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INSIGHTS ON LABORATORY DATA MANAGEMENT SYSTEMS

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Delivering the Paperless Lab Environment – a Game Changer

By Trish Meek
Thermo Fisher Scientific

Trish Meek, Director of Product Strategy for Life Sciences in the Informatics business at Thermo Fisher Scientific, spoke with Lab Manager about how the paperless laboratory concept could prove to be a game changer for pharmaceutical and other life sciences industries, and reports on the impact of achieving a truly paperless lab, which can significantly reduce human error, increase efficiency and facilitate integration, and ultimately foster more robust collaboration both inside and outside the organization.

What are the disadvantages of the traditional, paper-based laboratory environment?

Meek: We could start by asking "what are the benefits" of using paper, which are obvious – paper is for the most part easy to use, it's often convenient, frequently portable and much of the time legally defensible. And paper requires no "user training" so for the most part, new users can be trained on a process and quickly accomplish the task. Those are the positive aspects of paper. BUT, as you'd expect, the downside to paper is greater than the upside. Using paper-based methods for sensitive and complicated laboratory workflow creates a number of security, expense and productivity challenges. First of all, paper reports or workflow documents introduce significant security risks into what should be a completely secure process.

Paper processes also always introduce a human factor, and any human activity is inherently prone to errors to some degree. Organizations have to keep strict controls around their paper processes because they must control document access, version control, and cataloging the information to ensure that it can be located when required. Paper-based processes are costly, both in terms of the physical purchase of paper and in terms of the human capital that is expended to manually handle the process – human capital that is probably highly skilled and trained for scientific research and laboratory processes, not managing paper reporting. So there's a productivity factor in the cost equation to using paper.

Finally, in the current economic climate where every minute of research and scientific progress must be measured by a success factor, paper processes represent the antithesis of collaborative efforts. Today's pharmaceutical company works in collaboration with academia, Contract Research Organizations (CROs), and partner biotechnology companies. Their data is spread across these organizations. Paper isn't "searchable" and in this era of distributed research and development and outsourced testing, paper-based processes represent barriers to collaboration and a time drain on sharing valuable scientific information.

JUST HOW COSTLY ARE YOUR CURRENT OPERATIONS?

Here's an example of how a company could reap the benefits of reducing time spent on manual documentation efforts.

How does the paperless laboratory concept overcome these issues?

Meek: More and more laboratories are realizing that the investment they've made in setting up the state-of-the-art laboratory is not being fully optimized and they're looking for ways to optimize that investment. The typical lab has expensive instrumentation and other laboratory equipment, all of which are

generating data of some kind. Each of these instruments, if siloed, requires that a human has some interaction with that data to collate it with data from other instruments and compile reports.
A fully integrated laboratory will connect instrumentation to a central data system, such as a Laboratory Information Management System (LIMS) so that data storage and reporting is automated. You can imagine how this situation becomes more complicated when there are multiple laboratories across different geographies working together across an organization. Also in many cases lab data is required by management at some point to satisfy decision making that is reliant on key business metrics which some of the lab data may provide. In a manufacturing environment, this will require that the lab is fully connected with other existing enterprise systems, such as ERP, MES, PIMS, etc.

So what's occurring now with the paperless lab concept is that many companies are looking for ways to optimize the ROI for their lab investments. The key to this is integration of the lab itself, as well as connectivity of the lab with the rest of the organization.

In what ways does going paperless make a laboratory more efficient?
Meek: Efficiencies in the lab come from streamlining workflow and automating processes. When the lab is fully integrated, that is that the instruments and other information systems are integrated with the LIMS, then all data collection and analysis is automated, freeing up the lab's scientists to focus on science and more value-added revenue-generating activities. The reduction in time spent performing manual paper-drive tasks can produce an enormous improvement in productivity and also cost savings. For example, a modest reduction, say 20% in man-hours spent on paper-based efforts can produce hundreds of thousands of dollars in annual savings. It's worth thinking about how much more revenue could be generated by those man-hours if they were spent on novel research instead of paper-based data collation and reporting processes or if a problem with production was discovered and the organization was able to react even one hour earlier in the process. This is the value many companies are seeing when they fully integrate their labs and connect the labs with the rest of the organization.

How does a laboratory begin to take steps towards implementing the paperless concept?
Meek: We're advisors to our customers and the first thing we look at is the landscape of the lab. How is the lab set up, what instruments are in place or are planned for the future, what is the workflow required? It's important to ask these seemingly basic questions because often the existing workflow isn't the one that the lab actually wants – but it's the one that's in place. So part of implementing a paperless lab is to find a consulting ally that can honestly assess the situation in the lab and lay out a plan that will be flexible enough to grow with the lab and the business into the near future. Once this assessment is complete and an optimum workflow has been identified, the work can begin to make recommendations for integrating all those disparate instruments and connecting the lab's output with key business metrics for management to use.

