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ACCESSING LABORATORY INSIGHTS

for Improved Quality and Operational Transformation

NEXT

contents

Introduction

Toward Smarter, More Intelligent Lab Operations

Laboratory operations and the data they produce have never been more central to the success of Pharma enterprise. From critical pipeline-filling R&D, to day-in-day-out quality and compliance routines, lab operations deliver particularly valuable "knowledge," intelligence that supports just about every aspect of drug manufacture and, ultimately, the therapeutic success of the compounds that make it to market. Lab operational managers, under extreme pressure to provide robust, reliable, high quality data to key elements of the organization, are increasingly adapting data management and informatics solutions to get the job done. How to get there from here? Thermo Fisher Scientific has a vision, and in the following pages reveals how well designed, well implemented information technologies can fulfill the lab's critical mission.

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THE PHARMACEUTICAL MANUFACTURING IMPERATIVE TRANSFORM NOW

Used to its fullest potential, a LIMS is an enabler of business transformation

BY KIM SHAH, DIRECTOR MARKETING AND NEW BUSINESS DEVELOPMENT, INFORMATICS, THERMO FISHER SCIENTIFIC

Transform your business before it's transformed for you. These words convey a hard truth about modern business — external forces are rapidly conspiring to unravel even the best-laid plans. From geopolitical and economic macro trends to global threats to health and the environment, business change is now maddeningly unpredictable and capricious. Absent a proactive plan to address these new business realities, some businesses are in for challenging futures. But as always with business challenges, these pressures create opportunities.

First the good news: For decades, many businesses, including those in the pharmaceutical industry, have methodically added technology in preparation for this transformation. But all this investment could be for naught unless these businesses make a strategic commitment to align non-integrated, often disparate resources in ways that enable maximum agility. Over the next decade, the industry will see massive shifts in the way businesses approach investment, expansion, R&D spending, human resources and other critical drivers of growth.

FOUR DRIVERS

What has all this got to do with labs and laboratory management? Quite a bit, actually. To push the boundaries of innovation, companies must assiduously monitor performance and quality and be ready to capitalize on opportunities to transform and grow. For today's elite companies, there are four drivers of constant business transformation: integration, innovation, automation and business intelligence. When all four drivers are in sync, business transformation isn't just a strategy anymore; it's a state of being.

Adding to the complexities of business transformation is the constant pull of technology. Gartner describes the technical changes we are now experiencing as a "Nexus of Forces."

A Gartner analyst defines this Nexus as, "the convergence and mutual reinforcement of social, mobility, cloud and information patterns that drive new business scenarios. Although these forces are innovative and disruptive on their own; together they are revolutionizing business and society, disrupting old business models and creating new leaders. The Nexus is the basis of the technology platform of the future." Organizations that are looking at advancements in instrument technology alone are missing the benefits that can be achieved through IT technologies such as cloud and mobile computing that can not only affect business velocity, but also lower entry barriers to increasing competition. In this way, technology is an equal-opportunity catalyst that puts even more pressure on CIOs to stay ahead.

Data is the currency of business, especially in the lab, and business transformation is inexorably linked to effective data management. Even with the best laboratory instruments and information technology infrastructure in place, there is often little difference between solutions. It is how the data is managed and applied across the enterprise that becomes the unique competitive advantage.

Businesses today must have full visibility into laboratory operations and outputs and strategies to make new insights actionable. A one-day head start diagnosing an issue with raw materials in the supply chain or recalling shipments of tainted product could save millions. In other words, the benefits of agile decision-making are not trivial — bottom-line and top-line revenue hangs in the balance. This is why it's so important for companies to regard a laboratory information management

The Transformed Lab:

Paperless, Agile and Quality Driven

By Trish Meek, Director of Strategy, Informatics, Thermo Fisher Scientific

Traditionally, regulations and pressure to meet validation requirements have made it difficult for the pharmaceutical industry to make small adaptations to their process, let alone transform it. When the U.S. Food and Drug Administration (FDA) published "Pharmaceutical Quality for the 21st Century: A Risk-Based Approach," they introduced Quality by Design (QbD) to the pharmaceutical industry. According to the FDA, "QbD is a science and risk-based approach to pharmaceutical development and manufacturing. QbD in pharmaceuticals involves designing and developing pharmaceutical formulations and manufacturing processes to help ensure product manufacturing quality." QbD has since been adopted by other regulatory agencies, like the European Medicines Agency (EMA).

