Thermo Scientific Integrated Informatics Solutions for the

Pharmaceutical Industry

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introduction

Engine for Innovation: Integrated Lab Informatics

t's no secret that laboratory operations play a central, fundamental role in the success of Pharma enterprise. Whether filling the R&D pipeline, or seeing to day-in-day-out quality and compliance regimes, lab operations deliver particularly valuable intelligence that supports just about every aspect of drug manufacture. Decision makers up and down the operational chain of command rely heavily on robust, reliable, high quality data and operational managers are under extreme pressure to deliver it to key elements of the organization. Increasingly pharmaceutical manufacturers are looking to data management and informatics solutions to ensure that this critical information is not only accessible when demanded, but ready to provide decision support to the highest levels of the organization. Looking for an engine for innovation? The following pages reveal how highly integrated lab information technologies from Thermo Fisher Scientific can power innovation and ensure that operational excellence is the rule, rather than the exception in your organization's lab operations.

table of
contents

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

By Trish Meek, Thermo Fisher Scientific

As seen in *American Laboratory*

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 noncon-formance. 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 (SMDS), 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. ●

1. https://www.gartner.com/doc/2597215/product-innovation-requireslaboratory-informatics

2. http://www.fda.gov/ohrms/dockets/ac/03/briefing/3933B1_02_Pharmaceutical%20cGMPs.pdf

Leaving **Paper Behind**

By Trish Meek, Thermo Fisher Scientific

As seen in *R&D Magazine*

After another year of flat spending in 2013, global investment in R&D was forecast to grow by 3.8% to $1.6 trillion in 2014, according the annual *R&D Magazine Global Funding Forecast.* In the U.S., federal spending was forecast to increase modestly (1.5%). It's fair to say the pressure is still on to do more with less, particularly in Big Pharma where recent R&D cuts have been the most dramatic.

Transforming the lab into a tightly integrated paperless environment can enable improved access to real-time information, regulatory compliance and data integrity, as well as cost savings by automating processes and reducing manual data handling.

For modest growth in R&D spending to equal even modest return on investment, the industry must continue to reach new levels of efficiency and accountability. The shifting of R&D to Contract Research Organizations (CROs) and academic laboratories, for example, is just one example of how the traditional models are changing, particularly in Big Pharma. Despite these changes, however, significant work must be done to achieve critical productivity increases. According to Deloitte's fourth annual "Measuring the Return from Pharmaceutical Innovation", "the cost of bringing an asset from discovery to launch increased by 18%, rising from $1.1 billion in 2010 to $1.3 billion in 2013."

With fewer dollars to go around for R&D and increasing production costs, the life sciences industry must root out inefficiencies wherever possible and build in new processes to achieve improved productivity and greater efficiencies across an oftentimes much broader organization, starting with the laboratory. Many R&D laboratories have trimmed staff, but there's a limit to how much can be cut. Advanced technology certainly helps by accelerating discovery, but new innovation brings added complexity that now-smaller staffs must manage and do so with even stricter demands for quality control. Never has the need for comprehensive enterprise-wide information management and analysis been greater.
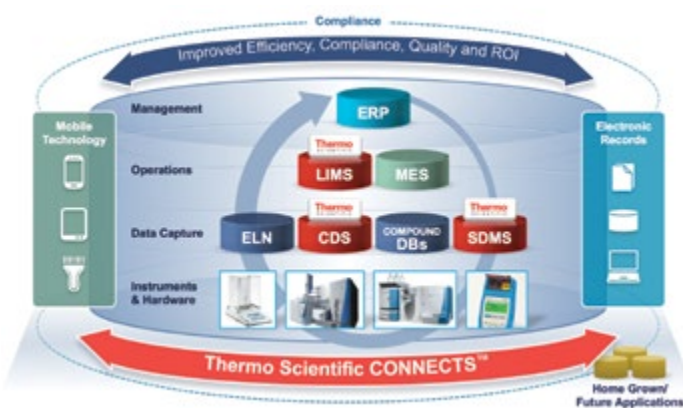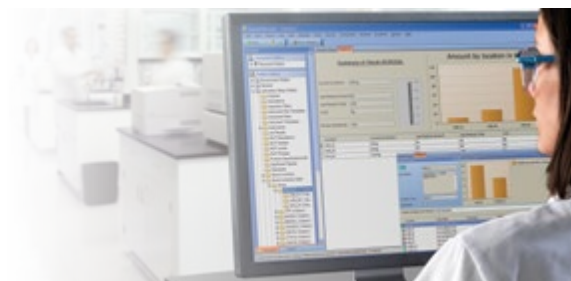
Connecting the dots