What tools are available to help companies achieve paperless status and ensure a smooth transition?
Meek: The paperless lab concept has been talked about off and on for a number of years and each time it resurfaces the technologies that support this movement are a little bit closer to fully achieving the goal. This time around we're closer still and a number of new technologies are now available that can fully integrate even the most heterogeneous of labs. This is an important distinction to make because most labs will have a fairly broad spectrum of vendors installed, something which in the past has been the perceived and sometimes practical obstacle for fully integrating the lab. The problem, up until now, has been the cost to integrate different software systems and equipment from each of these independent instrument vendors. But newer technologies based on open standards have led to big opportunities for life sciences labs today. At Thermo Fisher, we've spent time developing Integration Manager and Data Manager, which transform data from any instrument and deliver it to any source. While importing the final result is crucial, this solution takes it further by enabling scientists to see their real analytical data, chromatograms, mass spectra, and results from other instrumentation regardless of the instrument supplier. This type of automated data acquisition and point-to-point data distribution across the enterprise is what is enabling today's paperless lab.

Are a significant number of pharmaceutical companies beginning to move in the paperless direction?
Meek: We have had a tremendous response to CONNECTS. It is important to understand that life sciences industries are telling us that they want to get to a paperless lab. With CONNECTS, we are in a strong position to help our customers tackle this problem. We ensure that they understand that this is a process which starts with an evaluation of their existing organizations processes and how they are using their current software and hardware. We look at what works today and where paper-based, manual processes create bottlenecks that integration could address.

We are working with several customers at the moment to implement paperless lab projects. This is a customer-driven initiative, and our customers have just reached the point where they see the value in going completely paperless.

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For More Information about CONNECTS for the Paperless Lab, visit www.thermoscientific.com/paperlesslab, or email us at marketing.informatics@thermofisher.com.

A CLOSE LOOK AT LIMS AND ELNS

Paperless Lab Software
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Laboratories are awash in data. The two main data management packages in use today are laboratory information management systems (LIMS) for structured data such as pH values or sample weights and electronic laboratory notebooks (ELNs) for unstructured data such as images and chemical formulas. To simplify, a LIMS downloads data from a liquid chromatograph without the need to copy values manually, while an ELN replaces paper notebooks for more creative work. Together, these products represent the cornerstones of the "paperless laboratory."

ELNs and LIMS are part of two significant trends: the desire to automate the more mundane laboratory tasks and the availability of inexpensive, massive, and distributed computing power.

The benefits of automating data handling become obvious when one considers the four to five percent error rate associated with copying by hand. A 95 percent success rate is simply not good enough for regulated industries that live and die by the guidances and standards of the EPA, ASM, ASTM, FDA, and other organizations. Tom Dolan, senior account executive at RURO (Frederick, MD), puts the data automation imperative into perspective: "If you're dealing with a regulatory agency, my understanding is that if you don't have an ELN or LIMS today, as appropriate, you're behind; if you don't have something like this five years from now, you're in trouble."

On the computer side, the push has not been the power of modern microprocessors as much as it has been the enabling aspects of networking. In the old days, enterprise computing relied on mainframes, but the user experience was unsatisfactory or nonexistent. "With PCs, computing became decentralized," notes Mark Harnois, director of informatics product management at Waters (Milford, MA). "Now the technology has evolved to the point where you can bring back centralization, even globalization, but with much-improved user experience and functionality."

The advent of LIMS and ELNs presented regulated businesses with the huge challenges of ensuring electronic document longevity and demonstrating and validating the integrity of electronically stored data. The U.S. Food and Drug Administration devoted an entire guidance, CFR Part 11, to electronic documents and signatures.

LABTrack (Lake Forest, CA) claims to be one of the first ELN vendors to tackle the legal and regulatory requirements of replacing paper with electrons. Since paper notebooks have been used to support patenting in civil and criminal cases, legal standing is no trivial matter.

CEO Richard Stember notes that lab notebooks are one of the few exceptions to the legal hearsay rule—they are admissible as evidence even if the author cannot testify. "It all goes back to a British court ruling in the nineteenth century," he explains. "So we realized from the beginning that we would have to address this issue."

LABTrack uses a mathematical algorithm known as hashing, a technique similar to encryption that renders the data into a unique form that is virtually tamper-proof. The algorithm is public domain and incurs no royalties or usage fees.

Longevity is paper documentation's most notable characteristic, but according to Stember, electronic records are notoriously short-lived. File formats come and go, and updates are not always backward compatible. Proprietary file formats are the worst: if a software company goes out of business, older files become orphans in the event of an installation crash.