The FDA and EMA clearly believe that better planning and management of processes can play a major part in driving industry transformation and improving quality. By embracing QbD principles, for example, they make it clear to those under their purview that understanding critical process parameters and critical quality attributes are essential to ensuring product quality, and they further believe that those process improvements should be iterative as a product is moved through the development process and into final production Once in production, a high level of understanding of your product and your process enables organizations to identify when processes are trending towards product or process failure. This is why many labs are shifting to paperless environments to give them real or near-real-time access to the data.

The paperless lab concept is not new by any means but, until recently, many have incorrectly believed that integration costs outweighed benefits. While that could have been true in the earliest implementations, integration technology has now improved dramatically. Today we have direct Web service connections between multiple applications managed by intelligent bi-directional interfaces, and this enables labs to move data

system (LIMS) as much more than just a data collection solution for the lab; when used to its fullest potential, a LIMS becomes an enabler of business transformation.

When LIMS are tightly integrated with other enterprise operation systems such as ERP, insights from the lab have the potential to be even more central to businesses seeking true enterprise-wide agility. Organizations aren't simply capturing and collecting data; they are making data actionable across the enterprise, putting management in position to transform their businesses into agile organizations capable of responding to market trends or new regulations and flexible enough to recognize and capitalize on cost-saving or margin-growing opportunities in the future.

TOWARD AGILITY

The agile enterprise, one that is truly business transformation-ready, must rest on a platform that is supported by the four pillars identified earlier: integration, innovation, automation and business intelligence. Across the spectrum of biopharmaceutical companies, organizations are already taking advantage of the opportunities presenting themselves when any of these strategic initiatives are fully embraced. Now is the time to assess what you are doing today and what initiatives could benefit your organization.

- Integration – Integration is critical at two levels. At the laboratory level, scientists need access to the real scientific data regardless of vendor to correctly identify any product quality issues or potential environmental contamination as quickly as possible. At a high level, management needs to

forward based on pre-defined stage gates and checkpoints.

The pharmaceutical industry as a whole now understands the value of connecting systems such as LIMS to SAP QM. This is precisely the sort of transformation my colleague Kim Shah talks about in this article as a way to gain distinct competitive advantage. And it's no longer the enormous undertaking it once was.

The key question is how to take existing technology investments — whether that is a LIMS, ELN, SAP QM, etc. — and create an integrated process, from simple instruments through to chromatography and mass spectrometry instrumentation. The goal is to eliminate the manual steps that often invite errors and introduce risk. While this is by no means easy, because the integrity of specific business processes must be maintained, vendor-to-vendor solutions do exist in the market, and a custom product is no longer required to connect disparate interfaces. This is turning more pharmaceutical labs into instant converts.

Validation is a critical requirement in the pharmaceutical industry, and many companies turn to commercially available integration solutions that have been used and tested across multiple sites because they can be treated as lower risk when companies perform their risk-based assessment.

Surprisingly, we often find that documents that are created electronically from an instrument system or balance within a lab may still be printed and manually entered into other information systems, like the LIMS. This is a hard-to-shed legacy from a time when the industry was blessed with more people, meaning there was always someone available to do the manual step and ensure the process remained consistent. It was a person, not technology, which established discipline and adherence to processes. Ironically, the biggest stumbling block for many companies looking at this from an informatics perspective is that they don't know the rate-limiting steps in their processes and where integration would provide the most value. Vendors, like Thermo Fisher Scientific, can work with their customers to identify low hanging fruit and implement those solutions.

integrate these lab results with the overall manufacturing process. This provides true visibility to inform business decisions through executive dashboards built on comprehensive real or near-real time data. When people, processes, technology (and data) are stuck in silos, business agility is impossible.

- Innovation – Biopharma companies today are looking at big data to identify opportunities for improvement, market opportunities, optimizing costs and improving operational efficiency. Addressing challenges as diverse as accelerating drug discovery to more efficient ways to manufacture product, liberating laboratory data in dashboard form can be a new catalyst for continuous change. A LIMS, providing a centralized aggregation of all of the laboratory's critical operational and scientific information, holds the key to solving many of these challenges and is a critical component of any big data strategy. And the ability to recognize and exploit pathways for innovation is as much cultural as it is process-oriented. By aggregating this information and centralizing it for all to see, the LIMS is allowing everyone to see the value of organizational change and commitment.

