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Thermo Scientific Integrated Informatics and Chromatography Software Solutions for the

Pharma & Biopharma Industries

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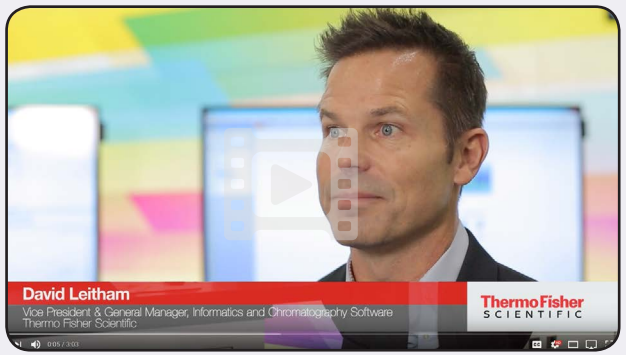
Introduction

It's no secret that laboratory operations play a central, fundamental role in the success of any 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 stakeholders across the organization.

To help our pharmaceutical customers manage the most complex data management challenges, we're introducing the latest evolution of our integrated laboratory software platform – Thermo Scientific Integrated Informatics, the center of lab data acquisition, management and storage. Integrated Informatics represents an essential development in laboratory software designed to help lab managers and scientists move more efficiently through their workflow – from 'sample to knowledge' – delivering data integrity, compliance, productivity and enterprise-wide data sharing.

The foundation of Thermo Scientific Integrated Informatics is the SampleManager platform – with comprehensive lab and data management functionality for laboratory information management (LIMS), Chromeleon chromatography data system (CDS), scientific data management (SDMS) and procedural ELN/lab and method execution. This comprehensive informatics solution is further supported by mobile and web access. With Integrated Informatics, lab managers can consolidate their lab software investments, saving time and money in software licenses, implementation costs and ongoing service contracts.

The following pages reveal how highly integrated lab information technologies from Thermo Fisher Scientific can help drive innovation and ensure that your laboratory data is generated, archived and delivered with compliance in mind. You can rely on Thermo Scientific Integrated Informatics – a complete package of integrated software solutions – to help you unlock the value of your data and leverage that data for business optimization.



▲ **The Age of Informatics In and Out of the Lab**
David Leitham, Vice President & General Manager
Informatics and Chromatograpphy Software, Thermo Fisher Scientific

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Pharma Manufacturing and QA/QC Labs

Data Integrity: How Does Your Lab Stand Up to Increased Scrutiny?

By Darren Barrington-Light, Thermo Fisher Scientific
As seen in *Pharma Technology*

New guidance in 2016 under the auspices of the U.S. Food & Drug Administration (FDA), the European Medicines Agency (EMA) and the Pharmaceutical Inspection Co-operation Scheme (PIC/S) will go a long way toward ensuring data integrity throughout the processes of testing, manufacturing, packaging, distributing and monitoring medicines. Ultimately, the goal is to encourage current good manufacturing processes (CGMP) globally.

In recent years, the industry has fixated squarely on the word "current." It's not enough for pharmaceutical companies to understand basic data integrity principles: to avoid deficiencies and possible penalties they must embrace the most current technologies available today. Otherwise, it will be increasingly difficult to comply with enhanced data integrity requirements and prevent lapses.

Below is a review of those seven key areas and current technologies the most up-to-date industry players are deploying.

1. **Validation documentation –** In the U.S., the FDA recommends that companies implement appropriate controls to manage risks associated with each element of a system, including software, hardware, personnel and documentation. Validation of chromatography systems, for example, generally includes installation qualification (IQ) and operational qualification (OQ) of instruments and software as well as ongoing performance qualification (PQ).

   As data becomes increasingly complex, however, labs are finding it much easier to manage validation using laboratory information management systems (LIMS) and chromatography data systems (CDS). While software on its own cannot help labs achieve full compliance, together a LIMS and CDS can provide a key piece of the validation picture that regulatory bodies expect pharmaceutical companies will have in place. A CDS provides certificates of software validation and supports documentation for on-site validation, offering fully automated software IQ and OQ and semi-automated templates for instrument IQ and OQ/PQ. Meanwhile, the LIMS will have its own validation toolkit, controlling user training records and providing electronic standard operating procedure control.

