SPECIAL REPORT



THE DRUG INDUSTRY'S VOICE FOR MANUFACTURING EXCELLENCE

INTEGRATING THE LAB WITH THE ENTERPRISE



Integrating the Lab with the Enterprise Leads to More Than Improved Efficiences – Look for a More Agile Business

contents

Linking Labs to ERP Lifts Enterprise-level Productivity p. 4 CLICK HERE	
Thermo Scientific Lab Execution System Helps Scientists Go Paperless	
Leaving Paper Behind p. 9 click here	
Are You Maximizing the Value of Your Laboratory Assets? p. 12 CLICK HERE	
About Thermo Fisher Scientific p. 16 CLICK HERE	

Introduction

Engine for Innovation: Integrated Lab Informatics

It'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.



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Linking Labs to ERP Lifts Enterprise-level Productivity

Laboratory informatics software, enterprise systems and document management tools provide Janssen-Cilag a fully integrated pharmaceutical manufacturing environment

BY KIM SHAH, DIRECTOR, BUSINESS DEVELOPMENT, THERMO FISHER SCIENTIFIC

Specializing in pain management and fungal disease, Janssen-Cilag Farmacêutica Ltda., is a research-based pharmaceutical company located in São Paulo, Brazil. Janssen-Cilag is a member of the Johnson & Johnson family of companies — the world's largest personal care and health products manufacturer with worldwide annual sales totaling \$63.7 billion. In an effort to streamline business processes, Janssen-Cilag's Global Pharmaceutical Supply Group (GPSG) Brazil recently adopted a comprehensive enterprise integration solution. As part of its quest for a state-of-the-art IT implementation, GPSG Brazil took advantage of the latest technological advancements from Thermo Scientific in its São José dos Campos laboratory complex in São Paulo.

Pharmaceutical manufacturing companies are required to control the quality of their analyses according to specific U.S. FDA guidelines, which apply to electronic format records that are created, modified, maintained, archived, retrieved or transmitted in their laboratories. These regulations are valid even for records that are not used in a submission, such as training records and SOPs. As a consequence, one of the

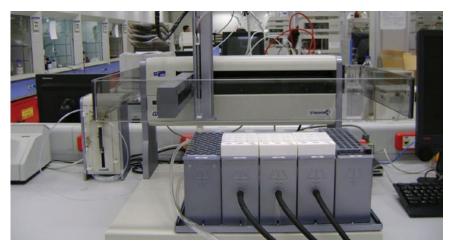


The LIMS implementation was divided into cycles reflecting the production flow starting with raw materials through the packaging cycle, the semifinished and finished products and stability.

major challenges facing GPSG Brazil was the need to use validated CDS and LIMS systems that enable compliance with standards and procedures enforced in this highly regulated environment. For the APILA unit, a coherent strategy that integrated data between the LIMS, CDS, ERP (enterprise resource planning), and Documentation system across the enterprise was a key business driver. GPSG Brazil wanted to deploy state-of-the-art technology that delivered significant flexibility to meet the specific needs of the pharmaceutical industry, including stability, supplier certification and microbiological analysis. The company has been using a Thermo Scientific LIMS solution since 1999 to store and control laboratory quality data; and CDS solution since 2001 to collect, process and ensure safety of the chromatographic data generated within its laboratories.

For GPSG Brazil, the incorporation of product quality information from the laboratory within ERP systems was a clear priority. Between the production plant and the laboratory that analyzes data from production, there is a need for regular exchange of information about guality and analysis values. Given the high sample throughput and high degree of reliability that any pharmaceutical company requires, proven systems and equipment help ensure maximum productivity and competitive advantage. To accomplish integration with its SAP R/3 corporate enterprise resource planning package, GPSG Brazil specified a Thermo Scientific LIMS to deploy in its laboratories to leverage the full benefits of a modern ERP solution. By interfacing the LIMS with its ERP, GPSG Brazil can expedite the data flow between the lab and the manufacturing functions, streamline data handling, and integrate data collection and reports.

Ronaldo Galvao, Quality Operations Director - GPSG Brazil explains, "At the time we selected Thermo Fisher as our



vendor of choice, we made the decision to standardize on a company with proven expertise in the pharmaceutical industry. We needed a validated product that provides us with sufficient flexibility to deliver all the requirements that a pharmaceutical plant has, such as data security and consistent quality data, a centralized repository for the Quality Management data, fast and accurate data storage and recovery, and all the industry functionality."