- Automation – Automating time-consuming tasks such as instrument calibration, compliance, user training and maintenance liberates more time for science, investing this perishable intellectual capital back into business transformation.

- Business Intelligence (BI) – In many enterprises, if a manager or executive wants to see laboratory progress or productivity reports, the IT department has to step in. Today, however, thanks to more mature BI approaches enabled by cloud computing, lab personnel can create real-time dashboard reports that are accessible to managers and executives 24/7 via desktop, tablet or mobile devices.

Today, however, consolidation has significantly reduced the number of personnel, including scientists, able to provide continuity and ensure process discipline. This is part of the massive transformation discussed earlier. Fewer people, unsupported in some way by technology, struggle to meet the industry's high quality and accountability standards. This is yet another area where informatics, especially an entirely paperless lab, is truly transformative for a lab — and the entire enterprise – making it smarter and more agile.

The way forward is clear. Some labs are already realizing an average improvement in performance of between 20-30%, based purely on the elimination of manual processes and the review steps associated with them. The reduction in cost alone is enough to pay attention, but it's only the beginning. Cost reduction is only one benefit of transformation — the rest, from streamlined drug discovery to simplified regulatory compliance, are waiting there for any pharmaceutical company that is ready to make transformation its number one priority.

A technology roadmap now exists for building a business transformation-ready enterprise. The first step, however, is liberating insights that are stored in laboratories around the world, enabling people to proactively query and use vast stores of knowledge. When that happens, a business is truly transformed; its laboratory is a growth driver; and the C-suite is fully engaged. The real measure of success is the improved profitability and increased revenues realized by these efforts.

Top 10 Pharma Company Improves Laboratory Productivity

In an effort to reduce the cost of maintaining and supporting multiple home-grown LIMS, the company sought to consolidate onto one corporate standard across all sites

Employing thousands of people worldwide, this top 10 pharmaceutical company operates research and development, manufacturing and distribution facilities in a multitude of countries on four continents. Bulk products are shipped from pharmaceutical plants around the world where they are used as the key ingredients in the production of injectables, tablets and capsules.

BUSINESS CHALLENGE AND OBJECTIVES

In an effort to reduce the cost of maintaining and supporting multiple home-grown LIMS, the company sought to consolidate onto one corporate standard across all sites with the following objectives:

- Business integration with IT systems such as ERP, MES, LIMS and other enterprise and laboratory software applications
- Laboratory automation with instruments and other data systems
- Global harmonization and standardization of best practices
- Paperless lab, reduced costs and improved quality

REQUIREMENTS

Thermo Fisher Scientific was selected not only for its products' rich functionality and extensive deployment history in Pharmaceutical QA/QC, but also for its services capabilities to implement, validate and provide language support across multiple sites and continents. Via Thermo Scientific CONNECTS for the Paperless Lab, it also had all of the tools to meet its integration, automation and harmonization objectives.

PHASE 1

The project initiated at the Active Pharmaceutical Ingredients (API) production facility to support both the Quality Control (QC) and In-Process (IP) laboratories. The implementation of Thermo Scientific LIMS in their new facility presented a number of requirements, including meeting strict deadlines for completion to coincide with production initiation.

In terms of functionality, the fundamental requirements of the LIMS were clearly outlined at an early stage. They needed a system that would allow users to store, manipulate

and retrieve information relating to samples and laboratory processes. In addition, the LIMS needed to act as a centralized repository storing all analytical data for release and stability testing purposes, along with environmental monitoring.

PHASE 2

The project team also identified the need to interface the LIMS both within the laboratory and to external systems to automate their workflows, improve efficiencies and facilitate communication. Inside the laboratory, the LIMS needed to integrate with their analytical instrumentation — from simple instruments such as balances and pH meters, to more complex instruments that collect and process the results, such as chromatography (Empower) and mass spec data systems. The LIMS also needed to act as the conduit to connect the lab to external systems and interface with the companies Enterprise Resource Planning system (SAP) specifically for QC, Electronic Laboratory Notebook and Operations Management software applications.