LABTrack's solution is to enter data in a word processor-like environment and to store the files in HTML. "Most people already know how to use a word processor, and HTML is a long-lived data format," Stember says. "PDFs, by contrast, enjoy a longevity of only eight years due to incompatibilities between documents and current readers."

ELN | STARLIMS
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THE PAPERLESS LAB

Laboratories are heterogeneous collections of instruments, appliances, and utilities that were acquired at different times from different vendors. Most labs still use paper to bridge among humans, instruments, and data systems. A paperless laboratory provides interoperability and data exchange regardless of the origin or destination of that data.

The notion of the paperless laboratory has been around for decades, but was only recently made possible through the emergence of enabling software and integration tools. The goals of the paperless lab are to lower costs, improve throughput, and maximize regulatory compliance by minimizing manual paperwork—objectives fully aligned with LIMS and ELN software. Staff reductions, mergers and acquisitions, and off-shoring are significant drivers toward paperless laboratories and overall operational efficiency. "There are simply fewer people around to carry out those manual tasks," says Trish Meek, strategist for life science at Thermo Fisher Scientific (Waltham, MA). In April 2012, Thermo Scientific announced an initiative based on CONNECTS for the Paperless Lab, a vendor-neutral suite of methodology, services, and technology that creates integrated paperless environments.

> "If you're dealing with a regulatory agency [and] you don't have an ELN or LIMS,... you're behind; if you don't have something like this five years from now, you're in trouble."

Customers, Meek says, recognize the manual steps as gaps in their workflows that are rate limiting and error-prone. Understanding those gaps is the first step in a more encompassing quality initiative that covers data as well as lab operations.

Laboratories interested in going paperless first undergo an audit to identify and correct rate-limiting steps, including paper-based transactions. "It could be as simple as switching to an automated balance," Meek tells *Lab Manager Magazine*. Most decades-old data systems are ripe for such a makeover.

Companies know they work inefficiently, but are often surprised when all the bottlenecks are identified and tallied. "This is the perfect time to take a holistic approach to the lab's data systems and workflows, which probably hasn't been done since the LIMS or ELN was first deployed," says Meek.

Thermo Scientific's principal laboratory data product is a LIMS, but the company also offers Integration Manager, an "enterprise bus" for transferring data, and Scientific Data Manager, an application that allows lab workers to view, in neutral format, any type of data. These advanced tools are what now make the paperless lab achievable, according to Ms. Meek.

MARKETS

Laboratory Information Management Systems - A Global Industry Outlook, a recent report by Global Industry Analysts (San Jose, CA), estimates that demand for LIMS will reach $1.4 billion by 2015 and that ELNs will enjoy $284 million in sales by 2017.

"Lab notebooks are one of the few exceptions to the legal hearsay rule—they are admissible as evidence even if the author cannot testify."

From the vantage point of Mike Elliott, CEO of market research firm Atrium Research (Wilton, CT), growth in ELN sales has cooled somewhat, from about 30 percent per year to about 20 percent; LIMS sales growth remains relatively flat at 1 to 2 percent per year.

ELN | ELN 6.7 | Accelrys | www.accelrys.com

Competition among LIMS and ELN vendors has been fierce, says Clive Baron, general manager for global commercial operations at STARLIMS (Hollywood, FL). A handful of vendors within both markets sell to global companies, but a much larger number of specialty firms serve smaller R&D facilities.

Sales numbers tell an incomplete story, however.

"The customer pool is in a state of flux," Baron notes. "We're seeing demand from odd areas, like a mattress company that uses a LIMS in their QC lab, and from general manufacturing, petrochemicals, and refining." On the other hand, installations in more traditional industries are aging. Baron adds, "These businesses have changed, but their LIMS have not."

ELNs are undergoing changes similar to the way in which LIMS were transformed in the 1980s and 1990s, namely a broadening of the market beyond pharma. "We're seeing changes in the market, from the top 10 pharmas to second-tier companies, as well as diversification into chemicals, foods, and beverage industries," Elliott observes.

Pharmaceutical industry mergers, acquisitions, and site closings, as well as the outsourcing of QA/QC, have been partly responsible for the stagnant demand for LIMS. Vendors are therefore pursuing new markets such as bioanalytical, which, while LIMS-like, also has ELN characteristics or formulations that fall more into the ELN camp but could benefit from the LIMS sample tracking.

SELECTING A DATA SYSTEM

Several factors go into the selection of a laboratory data management system beyond notions of "structured" or "unstructured" data. The first consideration, notes Earl Beutler, CEO of LabArchives (Carlsbad, CA), involves the size and type of data files the lab generates. Some facilities produce only small files such as spreadsheets, PDFs, and small images. Others regularly generate very large images or even gene sequencing data, which is measured in terabytes. "For the former, a cloud-based solution is often the best, simplest, and most cost efficient," Beutler says. "For the latter, a locally installed server works, because transferring very large files to the cloud is prohibitive." LabArchives provides both types of ELN product.