While the paperless laboratory has been a topic of discussion for more than 15 years, the pace of adoption has never been faster. This would be true even if CROs and academic institutions didn't play an increasingly larger role; but since the collaborative landscape has changed dramatically in the past several years as the speed of discovery has brought about more complex alliances between commercial, academic and private research, the need for integration of all aligned systems across a more diverse set of users is even greater. Today's laboratory is often a highly distributed laboratory, comprising a value chain that spans multiple constituents and geographies. If even a single laboratory (internal or external) still relies on a paper-based methodology that utilizes a lab notebook system, it's not hard to imagine how that could impact overall quality, speed and throughput. This argues for smart infrastructures in life sciences manufacturing that drive quality, not only in the laboratory and internally, but across distributed organizations. This, in turn, argues for state-of-the-art informatics solutions that are capable of connecting dots that, if left in silos, can lead to lost productivity, inefficiency and, in the end, stranded R&D investment.

The timely answer for accelerated R&D

The phrase "paperless laboratory" doesn't fully capture the scope of what changes inside the enterprise when key systems are integrated: the Lab Execution System (LES), which establishes Standard Operating Procedures (SOPs) for tests and processes; the Scientific Data Management System (SMDS), used for capturing, cataloging and archiving data generated by laboratory instruments; and a Laboratory Information Management System (LIMS), which integrates all data and information—and manages it—in a

highly efficient, highly productive paperless environment. Working as one holistic system, the LIMS/LES/SDMS trinity enables laboratory 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 ERP systems, for example, all in whatever format is required by recipients.

The benefits of having ERP meet R&D are obvious to any life sciences manufacturer. And they are becoming increasingly obvious to all the connected dots across the value chain of any pharmaceutical or biotech company. A tightly integrated solution, contained within a comprehensive software solution, dramatically streamlines laboratory operations while minimizing the cost of ownership, implementation, validation and ongoing maintenance. This type of integration and efficiency can be achieved across the most highly complex and distributed or organizations or research environments—from multiple laboratories across a campus to a collection of diverse users crossing multiple geographies.

An enterprise-level solution, which includes built-in functionality for a LIMS, as well as LES and SDMS, enables manufacturers to codify a "do it right every time" process approach, which can align everything from Quality by Design (QbD) processes to SOPs that are critical to achieving goals for increased pipeline productivity. When fully integrated, the LIMS removes non-value added processes and builds in the opportunities for greater efficiencies to occur. An enterprise-level LIMS, such as Thermo Scientific SampleManager, is able to receive and archive data from across the distributed enterprise so that information is more readily and easily available, allowing for imp oved collaboration amongst the range of participants in an R&D effort. The speed of discovery then can be said to be in direct relation to the speed in which information is available. Connecting all constituents is the critical goal of any modern research project.

Seeing the LIMS, LES, SDMS "stack" simply as something to manage laboratory samples and SOPs would be a mistake. It's so much more. In fact, today's enterprise-level LIMS, with functionality that addresses the needs of automating method execution (LES) and enabling access to archived raw data (SDMS), are more and more the engine of innovation that allows for more exciting and collaborative research and development to occur. When a LIMS is fully integrated with an organization's ERP system it's, in fact, part of an R&D engine, and consequently every laboratory manager, staff person, instrument or set of data is contributing to potential growth.