In addition, it was necessary for Thermo Fisher to develop and implement a comprehensive training program for the large number of staff to ensure the smooth running of the system from the outset.

Phase 1 LIMS implementation was to be used as a prototype system for future rollout to other global sites.

THE SOLUTION

In order to meet the key challenge of such aggressive timelines, Thermo Fisher assisted with the gathering and standardizing of business requirements across multiple sites. This was followed by customer workshops aimed at training and determining gaps in the workflow. Gaps were transformed into a design specification that formed the basis for system implementation and configuration.

Phase 1 implementation included validation Performance Qualification (PQ) and stability testing. The system was configured to meet all of the requirements including sample login via ERP interface, test assignment, label generation, worksheets, results entry and review, batch disposition, certificate of analysis, stability testing, environmental monitoring and management reporting and trending among many other items.

The SAP interface enabled the QC function to automatically login samples based on goods received into the warehouse and goods issued by production. The interface also addressed the requirements for automatic login of samples for materials approaching retest (expiration) date.

The local and on-site presence of Thermo Fisher for the entire duration of the project also ensured faster progress of the project through continuous access to all of the project team. Additionally the active involvement and “hands on” approach of both organizations enabled quick decision making and document turnaround. Thermo Fisher's SAP expertise was critical to the success of this project.

To facilitate remote deployments, Thermo Fisher leveraged a broad partner network to provide resources to help configure

local data and train end users in their native language. Orbis Information Systems works exclusively with Thermo Fisher products and its services include LIMS justification and cost benefit analysis, design, implementation and support. Orbis also provides LIMS integration solutions for instrumentation, CDS, business and manufacturing systems.

Thanks to Thermo Fisher's ongoing partnership and support, the LIMS is now implemented across 12 sites and four continents.

BUSINESS BENEFITS

The implementation of Thermo Scientific LIMS has resulted in a number of clear benefits including:

- Enhanced data quality, integrity and availability by eliminating manual, error-prone and time consuming paper-based processes
- Reduced the cost of ownership by eliminating high overhead and inefficient home-grown applications
- Optimized workflows by harmonizing and standardizing on unified methods, SOPs, specifications and other laboratory practices across all laboratories
- Consistent global deployment by leveraging network of Thermo Scientific staff and certified Partners
- Better flexibility to adapt to evolving business processes
- Improved productivity and efficiency by automating and integrating systems and instruments
- Operators trained via on-demand multi-lingual eLearning
- Manufactured lots traceable directly back to raw material and EM data

To support customers worldwide, Thermo Fisher offers comprehensive professional services ranging from implementation and validation to support, training and education. Deploying and maintaining LIMS and CDS software raises many challenges from defining your initial project requirements and implementing/validating your solution, to ongoing support and training. Expert knowledge to help make the right decisions, targeted assistance with deployment, and a clear understanding of the software and how it integrates in your application, all combine to help yield the long term benefits you look for when buying software.

Our comprehensive range of implementation and validation services delivered via a unique approach that integrates software deployment, project management, consulting, and instrument and systems integration. With a global network of some of the most highly experienced professionals dedicated to delivering the best informatics services in the industry, Thermo Scientific LIMS and CDS deployments are smooth and predictable. Our expertise is also reflected in our ongoing partnership with customers in the form of superior support and product training.

Are You Maximizing the Value of Your Laboratory Assets?

The paperless lab can add value by automating and integrating lab data with the enterprise and making it accessible in real-time

BY PAULA HOLLYWOOD, ARC ADVISORY GROUP

SUMMARY

Industries have been "kicking the tires" of the paperless laboratory for a decade or more. The benefits of immediate access to data, enhanced collaboration capabilities, and fulfillment of accreditation requirements, should be enough incentive for enterprises to convert to paperless. While most manufacturing plants have migrated to automated data capture for functions related to operations and maintenance, the analytical laboratory remains a paradox. Laboratories utilize some of the most advanced and sophisticated instrumentation in the plant yet, in many cases, still employ the oldest data storage method — pencil and paper. This lag in laboratory automation is rooted in lab culture and sustained by the lack of data and integration standards for laboratory equipment and systems.

The paperless lab can add value by automating and integrating lab data with the enterprise and making it accessible in real-time when and where it is needed for faster, more informed decisions about R&D and manufacturing operations. Laboratory software has evolved to the point where the paperless lab is readily achievable when implemented with an experienced partner who can provide the tools and methodology for the task.