The type of data files, and the ability to search and view these files, may also be a significant consideration. Some systems index the contents of many file types, such as PDFs and videos, providing searchability. Related is the ability to view file contents natively, without installing proprietary third-party software.

Many file management systems also include built-in collaborative functions, including access control, for users inside and outside the laboratory. If groups are collaborating across a continent, the data system should provide easy access without the need to e-mail files and install software.

Bruce Pharr, a software consultant who has held executive positions with GenoLogics Life Sciences Software (LIMS) and Symyx Technologies (ELN), says that choice of data management system labs primarily depends on the organization's "functional" applications. "These span

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the spectrum, from small dedicated analytical laboratories to fully integrated end-to-end biotechnology, pharmaceutical, and medical device operations."

For example, a LIMS would benefit a genetic testing laboratory through lower costs, streamlined operations, risk mitigation, regulated sample tracking, security, and auditing. "However, this narrowly focused lab will probably not arrive at a reasonable return on investment from an ELN or other enterprise data management software," says Pharr.

At the other end of the spectrum are chemistry or biology research labs, where the tracking of samples and reams of raw data are not top priorities and regulations are minimal. Such organizations can reap the rewards of an ELN but would not benefit from a LIMS.

Between these extremes lies a continuum of labs with varied functional applications and scales that require some combination of enterprise data management software and one or more downstream components.

Data decisions become complicated for large, fully integrated companies that conduct research, product development, and manufacturing. Almost all such organizations include service groups that generate hundreds of analyses per week (structured data) and scientific activities that are less routine and unstructured. These organizations usually adopt a "master data management" strategy and infrastructure, such as ERP, and within this supervisory system adopt ELNs and LIMS.

The hierarchy and differentiation within "big" laboratory software have created what Clive Higgins, VP of marketing for informatics at Perkin-Elmer (Waltham, MA), calls a collection of "point solutions." These include LIMS, ELNs, and LESs (laboratory execution software). "Businesses struggle with information from different systems and have difficulty obtaining a holistic view of the lab's overall operations to aid in decision making," notes Higgins.

LESs are similar to LIMS in their handling of executable lab processes. But where LIMS are primarily passive, LESs walk scientists and technicians through a process, feeding them information from the LIMS or ERP system. For example, an LES provides alerts on balance calibration and can validate an instrument user's credentials. "LESs build in checks and balances," Higgins explains.

"For LIMS, ELNs, and integrated data management, the end user is ultimately the decision maker, but the people pushing the latest trends—the latest investments—are the executives," explains Dominic John, Ph.D., director of product marketing at Accelrys (San Diego, CA). "When there's a new project, there's a tendency to throw everything in as requirements. Nobody fully understands what the system can do until they've implemented it. Adopt a system that immediately addresses one or two core needs, and then expand once you understand it."

The key is immediately demonstrating benefits to the end user, whose natural instinct is to ask, "What's in it for me?" Users will then become engaged and make their own recommendations. But managers trying to score quick wins will meet resistance, John adds.

IT RESOURCES REQUIRED FOR SOME FEATURES, MINIMAL UPKEEP FOR OTHERS

LIMS and ELNs do not pose care and upkeep problems that an IT administrator does not encounter with any database system: performing data backups, building in redundancy, and having a plan for power outages. Web-based systems entail no maintenance at all. Companies whose workflows and products/services do not change significantly are the easiest to maintain. Maintenance can be significantly higher, and upgrades or tweaks more frequent, for companies that deliver a wide range of products or services or whose product specifications change often or rapidly. Therefore, a biotechnology or chemical company could expect to devote substantial IT resources to its in-house data systems, whereas analytical labs performing the same three quality tests day in and day out will require minimal upkeep.

ELN | Labnotes
Terrington Data Management
www.terringtondm.com

When ELNs were first introduced, they were document-centric and therefore easier to deploy and manage. For many companies, products met 90 percent of end users' needs out of the box. The game changed significantly as ELNs were adopted by laboratories with less structured workflows, especially life sciences R&D. As the types of labs seeking ELN functionality broadened, so did demand for customization to specific industries and workflows.

"Users began to demand customized templates, integration of more applications, a converged look and feel, help with report writing and data organization, and a friendlier interface," observes Mike Elliott. There was a big pushback on vendors to satisfy these needs, which they couldn't handle. So they began building alliances with third parties across the globe to provide those services. "We saw the same thing in LIMS during the 1990s, where vendors couldn't handle a lot of small tailoring jobs, customization, and implementations. That's how the third-party service network came into being," says Elliott.

LIMS | Matrix Gemini
Autoscribe | www.autoscribelims.com

Unlike LIMS, where the network of third-party service providers is robust, ELN services are provided mainly by vendors.