2. **Data transfer between systems –** Data must be readable in its original form throughout the data lifecycle. This means that data must always be accessible and readable, even when software solutions are retired. A CDS can help here by

As data becomes more complex, pharmaceutical companies must constantly upgrade their systems and processes to ensure data integrity. To ensure that labs are current and in line with good data governance practices, they must achieve excellence in seven core areas: Validation Documentation; Data Transfer between Systems; Audit Trails; Data Capture/Entry; Review of Electronic Data; Storage, Archival and Disposal of Electronic Data; and System Security.

ensuring all data transferred is complete, meaning that all relevant raw data, corresponding methods, sequence data, report formats and audit trails are included in the transfer. In addition, when a CDS and LIMS are integrated, labs can create multiple lifecycles to separately manage both compliant and noncompliant processes within the same system.

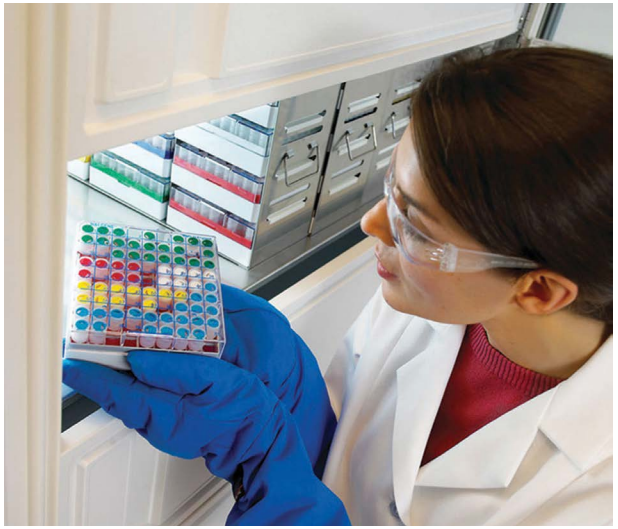
Data management software can also play a critical role in long-term data archiving and storage in vendor-neutral formats. When data are generated from multiple instruments across multiple labs, it becomes difficult to search, share and access that data. Without access, labs risk duplicating efforts or losing valuable time in translation. A good data software management tool eliminates the need for manual and paper-based data handling, enabling operators to integrate instruments across the lab and centralize data capture. Unlike simple data backup and archiving products, data manager software facilitates collaboration by allowing colleagues to share data for mining, comparison and visualization without the need to restore the data to the original instrument workstation or install the instrument software separately on every computer.

3. **Audit trails –** New guidelines call for secure, computer-generated, time-stamped electronic records that allow for reconstruction of the "who, what, when and why." Electronic record-keeping systems, which include audit trials, can fulfill these CGMP requirements. For example, the Chromeleon CDS contemporaneously tracks and automatically generates data audit trails by capturing all changes made to data objects that are done within the application. If, and only if, the system administrator allows modifications to be made, then the data audit trail tracks changes and retains details for all versions, providing users with a means to quickly and easily compare all changes, deletions and additions. When needed, users can also reconstruct and revert back to prior versions.

4. **Data capture/entry –** There are two primary types of data capture: static and dynamic. Static indicates a fixed-data document, such as a paper record or electronic image. Electronic records from certain lab instruments are dynamic, meaning the record format allows interaction between the user and record content. A CDS will capture data from instruments at the source, providing bi-directional communication and full audit trailing.

Labs may elect to implement a LIMS in addition to their CDS to enable finer control over samples and capture more granular data for compliance. And, to meet regulatory requirements labs must also capture data from non-chromatographic instruments. By bringing in data management software capability within a CDS and LIMS, labs can have a solution for every instrument – from balances and pH measures to inductively coupled plasma mass spectrometry (ICP-MS).