The LIMS delivered immediate improvements to the laboratory, says Galvao. "When we originally implemented the LIMS it was a culture change. The LIMS allowed automated control of testing. It optimized the procedures including the skip lot functionality which determines the frequency of microbiological testing. The stability functionality generated metrics both for performance and for productivity."

The Thermo Scientific CDS was necessary because GPSG



needed a validated system that controls quality of the analysis in line with Johnson & Johnson guidelines. "The main reason that we looked for a CDS," notes Galvao, "is for compliance with 21 CRF part 11 regulations. We need to use a validated system that demonstrates conformance with internal guidelines that 'applies to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted, under any records requirements set forth in agency regulations.' Using a CDS we can track and keep records, even if not used in submissions, such as training records and SOPs."

ON IMPLEMENTATION

The LIMS has been implemented in all of the São José dos Campos laboratories, including incoming laboratory, microbiology, R&D, Analytical Development and the chemical laboratory and is now used by about 118 Janssen-Cilag employees. The CDS solution used by 37 employees integrates 17 HPLC instruments in the chemical laboratory, enabling all the chromatographic data in the lab to be accessed via one central server. Thermo Scientific CDS offers GPSG Brazil a high degree of security and data integrity and is capable of storing the data archives and methods database for the workstations, plus it takes care of the GLP requirements. The CDS allows security accesses to be managed in line with 21 CFR part 11; the approvals and rejections function follows the rules for electronic signatures, and the raw data integrity is taken care of. The application also contains modules for traceability and auditing that are used for management accesses. The combined implementation of the two systems generated considerably high data reliability, which led the

company to upgrade to the latest versions of the systems and ensure their tight integration.

The LIMS implementation was divided into cycles reflecting the production flow starting with raw materials through the packaging cycle, the semi-finished and finished products and stability. The CDS implementation was divided into four areas: solids, liquids, validation and residue analysis, because of the different types of inputs and reports specific to each one of these areas.

POST-IMPLEMENTATION BENEFITS

A seamless integration of laboratory instruments to the LIMS and the LIMS to the ERP system by GPSG Brazil supports full regulatory compliance. For example, the U.S. Food and Drug Administration's 21 CFR Part 11 standard covers storage and integrity of computer systems data. Controlled and traceable versions of the original data are created and the whole history of any modification carried out is securely stored, thus assuring complete system validation. The CDS/ LIMS integration also supports and enables the periodical auditing of the supplier certification system utilized by the company to guarantee the quality of its raw materials. Galvao explains: "The LIMS/CDS solution achieves guick and accurate transfer of high volumes of data, increasing sample throughput and improving laboratory productivity." In the case of failed data, the company can track both the original failed result and the actual chromatograph in the system. In this way, GPSG Brazil is able to find out if there was an operator error or a serious issue that would impact the quality of the product so as to take all of the appropriate actions to protect consumers. "Since the

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LIMS provides increased traceability, the system enables easy and quick access to background data associated with batches allowing for automated batch control," adds Galvao.

CHANGE DETECTIVE

The integrated system detects changes in the production line, determining new analyses to be made. Chromatograms can be viewed during the analysis, and the workbook can be customized in order to view the analytical results. All required modifications may be performed in advance, preventing unnecessary and time-consuming rework. The configuration of a list of user profiles enables controlled access to the system as well as to certain functions, efficiently protecting data. The use of this resource allows data to be available as a function of the user's responsibility and his/her role in the laboratory. In addition, the system may incorporate a sequence and/or levels to allow access to the workbooks. The configuration of auditing actions for each user category makes it possible for researchers at GPSG Brazil to trace the modifications performed in the workbooks, record the names of the individuals who performed a given action, determine when it was performed and what was modified. Even if the network fails, data are safe since protection mechanisms ensure the workbooks' integrity.