According to Michael Kelly, director of sales and marketing at LabWare (Wilmington, DE), the single most important aspect of maintaining a LIMS, other than the accumulated data repository, is the "configuration," defined as the codified instructions the system follows to automate the company's processes and workflows. "Enormous energy is expended during implementation to optimize the configuration of a LIMS to derive optimum value from the system," says Kelly.

The ease with which the configuration is maintained and adapted over time is a primary contributor to the LIMS's longevity and, ultimately, to the benefits that it delivers. "Commercial software products differ substantively in how configuration

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is performed, which in turn affects the cost of ownership and overall value proposition," Kelly says.

Few systems feature purely data-driven configuration models, and fewer still store literally all configuration data within the system's database. More commonly, how a system behaves is the end result of program code and other custom attributes that exist outside the relational data store. Such designs are complex to implement, difficult to alter, and are typically reliant on explicit and narrowly defined technology "stacks." However, those that are based on a data-driven configuration and that store the configuration in database tables are easier to design and implement, may be readily adapted as the business evolves, and are compliant with a broad range of underlying technologies and platforms.

"Such systems can be maintained with fewer resources and adapt to business challenges more rapidly, thereby offering more responsive service at less internal cost," Kelly adds. Because they are less constrained by explicit technology and platform dependencies, such systems allow the business to adopt new technologies more readily and to more easily gain the benefits they offer.

LIMS and ELNs were traditionally purchased outright as software that resided on the customer's computer system. This business model involved high initial costs and dedication of human resources to installation and training. Customers have been warming up to the LIMS as an Internet-based "software as a service" (SaaS) model where the software lives on the vendor's secure server and data is maintained in the cloud.

"The overall cost of maintaining our product is about as minimal as you can get from an enterprise-level LIMS," says Clive Baron, whose firm's STARLIMS product is 100% web-based. "If you get into the client-server piece where you have to go and install the software on all the machines, the cost to get there is much more, and the cost to upgrade is much more because you have to go out and touch every PC."

Web-based LIMS are not quite standard, and not every vendor has committed to the Web as fully as STARLIMS has. Some firms provide a portion of their LIMS services online but have not yet taken the full plunge.

The Web was a disruptive technology in the LIMS industry six years ago when STARLIMS and other vendors introduced cloud-based products. Today, says Baron, tablet PCs have become the disruptive force, or soon will be. He states, "Everyone is trying to introduce a product to take advantage of tablet features; not everyone is clear on the best use of tablets in the laboratory."

"It used to be said that a good LIMS is never done; even more so for an ELN," quips Elliott. "What someone does today may not be what they want to do tomorrow. It's natural to want to do more and more."

He calls the evolution within a lab, from paper to "paper on glass" to true ELN full functionality, a "tricky transition. Some organizations do it very well; some are cautious; others jump off the deep end. But in the end, you must build out features at a rate that people can absorb them."

The term "electronic notebook" doesn't describe these products very well, Elliott says, because it implies that the software merely replaces what was done on paper. He states, "But people want more than that. They don't want a separate inventory or registration system and another for ordering; they want a single interface, an ELN that communicates with different systems within the organization."

LIMS | BSI Information Management Services (IMS)
www.bsi-ii.com

LIMS | Qualoupe 1.1
Two Fold Software
www.twofold-software.com

Not allowing time for features to sink in is the mistake that LIMS made years ago, according to Elliott. Management mandates as executed by IT professionals and ill-planned deployments resulted in strong pushback. "Cultural" issues with ELNs were, moreover, always more serious than with LIMS because of the nature of the workflows and the experience of users: unstructured, senior level for ELNs; structured, less senior for LIMS.

ELN | Sciency | Ruro | www.ruro.com

CONSIDER A LIMS OR ELN REPLACEMENT OR UPGRADE CAREFULLY

Collaborative research is one of the justifications cited most often for acquiring lab data software. While such "soft" benefits are difficult to quantify, the "hard" benefits are easy to measure, after some digging. According to data provided by PerkinElmer, installation of a PerkinElmer ELN at a global pharmaceutical firm reduced experimental setup by 24.5 percent and experiment write-up by 33.6 percent. This company saved 23,000 hours per year through "elimination of experimental failure" on such tasks as drawing chemical reactions, performing calculations, and importing data. "Although it requires collecting productivity data, elimination of waste is where true ROI occurs with ELNs," says Clive Higgins.

Improvements of this magnitude hearken to what Waters's Mark Harnois refers to as the Lean Six Sigma component of laboratory data systems. "Lean" originated in manufacturing but has crept into all aspects of "operational excellence."

A good case can be made for upgrading a LIMS or ELN based solely on the software's age. According to Higgins, the LIMS installation base is aging, with only around two percent of existing deployments dating from recent years. "About 70 percent of LIMS are ten years old," says Higgins. One reason is that LIMS deliver specific "point" solutions, solving the same problems year in and year out.