5. **Review of electronic data –** The FDA recommends that audit trails are reviewed with each record and before final approval of the record. In addition, the FDA recommends routine scheduled audit trail review based on the complexity of the system and its intended use, for which a CDS is instrumental. Within the CDS, users can review any instrument's daily audit trail, search and filter for events, and add audits to reports for review.



Labs that rely on an advanced LIMS can also view any data at any time: SampleManager offers built-in scientific data management system (SDMS) functionality for this very purpose. It uses rapidly configured, sophisticated paperless review and approval procedures and has advanced data mining tools to review chromatography and mass spectrometry data, giving labs a complete overview and showing when processes are drifting toward nonconformance.

6. **Storage, archival and disposal of electronic data –** All data generated to satisfy a CGMP requirement become a CGMP record and must be documented at time of performance to create a record in compliance. Chromatograms, for example, should be sent to long-term storage upon completion. Saving electronic data automatically into temporary memory does not meet documentation or retention requirements. With a LIMS, however, labs can automatically save records after each separate entry to meet CGMP documentation practices. Labs can also capture simple data, such as weights from a balance or readings from a pH meter, directly in the LIMS record.

7. **System security –** Changes to records should only be made by authorized personnel. The FDA recommends restricting the ability to alter specifications or methods to authorized individuals with access privileges for each CGMP computer system in use. While lab managers may have reservations about entrusting software with system security, using a LIMS and CDS actually gives labs the ability to control what users can do and access, monitoring users' instruments and runs through e-signatures, e-reports, auditing and versioning. E-signatures are linked to electronic records, ensuring the signature cannot be excised, copied or otherwise transferred, prohibiting the falsification of electronic records.

Conclusion

As data becomes more complex, pharmaceutical companies must constantly upgrade their systems and processes to ensure data integrity. They must endeavor to always be current. While software and related technologies are just part of a company's compliance strategy, they are critically important. Ensuring data integrity isn't a one-and-done exercise; there are many boxes to check, including those described in the seven areas above. Meeting increasingly more complex CGMP requirements around the world won't get any easier, but thanks to technologies such as LIMS and CDS, especially when tightly integrated, the road ahead can be easier than many think.

Thermo Scientific Lab Execution System/Procedural ELN 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.

▲ **Thermo Scientific Lab Execution System/Procedural ELN Helps Scientists Go Paperless**
Trish Meek, Director of Product Strategy, Thermo Fisher Scientific

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Contract Labs

Vaping Goes Mainstream: Pioneering GMP in a Burgeoning Industry

By Leslie Henderson, Broughton Laboratories and Darren Barrington-Light, Thermo Fisher Scientific
As seen in *R&D Magazine*

Manufacturers in the relatively new, unregulated, niche electronic cigarette industry have had little need for analytical testing, until recently. As vaping has become mainstream, the market for e-cigarettes has come under increased scrutiny. In May of 2016, the EU updated its Tobacco Products Directive (TPD), which governs the manufacturing and selling of tobacco products, to include e-cigarettes. The U.S. Food and Drug Administration (FDA) has also stepped in; this past August, it authorized the marketing of new tobacco products through the pre-market tobacco application (PMTA), requiring manufacturers to register and rigorously test new products. As regulations continue to evolve, the industry is looking to advanced instrumentation and analytical testing to comply with new quality standards.

Meeting New Emissions Requirements

An electronic cigarette, also known as an e-cigarette, operates by heating a nicotine-containing solution (e-liquid) to create a vapor the user inhales. As of this date, the components in the e-liquid are unregulated, putting users at greater risk of consuming potentially toxic compounds. There is also a risk of trace metals coming from the heating unit of the device. In addition, vaping and e-cigarette solutions may contain as much as two to three times more nicotine than indicated on the product label.