Conclusion

An enterprise-level LIMS, especially when it's built with full functionality for LES and SDMS capabilities, goes far beyond just the management of samples, tests and results or the assurance of compliance. This LIMS enables comprehensive resource management, allowing organizations to forecast resource requirements and plan for change, which means the data stored in the LIMS becomes a critical component of key management metrics and the value of the data generated in the laboratory is elevated across the enterprise. The LIMS provides dashboard views of the entire laboratory operation, from daily workflow to personnel training, resource use and stock refill requirements and delivery records, to customer requests and workflow change-over requirements. Such a view of the overall health of the laboratory allows management to gauge laboratory efficiency and track overall progress toward objectives—after all, the time to course correct is not well after the finite resources have already been spent.

While R&D spending is projected to increase this year, productivity gains won't come from investment in new people and instrumentation alone. Investment in smarter infrastructure is just as—if not more—important if the industry is ascending up the productivity curve. The paperless laboratory isn't just a concept, it's a proxy for a highly efficient, R&D management system that features full transparency and delivers true agility. And at the center of this management system is the enterprise-level LIMS, enabling organizations to continuously search for productivity improvements, automating those steps than can be moved away from manual or paper-based methods and integrating the laboratory with the enterprise and beyond. Allowing the laboratory to be fully integrated with the rest of the organization sets up a scenario in which management can count on the laboratory as a contributor to its KBM dashboard, investors can count on the promises of that organization and, ultimately, the consumer can count on delivery of the new drugs. •

Take Your Lab Informatics to Another Level With SampleManager LIMS

SampleManager LIMS puts decision-making where it belongs – in the hands of users who can make logical choices about workflow, instrument integration and data reporting for management metrics and regulatory requirements. New workflow capabilities in SampleManager LIMS allow lab managers to easily model their processes in the LIMS – so that as your laboratory's needs evolve, workflows can be modified to change with them.

SampleManager LIMS delivers:

- Configurable workflow and extended lifecycle features
- Simplified sample login and user-friendly search syntax
- Complete control over methods and SOPs with Lab Execution System (LES)
- Raw data storage and retrieval with Scientific Data Management System (SDMS)
- Enterprise-level Instrument Integration with Integration Manager

For more information about the benefits of SampleManager LIMS, please visit www.thermoscientific.com/SM11 or email us at marketing.informatics@thermofisher.com

Thermo Scientific Integrated Informatics
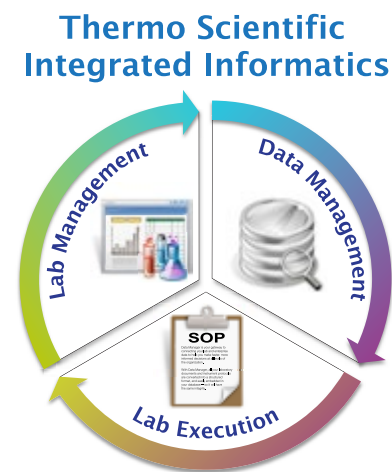
Thermo Scientific Lab Execution System Helps Scientists Go Paperless

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.

The Pharmaceutical Manufacturing Imperative: **Transform Now**

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

By Kim Shah, Thermo Fisher Scientific
As seen in *Pharmaceutical Manufacturing Magazine*

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 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 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.

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. ●

The biggest challenges many elite enterprises face are actually external forces completely out of their control, from geopolitical and economic macro trends to global threats to health and the environment. This lack of control creates a tumultuous global business climate that conspires to unravel even the most well-thought-out strategic plans. Businesses can no longer adopt a wait-and-see approach. To have any chance of sustained success, today's enterprises must be more agile and aggressive than ever.

10

Using Smart Instruments and Infrastructure to **Improve Data Reliability**

By Nicole Keppy and David Joyce, Thermo Fisher Scientific

As seen in *Drug Discovery & Development*

Safe pharmaceuticals may be the end goal of pharmaceutical QA/QC laboratories, but reliable, accurate and accessible data is what makes that goal possible. When data isn't collected and organized well, labs become inaccurate and inefficient, which can result in delays – and even product recalls. These errors quickly become lost revenue through reduced productivity and time-consuming rework.