Users may decide to upgrade or replace a LIMS or ELN for a variety of reasons. Rarely, workflows or instrument configurations change such that the old system is rendered obsolete. More frequently, the user is interested in adding some capability that is not present—for example, notebook-like functionality to a LIMS or sample tracking within an ELN.

But major software upgrades (versus new installations) entail substantial risks. Upgrades are costly, demand commitment from IT personnel, and may disrupt some operations. "A valid business case for upgrading a LIMS or ELN," says LabWare's Mike Kelly, "can only be made if 'moving up' can be accomplished by changing only the application code base while retaining the existing data repository and configuration. This enables the business to spend time and resources solely on leveraging increased sophistication that will provide new and increased value to the business."

The business case diminishes to the extent that any of the historical data needs to be migrated or revalidated or the existing configuration must be reengineered. "Unfortunately, in many such scenarios, the extent of that erosion is so great that it is clear that a version upgrade is simply too costly or too complex," Kelly adds. Conversely, systems that allow the business to upgrade the application "in place," with no need for migration of existing data, preserve both the data repository and the existing configuration. The effect is that the testing and validation effort is reduced, the

LIMS | Scientific Water and Environmental
Thermo Fisher Scientific | www.thermoscientific.com

transition process occurs more rapidly and with less disruption to the business, and the benefits provided by the more advanced platform can be leveraged more effectively.

CONVERGENCE

Convergence refers to the overlap of functionality between the LIMS and the ELN, which could reduce demand for either product under certain circumstances. Experts are split as to whether convergence is inevitable or even possible.

ELN/LIMS companies can affect convergence through several strategies, including adding functionality to their products and partnering with other software providers. LabArchives, for example, has integrated its software with GraphPad Prism (for scientific graphing and statistical analysis) and TreeStar's FlowJo (flow cytometry analysis) packages. LabArchives' ELN already captures some LIMS functionality. "As integration continues, many labs will make the ELN the hub of their laboratory workflow," says Earl Beutler of LabArchives, while conceding that this strategy "will not address all desirable features."

RURO bundles 40 percent of its Sciency ELN packages with FreezerPro, a RURO frozen-sample management package. FreezerPro is not as sophisticated as a full-blown LIMS, but, as Tom Dolan notes, not everyone needs a freestanding LIMS (e.g., RURO's flagship LIMS247). "Although some features are missing, many users would find it difficult to distinguish the resulting functionality from a LIMS," says Dolan

Convergence is popular where QA/QC overlaps with other business functions, including R&D, says STARLIMS's Clive Baron. "I think eventually, you'll see a more general convergence, where ELNs and LIMS become a single product or part of an informatics platform with components of both," says Baron.

Because its features are more easily duplicated, LIMS are more vulnerable than ELNs to "feature creep." Rather than acquiring a new LIMS, some companies might add a quality management module to their ERP system. "Quality modules are cascading down into traditional LIMS territory," says Higgins. Installing an already compatible module reduces the number of vendors, which is highly desirable.

"People in R&D don't want a big, heavy LIMS in many cases," says Atrium's Mike Elliott. "They can start out with an ELN and add workflow functions, the ability to manage structured data, or track samples. It's not the ideal way to go about it, but that is how the market is evolving."

The overlaps have not gone unnoticed by vendors, who have embarked on an acquisition spree of their own to capture technologies serving disparate markets and companies and both structured and unstructured data. In some cases, they offer both products separately; in others, as integrated applications. "The vendors are defending turf as well as expanding capabilities," Elliott comments. "We're seeing the ELN companies coming from one direction trying to fit into more structured data and LIMS vendors trying to add ELN-like flexibility. You don't necessarily get the best in breed by going to these integrated converged solutions, but many users perhaps don't need all those features; the converged products may be good enough."

"It's natural to question why a laboratory needs two distinct data systems," observes Dominic John, who sees the "general convergence" of the two software packages. "When you look at what people ask for—low cost of ownership, simplicity, centralized systems—that cuts against the grain of having a LIMS *and* an ELN because multiple systems create cost and complexity." He predicts that within a decade, users can expect to see a unified system that might be called a LIMS or an ELN "or something different" that will manage primary data as well as provide workflow capability according to each customer's needs.

ELN
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Not everyone agrees that convergence is in the cards. The notion of supplying LIMS and ELN functionally in a single software package does not resonate with consultant Bruce Pharr, who calls attempts at integration "limited in terms of specific applications and operational scale." LIMS and ELNS, he notes, are designed to solve two very different data management problems to distinct end-user populations. "While a single package may address a very narrow range of applications on a small operational scale, most organizations are better off integrating LIMS and ELNs as separate programs," says Pharr.