Did you know? By automating the laboratory companies save a tremendous amount of time and resources on manual activities in the lab. By automating the lab, CONNECTS for the Paperless Lab delivers improved efficiency, productivity, consistency, quality and reduced costs typically by over 20%.

MAKING THE BUSINESS CASE

Paperless laboratories are a disruptive innovation to the enterprise in that they represent a departure from existing

practice. Disruptive innovations are often the most difficult to justify in terms of hard benefits.

In the current competitive business environment, industrial organizations seek opportunities to improve efficiencies in all areas of the plant and the analytical lab should not be an exception. Yet for many organizations, this remains elusive. This is partly due to the fact that labs are often surrounded by the mystique of science. However, enterprises should not be intimidated by the science and, instead, should cut through the mystique that has traditionally isolated the lab to be able to reveal data that can add value to the enterprise as a whole.

Certainly, paper-based systems are easy to use and require minimal training. They are also convenient and support multiple data types. Aside from the "that's the way we've always done it" argument, the best argument for the continued use of paper is that it is legally defensible in a court of law should that need arise. The drawbacks of paper include security risks, and maintenance and storage issues. More importantly, with paper systems, records are not searchable; inhibiting collaboration both across internal groups and with external partners.

The decision to implement a paperless lab should be based on the value it will bring, not just to the lab, but to the enterprise as a whole. For example, a paperless system facilitates collaboration across multiple sites through a centralized platform accessed via the Web. A paperless system can also improve lab productivity by integrating the chromatography data system (CDS) with the laboratory information management system (LIMS) and Electronic Laboratory Notebook (ELN) to eliminate time-consuming manual transcription and associated errors. Taking the paperless route also frees the technician to perform more value-add work.

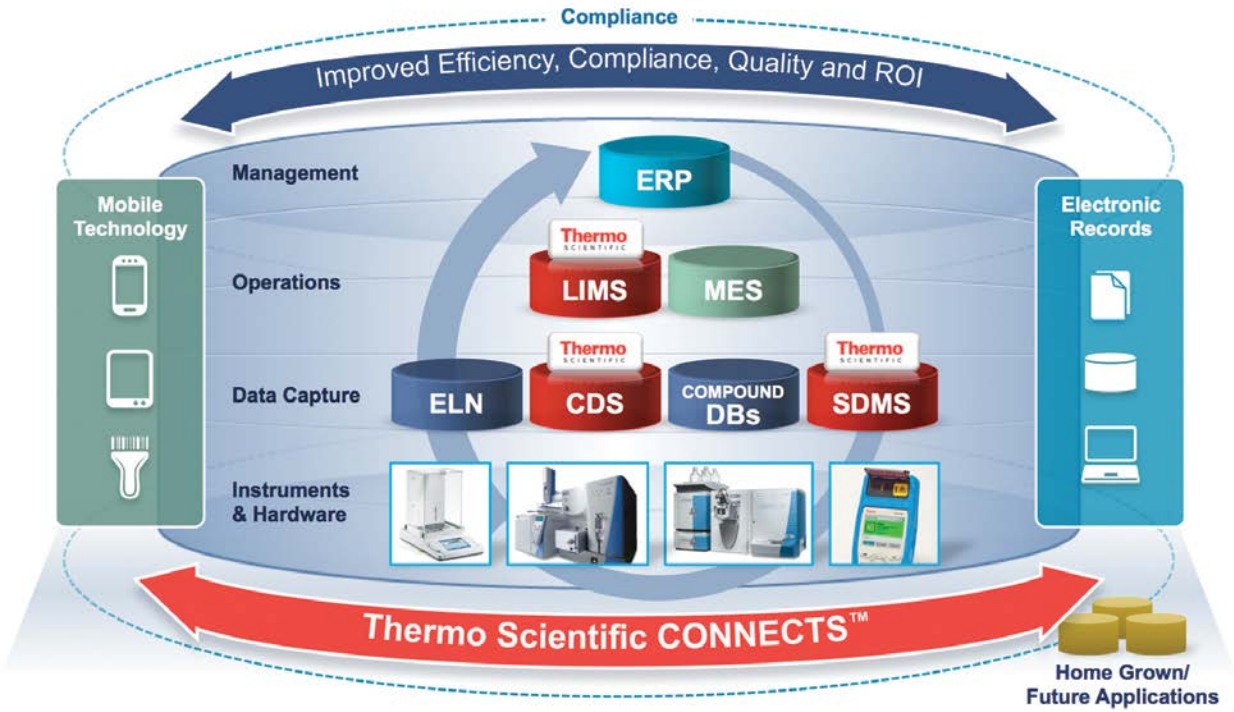
STANDARDS NEEDED TO FACILITATE INTEGRATION