Errors in laboratory data fall into two categories: the first, data collection, encompasses all errors made at the instrument level. This includes improperly calibrated or misused instruments, user error and problems with sample collection or preparation. The second category is information management, which includes how the collected data is transmitted, stored, accessed and analyzed.

Ensuring data integrity by reducing the potential for error in both these categories is one of the most critical challenges that QA/QC laboratories face. Successfully meeting this challenge requires two things: smart instruments and a smart laboratory infrastructure. The cornerstone of a smart lab infrastructure is a Laboratory Information Management System (LIMS), which can collect and manage raw instrument data from a series of integrated smart instruments in the lab. Every lab instrument – from simple scales to complex spectroscopic and chromatographic instruments – can be integrated into the LIMS (also known as a Scientific Data Management System, or SDMS), ensuring that data is easily, reliably and efficiently collected.

Just as business innovation is facilitated by a well-organized, collaborative team, reliable QA/QC is the product of seamless integration between laboratory instruments and software. The end result is a highly-automated paperless laboratory where all instrument data is accessible enterprise-wide in real-time, increasing efficiency and ensuring reliable QA/QC data. To create this environment, QA/QC lab managers need to focus on two things: data collection and information management.

Data Collection

The first step in creating the paperless lab is to select the right instruments – not only do they have to be appropriate for the application, but they also must be able to interface with a LIMS. Most common instruments for pharmaceutical QA/QC labs, such as UV-visible spectrophotometer, have many different variants that are each appropriate for a different application. For at-line measurements using a UV-visible spectrophotometer, an instrument equipped with a sipper module is the best choice. Biopharmaceutical samples, however, are best analyzed using a double-beam instrument equipped with a thermal accessory and xenon lamp. Regardless of the application, it's critical that the instrument has the capability to interface with a LIMS.

Laboratory managers must also decide the appropriate time interval for performance verifications of smart instruments – their smart technology does not exempt them from the need for maintenance to ensure that they remain on specification. Lab administrators must make this judgment based on the level of risk acceptable for the lab. The cost and frequency of maintenance is indirectly proportional to the possibility for instrument error, and each lab must decide the appropriate balance of these two factors.

In addition to performance verification, many laboratory instruments and accessories also require periodic alignment or calibration to perform accurate analysis. This is another facet of laboratory management that can be made more efficient using a LIMS – automating these vital procedures and executing them on a pre-defined schedule saves time, keeps labs up to specification and helps ensure regulatory compliance. Additionally, processes defined for one smart instrument, such as a spectroscopy system, can be easily applied to other instruments in the lab via the LIMS.

Information Management

In addition to being properly collected, the data from laboratory instruments and systems must also be properly analyzed and managed. This is best done using a combination of software that starts at the instrument level. The GRAMS Suite of software, for example, is used by many QA/QC labs to automate and integrate data collection from multiple spectroscopy systems and other lab instruments. Automating this data integration not only speeds up the process but also significantly reduces the possibility of human error by eliminating manual data collection. Many software suites – including GRAMS – are instrument agnostic, which minimizes training expenses by requiring technicians to only learn one software package.

Despite their high level of automation, many of today's software-enabled instruments still require human operation – and are therefore still subject to human error. Fortunately, software solutions exist to help lab managers
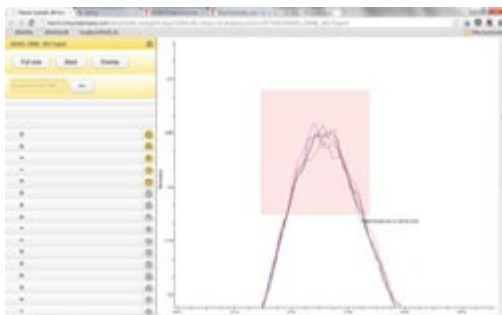
reduce the possibility of user error. Labs that use Thermo Fisher INSIGHT 2 software, for example, can custom configure their spectrophotometers to better serve the specific applications of their instruments. Used in conjunction with Customized User Environment (CUE) software, the spectrophotometer can guide the user through a step-by-step process to ensure proper operation. All data collected can be easily audited by an administrator, as well as formatted for use by customers and/or other systems further downstream.