Thermo Scientific's Trish Meek concurs. "ELNs have evolved as being the application within which scientists work, while LIMS have evolved as a tool for managing laboratory processes. They present different strengths," she says.

A Q&A WITH SELECT LABORATORY DATA MANAGEMENT SYSTEM EXPERT END USERS

OUR EXPERTS:

Gijsbert Woudenberg,
Operational Manager,
ProQares, Rijswijk,
The Netherlands,
Hazardous materials testing

C.H. Rakesh Kumar,
Business Analyst,
Novo Nordisk,
Bangalore, India,
Pharmaceuticals

Greg Mendizabal,
LIMS Analyst,
Seattle Cancer Care Alliance,
Seattle, Washington,
Medical research, treatment

Q: What kind of information systems do you use? What is your general impression of these products?

A: **Gijsbert Woudenberg:** We work with many toxic compounds, including chemical warfare agents and toxic industrial chemicals. Our company inherited a Thermo LIMS and a chromatography data system (CDS) for logging commercial industry orders and processing chromatography data. The LIMS was introduced 10+ years ago and has been upgraded periodically.

Our LIMS was functionally rich, but we used only parts of it. We were also interested in using web- and cloud-based applications that interfaced through tablets. Integration of the LIMS and CDS was only possible by "in between" steps that created another data island.

In late 2011, we discussed the possibility of a paperless lab, and improving our current workflows, with iVention, a provider of laboratory information software. We introduced the iVention Scheduling Web and Forms application, which succeeded in streamlining our operations by integrating data islands from LIMS, CDS, and other data entry points.

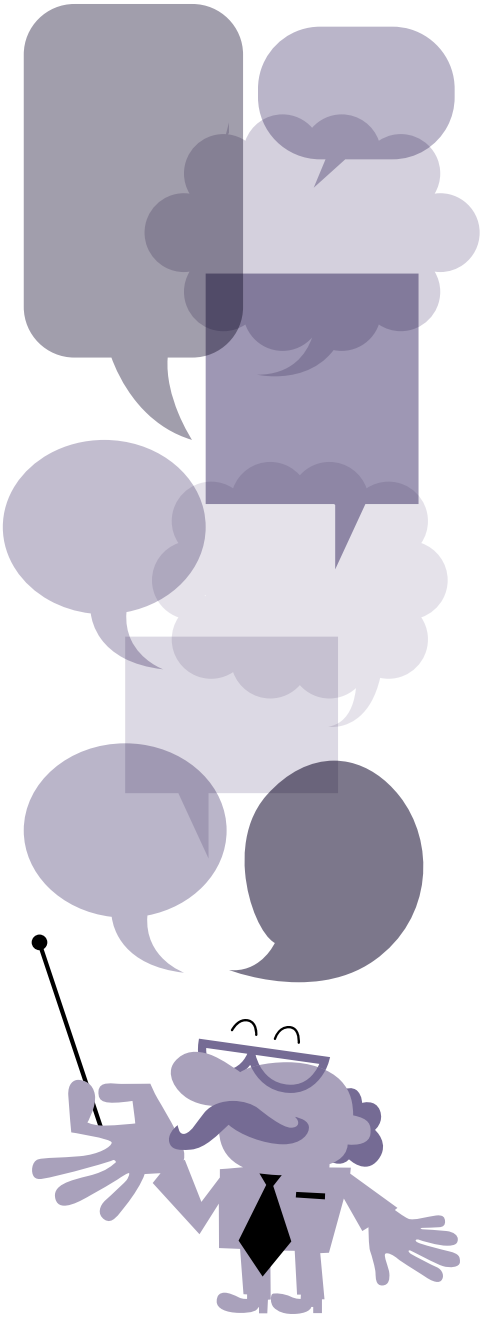
The added value of the operational procedures and tracking the orders, tests, and results have been achieved with the unique and innovative Laboratory Execution System (LES) solution from iVention. iVention is a leader of innovation in Laboratory Informatics Solutions and enables laboratories to work via the Web, cloud, and tablets for the paperless lab. iForms provides bridges between the islands of data generated in the lab and transforms that data into information that can be used across the organization.

C.H. Rakesh Kumar: We have been using systems such as the LIMS, LimsLink, and Empower for the past 10+ years. I have been working in this area for the last six years. These systems are critical to our business as they create great value, add in storing all the information related to the laboratory, and can be retrieved at any time during inspections at a single point source. Overall, these systems meet all stakeholders' expectations.

Greg Mendizabal: We have been using a LabWare LIMS since 2007. I've been working with LabWare since 2006. In the past, I've used and managed a Beckman LIMS and SQL*LIMS. Beckman was quirky and old but very flexible. We were not happy with the SQL*LIMS. By comparison, LabWare is flexible, which is great for molding it to your business processes, but this feature extends implementation time.

