in a structured approach Frequently the focus of informatics projects is about the technology. The key to success is the use of technology in a given environment. The project manager must be concerned about all aspects of the project—management, stakeholders, process, technical architecture, site variations, and more as shown in Figure 4. Employing a structured, deliberate approach enables the project team to adjust to many variables moving R&D in a new direction.

Involve the right people; work collaboratively At the end of the day, a new informatics system is about changing the way people work. The right people can make things happen. Working collaboratively enables people to solve problems that otherwise might not be apparent until they become obstacles to success. A determined, persistent team will stay focused on the vision.

Approaching new informatics projects as an opportunity to encourage, or rather adopt, new behavior, raises project stakes. And why not, there is a lot at stake in the life sciences industry today. Investments are more carefully considered than ever before. By taking a structured and people-oriented approach to the implementation of your informatics solutions, not as another set of tools, but as an opportunity to reshape R&D business processes, the technical architecture, and even organizational alignment, you have a head start toward shifting the R&D paradigm.

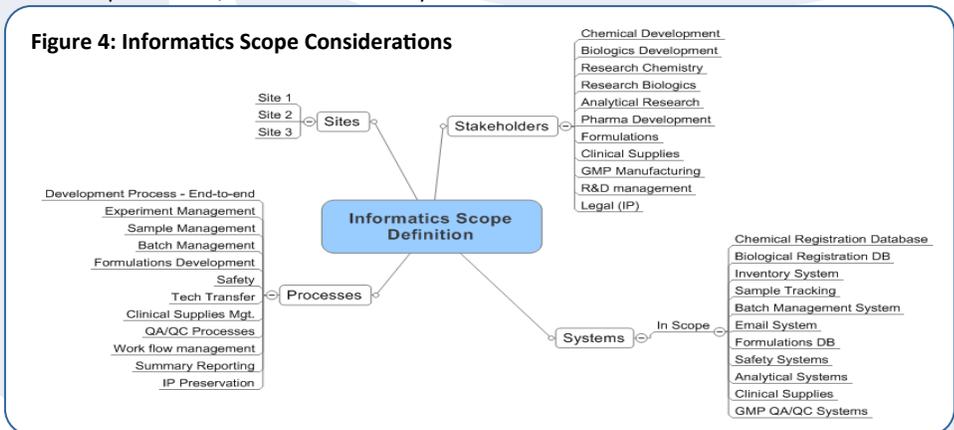


Figure 4: Informatics Scope Considerations



ELN BEST PRACTICES & PITFALLS

Selecting an ELN Solution

Best Practice: After defining ELN requirements, it is time to select the solution that will best meet your unique requirements and available funds. First, determine which ELN vendors are best suited to your R&D workflows and the footprint of your ELN solution. Some vendors are better at Synthetic Chemistry while others excel in Biology. Some vendors have highly configurable relational database solutions while others focus more on documents. After identifying the vendors having solutions that fit your needs, consider narrowing the list through a Request For Proposal (RFP).

The RFP process allows you to test how well the selected vendors meet your requirements while learning about their individual solutions. Also consider contacting existing customers for each vendor to learn where the vendor excels and where they may require more attention or oversight. Use the RFP and customer references to create a short list of vendor solutions, then invite these vendors to demonstrate their proposed solution to your team of stakeholders. Evaluate the vendor demos based upon their ability to meet your workflow requirements. This set of criteria-based selection activities provides a deep and thorough analysis leading to consensus among your stakeholder teams and support from executive level management.

Pitfall: Too often organizations select vendor solutions based on demonstrations, trade show visits, user group meetings and recommendations from people within their network. While these are all good sources of information, this selection process doesn't stand up to executive level scrutiny and often lacks the executive funding and support needed to launch and sustain a broad strategic initiative like an ELN. Selecting an ELN solution in this way also leads to a lack of trust and support among the stakeholder groups who were not involved in developing the selection criteria and gathering the solution information. This can be disastrous at the funding approval stage or later, when stakeholder teams are expected to accept a solution that may not fully match their expectations.

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.

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INFORMATION DRIVES LIFE SCIENCES DECISIONS

10 Principles of the New Business Intelligence

By Tom Davenport, Harvard Business Review

In this Harvard Business Review blog, Davenport argues that "organizations need to increase their focus on decision-making. In particular, they need to think again about the relationship between information and decision-making."

"Providing access to data and tools isn't enough if you want to ensure that decisions are actually improved."

In the Life Sciences R&D we are overloaded with loosely managed data that most organizations are now trying to bring under control. There is no doubt that better information management is critical. But what do we intend to do with that information. Decision making in research requires sifting through volumes of loosely coupled information while in late stage development and manufacturing more of the decision making can be automated.

This article offers ten areas where business intelligence needs to evolve. The focus is on using information to make better decisions. For the entire article [click here](#).

ResultWorks News

Sample client initiatives:

Formulation ELN Project, CTMS Definition & Selection
Global LIMS, Strategy Roadmap Development,
Lessons Learned on Informatics Projects

Recent appearances:

InnovationWell: KM & Collaboration

Bob O'Hara, Managing Partner presented
"R&D Knowledge Management – Technology Initiative or Business Fundamental?"

LabAutomation — January, 2010

Bob O'Hara, Managing Partner presented
"Use your ELN Implementation to Shift the R&D Paradigm"

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 LIMSLIPhilly@Yahoo.com, or contact Bob O'Hara directly. He will be available in person at the LRIG Philadelphia meeting on March 18th to discuss more.