When smart instruments and smart infrastructure work together, laboratories can reach an unprecedented level of connectivity, reliability and efficiency. Labs that integrate their instruments with LIMS, GRAMS and SDMS software also benefit from a data "safety-net" that reaches from loading bay to final shipment and ensures the reliability of accessibility of their data – not only across labs, but across continents. Critical lab data can be easily accessed by anyone within the enterprise using desktop, mobile and web applications. Perhaps most importantly, automated smart laboratories reduce the time employees waste on routine tasks, freeing up human capital for more valuable and productive work. ●

For more information about Thermo Scientific Integrated Informatics solutions for the pharmaceutical industry, visit our **Pharmaceutical Data Management** website, visit **www.thermoscientific.com/SM11** or contact us at **marketing.informatics@thermofisher.com**

The Case for User-Friendly Informatics in the **Pharmaceutical QA/QC Lab**

By Trish Meek, Thermo Fisher Scientific

As seen in *European Pharmaceutical Review*

It's hard to believe but today, lab software productivity is less about raw computing power and more about user-friendliness and integration. As Moore's Law predicted, our computers can indeed process orders of magnitude more today than even a decade ago. But putting more transistors on a chip isn't all that's making modern lab workers more productive: new business models, system architectures and software delivery models play major roles too. Cloud computing and infrastructure-as-a-service (IaaS) in particular have lowered the costs of accessing computing power so much so that today it's more about the idea, not the infrastructure to operationalize it.

All the computing power in the world isn't useful if the software designed to access it is poorly designed. And we're all much more discerning about user interfaces and usability: we expect our laboratory software to behave as intuitively as our smartphones. After all, laboratory employees are unlikely to be preoccupied with lines of codes and processors – they're focused more on how easy the software is to use.

Intuitive software is useful software, and users will require little encouragement to make it central to their daily regimen. Equally important, well-designed software is a stabilizing constant in a workplace that is increasingly marked by turnover and change. Staff may leave and projects may transition, but an informatics system never loses track – from workflows to SOPs, it helps new staff quickly adapt and ensures that all people and processes are achieving maximum productivity at all times.

Now begins our conversation about how this wish for more user-friendly software can find its way to the pharmaceutical QA/QC lab and what role today's integrated informatics solutions can play to help move this process along. So what should an informatics system offer its users in a pharma QA/QC setting? First, it is important that we differentiate the system users and how the software can provide the most value. The first group is the scientists and the technicians. These users are documenting their day-to-day activities. At the very least, lab informatics software should then walk these users through common tasks and automate their SOPs; the ability to record, transcribe and manage all data digitally; prevent them or warn them about instruments requiring system maintenance or calibration and expired solutions or reagents; and user-friendly functionality for reporting data.

The second group is the lab managers and directors who need to manage the day to day operations of the laboratory and make it run as efficiently as possible. For them, the first and perhaps most critical step is that this information is captured in the system. The system needs to ensure that SOPs and regulations are followed ensuring good scientific process and valid results. Once the process is executed and the data captured, they need sophisticated data analytics to monitor data trends and stop nonconformance before it occurs.

Intuitive software is also integrated software. Many laboratories today operate with disparate systems that could – but don't – share interrelated data that if combined would reduce complexity, workload and, at times, frustration. The ability to network systems is critically important to modern labs – silos are not conducive to productivity.