Q: Describe your company's experience in terms of learning curve and acceptance of the product by lab workers.

A: **Gijsbert Woudenberg:** ProQares has a track record, with respect to lab informatics, of involving the entire organization early on. Providing awareness of the business motivators for introducing new and innovative software is crucial. Being prepared for the future, while introducing new solutions and having the whole organization supporting this, is key for end-user acceptance.



C.H. Rakesh Kumar: Learning to use these information products is an incremental process—a journey—as new challenges arise daily. It requires the presence of an informatics subject matter expert with knowledge of the product's technical features. We measure our end-user acceptance of the product based on feedback, and based on that we implement corrective and preventive actions to improve the user experience. Key factors we examine are system changes, technical performance, ease of use, supporting business processes, system stability, and system availability.

Greg Mendizabal: Getting acceptance isn't usually difficult. Scientists and technical people are interested in LIMS. The keys are showing them a benefit and assuring that management supports the project. Indifference or negativity by management will dampen user enthusiasm. If lab resources aren't committed to the configuration process (as subject matter experts) and time is not provided for working on the configuration, the system will be ineffective. It may capture all the data, but not in a way that makes sense to users.

Maintaining the LIMS configuration as business needs change is critical to maintaining user acceptance. As the LIMS configuration gets stale, "underground" LIMS supplements appear, such as spreadsheets, access databases, and paperwork.

From a technical perspective, the LabWare LIMS interface is straightforward for data entry. The key to easing acceptance is appropriately configuring the system to facilitate the lab workflow. Right out of the box, LabWare could overwhelm users, particularly in high-volume laboratories. But if the configuration is done well, the "folder metaphor" for this product makes sense to users.

Q: Do you notice an improvement in your workflows or data acquisition?

A: **Gijsbert Woudenberg:** We noticed a higher level of integration of data islands. In the past, each of our process stations generated paper input forms that needed to be taken to the next lab environment. The system was entirely manual and extremely intensive in human input. The

"Learning to use these information products is an incremental process."

iVention Laboratory Execution Software allowed us to transform the paper flow into a paperless flow, and integrated the CDS directly into our process. We reduced documentation efforts, enjoy real-time access to information, improve compliance and data integrity, automate processes and reduce manual data handling, and automate and completely integrate the lab with the enterprise —at the same time providing immediate access in a centralized view of all raw, intermediate, and final data.

C.H. Rakesh Kumar: We have observed great improvements in our business workflows, although we can do even better. Ultimately, we must consider our budgets and time to consider the value added to workflows. The instrument integration to the LIMS using LimsLink is an additional add-on advantage that saves time and reduces manual errors by directly transferring the results from instruments to the LIMS.

Greg Mendizabal: Improving workflows is a two-way street. Just putting in a LIMS will not improve anything by itself. The key is getting user buy-in to reengineering the laboratory processes in concert with a LIMS. The biggest misconception when starting a project is that it will get done faster and add efficiency if "we just do what we're doing now, except in a LIMS." What results is a system that doesn't take advantage of the electronic system efficiencies and simply moves cumbersome paper processes into an electronic form that may require double data entry—for example, recording on paper and then transcribing into the LIMS.

Generally, the greatest efficiency was gained when a data acquisition process was brought under control and data were extracted and parsed into the LIMS. That eliminated the transcription processes and review and was a huge success from the perspectives of time and user experience. Unfortunately, instrument interfacing has been problematic in the past for various reasons, specifically lack of interfaces, communication difficulties, and vendor support.

A second valuable area where the LIMS has improved efficiency and accuracy is providing printed labels for samples.

For management, the LIMS brings a degree of real-time vision into laboratory processes that is otherwise lacking. No longer do managers need to track down paper or analysts, provided they have the discipline to enter data into the LIMS in a timely manner.

Q: What improvements could vendors undertake to make this product more usable or functional?

A: **C.H. Rakesh Kumar:** The most important considerations are improving ease of use and ease of configuring the system. Systems that require lots of customization are highly undesirable. We generally hesitate to do customizations, as it entails time, money and, as a regulated industry, validation as well. Vendors should consider a mechanism for evaluating real-time feedback.

Greg Mendizabal: Any improvements in tool debugging would be welcome. LabWare is pretty good with its tools compared to previous LIMS I've used, but they could still use some improvement. An advantage with LabWare's architecture is that new modules of functionality can be added in at any time. The vendor can produce a module with novel functionality, and it could be sent out and incorporate the existing code dynamically. The downside is that sometimes the modules do not interact well with one another, and bugs can arise in seemingly unrelated areas.

The single most effective (but probably impossible) improvement that all vendors could make is to be able to produce a standardized data export that can be used to move data between systems. Unfortunately, this would facilitate the ability to move easily from one platform to another, which would not be seen as a benefit to vendors.