The implementation has enabled GPSG Brazil researchers to view information that was previously only available in data reports. As a result, delivery of results has been accelerated since fewer steps are required within the analysis process. Further fundamental functions are also offered such as the ability to withhold and return acquisition queues, full-



GPSG Brazil's LIMS implementation allowed automated control of testing. It also optimized the procedures including the skip lot functionality which determines the frequency of microbiological testing.

screen chromatogram expansion and baseline editing defects correction. Additionally, the acquisition date is displayed on the chromatogram's screen. This precludes an analysis sequence from being saved over another one, thus ensuring the integrity of the original data. "The overall integration of our connected informatics solutions provides a seamless and secure quality environment at GPSG Brazil," says Galvao.

TO THE FUTURE, NOW

The LIMS is integrated with both the enterprise via the SAP system and the Janssen-Cilag proprietary documentation

system. GPSG Brazil is also looking for enhanced integration of its chromatography data system, aligned with a company upgrade of Thermo Scientific CDS intending to link the CDS to SAP in addition to the existing integration with the LIMS. When the system migrates from the data servers to the 247 controller, GPSG Brazil will include the 3D spectral analysis module.

"In addition," says Galvao, "the LIMS has the potential for integration with other business systems. With a longstanding LIMS in place, we are confident that we can meet any future challenges. And our CDS is flexible to deal with changes in our procedures and guidelines. If the data reliability is already high with our Atlas 2000 system, whose task is to collect process and ensure the safety of chromatographic data, then this reliability will be enhanced further with the new version."

The connected integration solutions deployed in its multiple laboratories help GPSG Brazil to guarantee tight quality control throughout its business processes in compliance with strict regulatory controls — from material delivery, through production, packaging and distribution, to worldwide customer service. For GPSG Brazil, these systems are capable of storing data and methods in a safe and consistent way, thereby ensuring ultimate data security and integrity as well as effective processing distribution. As a consequence, the company is able to easily, timely and effectively access data in order to make better informed decisions in a faster and more reliable fashion. Galvao says, "With Thermo Scientific CONNECTS, GPSG Brazil is supported as processes change and business needs evolve."

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.

Leaving Paper Behind

BY TRISH MEEK, DIRECTOR OF PRODUCT STRATEGY, THERMO FISHER SCIENTIFIC, PHILADELPHIA, PA.

After another year of flat spending in 2013, global investment in R&D is 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 is forecast to increase modestly (1.5%), another promising sign, but 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.

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% [last year], 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



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.

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 enterprisewide 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 guality, not only in the laboratory and internally, but across distributed organizations. This, in turn, argues for state-of-theart 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 enterpriselevel 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 improved 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

A 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 reguests 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.

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.



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%.

ANNUAL SAVINGS



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.

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.

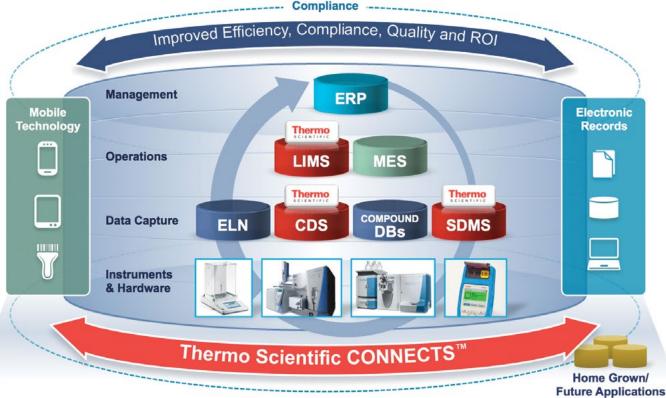
The decision to implement a paperless lab should be based on the value it will bring, not just to the lab, but to the enterprise as a whole. For example, a paperless system facilitates collaboration across multiple sites through a centralized platform accessed via the Web. A paperless system can also 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 "freeware" 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, wellestablished 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 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 Fisher Scientific has been providing state-ofthe-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

Additional Resources

FOR MORE INFORMATION CLICK ON THE LINKS BELOW

CLICK HERE 😵	Thermo Scientific SampleManager LIMS with Lab Execution System
CLICK HERE 😵	Thermo Scientific SampleManager 11 LIMS
CLICK HERE 😻	Thermo Scientific SampleManager LIMS with Chromeleon CDS Link
CLICK HERE 💙	Thermo Scientific SampleManager LIMS, with Configurable Data Flow-Through

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 software, 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, please visit <u>www.thermoscientific.com/</u> <u>SM11</u> or email us at <u>marketing.informatics@thermofisher.com</u>.