An integrated informatics system eliminates silos, combining the complementary capabilities of a Laboratory Information Management System (LIMS), Scientific Data Management System (SDMS), Laboratory Execution System (LES) and an Electronic Laboratory Notebook (ELN). It's not enough to have each of these systems – they must be integrated and the communication among them must be rationalized and automated. Labs that manually share data between systems are not only sacrificing productivity, they are introducing risk.

The single-system requirement leaves only two real options: either buy the entire system from a single vendor or ensure that all systems can share data via digital interfaces or utilizing integration tools that can translate and communicate data. The system must enable bidirectional data flow, including the ability to acquire and assimilate data directly from all laboratory instruments, regardless of vendor or format. This means that data must be assimilated from the most complex laboratory instruments, like mass spectrometers or chromatographs, as well as basic lab essentials like pH meters, balances and scales.

While productivity has always been important to pharma QA/QC labs, greater complexity and more onerous regulation is sharpening the focus on productivity-enabling systems and tools. An often-cited example is large molecule drug production, where complex production processes and evolving regulatory oversight are intensely data dependent. Large molecules can be more difficult to characterize during production, and this requires greater vigilance and reporting. The environment is significantly more dynamic, so too must be the approaches to QA/QC.

It would be impossible to manage today's dynamic production environment with data in silos. The data must be integrated and it must be actionable at all times. Consider Quality by Design (QbD) principles introduced by the FDA in 2004. How can a manufacturer monitor quality at every stage of the production process if that data isn't readily accessible and easy to manage? The answer is that they cannot, and this means that an integrated informatics system, combining a LIMS, SDMS, LES/ELN functionality, as well as full integration capabilities with the full complement of lab equipment and enterprise systems, isn't a luxury, it's a necessity.

The key to highly functioning and dynamic QA/QC is a system that is designed for how today's laboratory staff work. We can now be fairly certain that the necessary computing power will be there, but not all software is created alike. It must have an interface that adapts to users, end-to-end automation that mitigates risk and

integration that enables a more comprehensive approach to production quality and compliance.

Intuitive software is both useful and integrated. Seems simple, but yet many manufacturers still struggle with interfaces that neither match how they work nor pull in data from all the systems on which they rely. By focusing on the users, making the system truly friendly to the way QA/QC is done today, integrated informatics systems can and should be drivers of greater productivity even as production and regulatory environments become more challenging and complex. •

Additional **Resources**

Technical Bulletins

Handy Web Links

Customer Case Study:

Top 10 Pharmaceutical Company
Improves Laboratory Productivity

Employing thousands of people worldwide, this top ten 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 company's 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 twelve 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. •

ThermoFisher
S C I E N T I F I C

Thermo Fisher Scientific has been providing state-of-the-art and enterprise level Informatics solutions for more than 30 years. We are proud to count amongst our portfolio some of the largest global organizations across every industry, including the broadest range of complex customer requirements related to integrated, enterprise-level informatics solutions. Our comprehensive Informatics solutions are designed to deliver full laboratory functionality for method execution, laboratory and data management on one proven platform – LIMS, LES, SDMS, in addition to full integration with CDS and other laboratory instrumentation.

As an organization, Thermo Fisher Scientific is committed to providing comprehensive enterprise-level informatics solutions that encompass ISO 9001-certified quality soft-ware, implementation, training, and ongoing technical support. Our Quality Management System (QMS) is registered and certified by ISO 9001 requirements, and includes all of our software development locations around the world. This ISO registration covers our Quality Management System for the design, development, sales, implementation and support of all our computer based laboratory information automation systems.

The global scale and comprehensiveness of the continuous ISO certification of our Quality Management System is unique in the industry. Across the full range of life sciences, from bioanalytical labs, to R&D, pharmaceutical manufacturing and QA/QC labs, Thermo Scientific Integrated Laboratory Informatics are helping our customers meet their laboratory and business goals.

For more information about Thermo Scientific Integrated Informatics solutions for the pharmaceutical industry, visit our Pharmaceutical Data Management website, visit www.thermoscientific.com/SM11 or contact us at marketing.informatics@thermofisher.com