Lack of standard instrument data formats is the primary inhibitor to enterprise-wide electronic access to laboratory data. To date, the collective voice of the end-user community has not been strong enough to drive standard lab device interfaces. Without standards, automating data capture from disparate devices and integrating lab data with higher level systems can be challenging, making it difficult to provide decision makers with a single version of the truth. New tools and technologies are emerging that make the paperless lab a reality.

SOLUTIONS ARE AVAILABLE NOW

Numerous solutions for implementing paperless lab functionality are available on the Internet. However, while these might be suitable for the academic environment, some of these solutions (and particularly "free-ware" solutions), may not provide the data security and IP protection required in industrial environments. Manufacturers and other industrial organizations also need a clear understanding of who is responsible for integrating and supporting the solution over time. For these reasons, ARC believes that industrial users should look to experienced, well-established suppliers such as Thermo Fisher Scientific for these types of solutions.

The company's CONNECTS for the Paperless Lab provides a combined methodology, technology, and service solution



for integrating laboratory equipment with each other and with enterprise systems to enable organizations to move to a more efficient, integrated, paperless environment that can benefit the entire enterprise. According to Thermo Fisher, this solution provides the bridge between laboratory-generated data and enterprise-level information required for mission-critical management decisions.

THERMO SCIENTIFIC CONNECTS FOR THE PAPERLESS LAB

The CONNECTS methodology involves an assessment of current laboratory automation and device integration to identify points of data exchange and opportunities to streamline work processes. Thermo Scientific Integration Manager is the backbone of the company's technology component. It provides a single connectivity platform for connecting disparate laboratory data sources with data destinations. Integration Manager acts as translator for disparate instrument languages and converts raw data to a vendor-neutral storage format for data archiving. As an objective third party, Thermo Fisher can also help organizations overcome internal resistance to change, minimize internal conflicts of interest, and supplement internal resources.

UNDERSTANDING IS PRICELESS

In a typical paper-based lab, eight manual processes are involved prior to recording final testing results from a CDS into the LIMS. Automating data capture eliminates human error and reduces system complexity, and higher lab efficiency reduces cycle times. The ROI on these types of improvements are relatively easy to quantify. For example, it's relatively simple to calculate the savings attained by eliminating manual documentation activities. While those savings can be significant, they may not be sufficient to justify the cost of the change to a paperless process.

ARC believes that the true value of the paperless lab to the enterprise is in the more-difficult-to-quantify intangible

benefits. Enterprises make significant investments acquiring lab equipment and software, but do not realize the full value if the data remain stranded in the laboratory. Connecting lab data with ERP, PIMS and other manufacturing floor solutions, provides the real-time data needed to improve efficiencies, streamline work processes, improve product quality and, ultimately, improve customer satisfaction.

CONCLUSION

ARC believes that the lack of standards for laboratory devices in this automated age inhibits operational excellence (OpX). Manufacturers that employ sophisticated laboratory equipment, but don't integrate that equipment to enable enterprise access to the lab data will inhibit their ROI. To be of value, information must be accessible to the right people at the right time. An enterprise strategy in which lab data is integrated with higher-level business systems provides information transparency for real-time decisions, enhancing the value of the lab data throughout the organization.

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THERMO SCIENTIFIC LAB EXECUTION SYSTEM HELPS SCIENTISTS GO PAPERLESS

Analytical and QA/QC labs, under ever-increasing pressure to improve time to market, ensure compliance and realize cost savings, now have an all-inclusive informatics solution that gives them complete control over their methods and standard operating procedures (SOPs) without having to purchase, integrate and validate software from multiple vendors. Trish Meek, director of product strategy for informatics at Thermo Fisher Scientific, explains how the new solution helps get scientists closer to the paperless lab.

QA/QC Labs and Smart Infrastructure Equal End-to-End Quality by Design

By Trish Meek, Director of Product Strategy

In his report, "Product Innovation Requires Laboratory Informatics Systems to Transcend Phases,"[1] Gartner analyst Michael Shanler recommends that manufacturers "prioritize end-to-end informatics investments and align metrics for innovation, domain expertise, operational efficiencies and quality." His recommendation is based on an observation that today's laboratories "are, for the most part, disconnected."

The move to a more connected laboratory is driven by both the productivity drivers Gartner describes and significant technology improvements. The paperless lab has been discussed for the past 15–20 years, but it is finally happening and nowhere is this more evident than inside quality assurance/quality control (QA/QC) laboratories. Few QA/QC labs still cling to the paper-based notebook systems of the past and, while this is a critical step, it is only part of the story. There's far more to becoming a paperless lab than simply eschewing paper. Labs must adopt a smart infrastructure that drives quality, not only in the lab, but throughout the organization. An integrated informatics solution is the engine that drives quality product release and a culture of continual process improvement.

QUALITY BY DESIGN

In 2004, the FDA introduced Quality by Design (QbD) in "Pharmaceutical cGMPs for the 21st Century—A Risk-Based Approach."[2] While this concept is not new to many industries, it was the first attempt to apply these principles to the pharmaceutical industry. Quality by Design is built on the concept that well-understood products and processes are more efficient and produce higher-quality products resulting in less product nonconformance. The FDA's goal was to improve pharmaceutical companies' productivity, ensure patient safety, and prevent drug shortages in the marketplace. The quote below, from a 2012 FDA presentation on the pharmaceutical quality system, makes this point succinctly:

We rely upon the manufacturing controls and standards to ensure that time and time again, lot after lot, year after year the same clinical profile will be delivered because the product will be the same in its quality.... We have to think of the primary customers as people consuming that medicine, and we have to think of the statute and what we are guaranteeing in there, that the drug will continue to be safe and effective and perform as described in the label." (Janet Woodcock, M.D.)

Uncompromising quality is essential to any pharmaceutical company. Informatics plays a critical role in ensuring that organizations realize the improved product quality and operational efficiency provided by adherence to QbD principles.

TODAY'S INFORMATICS INFRASTRUCTURE

QA/QC laboratories need a tightly controlled process and a well-managed laboratory to drive predictive analytics and to prevent substandard products before they occur. An end-to-end informatics solution warns the organization before nonconformances occur by monitoring critical product attributes creating a proactive versus reactive environment. Laboratories address these needs through the use of several systems: Lab Execution Systems (LES), Scientific Data Management Systems (SDMS), and Laboratory Information Management Systems (LIMS).

LAB EXECUTION SYSTEMS

LES has become a critical component of today's paperless lab, ensuring that quality processes are followed in the laboratory and that the methods built on QbD principles are followed in day-to-day laboratory operations. LES drives users through any laboratory procedure in a stepwise fashion. This provides technicians with the direction they need to execute processes safely, and in a consistent manner. It also assures laboratory management that good laboratory practices (GLPs) are used and that standard operating procedures (SOPs) are being followed by experienced and newly trained laboratory personnel. Maintaining a consistent approach to activities like sample preparation, instrument calibration, maintenance, and analytical testing is critical to a good scientific process. Lab managers can then be certain that all of their results are a true assessment of final product quality.

SCIENTIFIC DATA MANAGEMENT SYSTEMS

An SDMS lets you integrate instruments across the lab and centralize data capture, allowing for long-term data archiving and, more importantly, data visualization from the archive—all accessed from the LIMS. An SDMS archives the original raw data files from the instrument along with a normalized representation in XML, without the need to restore the data to the original instrument workstation or install the instrument software on every computer.

The real scientific data and the results gleaned from them are a critical part of QbD. The final product specification is determined by comparing the analytical results to determine which formulation and process parameters yield the best product. As part of a paperless lab environment, an SDMS integrated with the LIMS reduces paperwork, manual review time, and data transcription, which improves efficiency, productivity, consistency, and quality while reducing costs dramatically. SDMS also provides secure access to archived files for as long as necessary, and enables more efficient and defensible reporting to regulatory authorities.

LABORATORY INFORMATION MANAGEMENT SYSTEMS

LIMS remains a critical part of the infrastructure of any pharmaceutical manufacturing organization. Today's LIMS goes far beyond just the management of samples, tests, and results. It also provides resource management, allowing

organizations to forecast fewer sample volume and resource needs. It provides dashboard views that allow organizations to see how their lab is operating and identify any data that are trending toward warning or failure limits. These lab management activities are essential, but organizations need to be able to drive the day-to-day operations of the laboratory as well.

Having a smart infrastructure built on a state-of-the-art informatics solution at its core enables another critical benefit in the lab: automation. Even smart instruments must undergo regular performance verification. How often this is done depends on many factors, including the frequency of use. Because instrument failure—or having a system go out of specification—can negatively impact quality, production, or compliance down the road, any risk is unacceptable. A LIMS can save considerable time by helping labs adhere to precise rules and requirements, automating critical procedures on predefined schedules.

When all systems are aligned, the convergence of people, processes, and technology is transformative. Problems arise when these systems are not fully integrated, and these disparate systems become out of sync. At a macro level, breakdowns occur at three key points: data capture, data transcription and data management. Put another way, the key to an efficient lab that delivers uncompromising quality is having smart instruments within a smart infrastructure. This starts with SOPs for highly standardized methods and processes, which are handled by the LES, and includes raw instrument data generated by the analytical instruments used in those experiments, all of which are handled capably by the SDMS.

What lab managers really want is a truly connected system that provides lab management, drives lab operations, and integrates all of the data-generating sources and ties all the data together in one centralized location. A modern LIMS needs to be a complete informatics infrastructure by providing a LIMS, SDMS and LES in one.

ACHIEVING MUCH-ANTICIPATED INTEGRATION

Today's paperless lab can more aptly be called an integrated lab. The trinity of LIMS/LES/SDMS enables lab managers to achieve full instrument integration, manage their methods and workflows, retrieve and archive any kind of raw laboratory data, and export those results across the organization to enterprise resource planning (ERP) systems, for example, all in whatever format is required by recipients.

The ability to manage the entire process in a tightly integrated solution, one that functions as a single piece of software, dramatically streamlines laboratory operations while minimizing the cost of ownership, implementation, validation, and ongoing maintenance. An example of this is SampleManager LIMS (Thermo Fisher Scientific), which includes built-in functionality for LIMS, LES and SDMS as well as integration technologies. What's more, when labs plan for such seamless integration it enables lab managers to codify a "do it right every time" process approach, which is in alignment with QbD processes, providing the transparency necessary to identify and remove nonvalue-add steps, while

lowering the cost of training new staff. With LES functionality available as part of a LIMS implementation, SOPs and methods are automatically established electronically so that for any lab personnel, new or seasoned, the LIMS acts as their workflow, manual and constant guide.

It is easy to see the LIMS, LES and SDMS "stack" as a lab-centric view of pharmaceutical business, but that would be a mistake. The ability to run efficient labs and protect the brand by safeguarding product quality is an enterprise-level concern. As such, the LIMS needs to be fully integrated with ERP systems; in fact, many work requests coming into QA/QC laboratories are actually initiated in a manufacturer's ERP system, which for many companies is the bridge between its manufacturing execution system (MES) and other systems such as the LIMS.

CONCLUSION

In many organizations, a LIMS is a standalone investment, managing workflow and sample testing and generating appropriate reports. If the lab needs additional software, such as an electronic laboratory notebook (ELN) or SDMS, those systems are then implemented and sometimes, but not always, integrated with the LIMS so that lab operations are more streamlined and data are easier to manage. In a QA/QC lab, however, a LIMS such as SampleManager, that is prebuilt with LES and SDMS functionality and delivers end-to-end workflow and data capture, is literally designed for quality. The benefits of having all these capabilities resident in a single system are myriad, starting with lower total cost of ownership, ease of training and administration, streamlined compliance, and better overall quality control. All of this is possible across vast geographies or contractual partnerships, and can all be managed holistically.

Organizations that have not done so already need to make this year a major inflection point for laboratory technology, especially within the QA/QC function. After all, the evidence is stacking up that the costs of inaction clearly outweigh the investment that is required for change.

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CLICK HERE **Thermo Scientific SampleManager 11 LIMS**

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