Careful control of input materials during e-liquid manufacturing ensures that only ingredients of the highest purity are used, verifying that consumers get what they paid for as well as safeguarding them from potential health risks. To protect consumers,

By choosing a CDS that supports full integration of the MS detector, it is easy to combine all data and eliminate manual, multi-step processes for data entry and analysis. The integrated system reduces user errors by simplifying workflows, keeping labs running during outages, and supporting documentation and validation to ensure data integrity and compliance for the whole laboratory.

new guidelines dictate that e-cigarette manufacturers must list all ingredients contained in, and emissions resulting from, the use of their products, along with information on the nicotine doses and uptake when consumed under normal or reasonably foreseeable conditions.

To meet upcoming regulations, including the first new nicotine dose assessment and emissions testing requirements, manufacturers can now choose from a range of techniques for collecting and analyzing nicotine and other potentially undesirable compounds. That's where a company such as Broughton Laboratories comes into the picture.

As a privately-owned global GMP lab, Broughton has been serving the e-cigarette and vaping industry since 2010, using robust testing and sampling methods, along with advanced instrumentation, to determine, extract and analyze nicotine dosage and uptake with a high degree of specification and quality assurance. A history of testing e-cigarettes for current manufacturers has made it possible for Broughton to anticipate upcoming market testing needs and more reliably respond to potential regulatory changes, with best practice lab and analytical techniques, as they occur.

As a whole, to comply with new requirements, manufacturer-based e-cigarette testing labs across the industry are producing more emissions data to demonstrate the integrity of their products. While currently much of this data is being generated with limited oversight or method validation, over time the industry will apply its own good manufacturing practice (GMP) standards for improved quality control. Regulations driven by health concerns are also likely to put more pressure on e-cigarette manufacturers to disclose their product make-up and to develop new products in line with these regulations. Consequences of non-compliance could lead to an inability to sell to this growing market of consumers.

We're already starting to see some groups take on the role of standard-bearers in this movement. In the UK, a working group of the Medicines and Healthcare products Regulatory Agency (MHRA) has published a series of draft guidance statements referring to nicotine dose assessment and emissions testing requirements under new TPD guidelines. We'll also likely see manufacturers in the U.S. re-evaluate their methods as the FDA product-approval process phases in over the next three years.

More Flavors, More Complexity

The regulatory landscape is only one factor changing how e-cigarettes are produced and tested. E-liquids used for vaping are usually made up from solutions containing propylene glycol (PG) and vegetable glycerol (VG), to which nicotine and other flavorings are added. The issue is that PG and VG can break down at high temperatures, generating low molecular weight carbonyl compounds with established toxic properties (e.g., formaldehyde, acetaldehyde and acrolein).

In the last year, we've seen a relatively simple assortment of basic e-cigarette flavors expand into a wide variety of complex flavor concentrates. While the ability to create

unlimited offerings for consumers is a marketer's dream, it creates new challenges back in the lab. Where an end product was historically made up of four to five different chemicals, the number of chemicals in any given product may now have doubled or even tripled. The ability to continuously satisfy and surprise the consumer requires an ever-increasing mix of ingredients in the chemical cocktail.

Due to the increasing range, diversity and complexity of e-liquids in the globalized e-cigarette market, we've had to become more innovative from a chromatography and compound detection standpoint to generate data that meets the rigid requirements of regulatory authorities. To ensure accurate and precise results, a scientifically sound approach must be taken, and the more simplistic testing methodologies utilized in the past may not be rigorous enough now with the more complex and vast range of flavored products being offered, vastly increasing the number of unique chemicals that can interfere with quantification.

To remove potential interference from flavor compounds, Broughton has adopted a workflow that features liquid chromatography with mass spectrometry (LC-MS) as a highly sensitive and selective method to help eliminate interfering peaks in the carbonyls analysis. Using a combination of chromatography and advanced detection systems, the lab now integrates, quantifies, verifies and reports on a total of 16 peaks. At first, the team was spending a significant amount of time manually integrating and processing the LC-MS data. That's why the lab decided to invest in an enterprise chromatography data system (CDS).

A New Workflow Gets Results

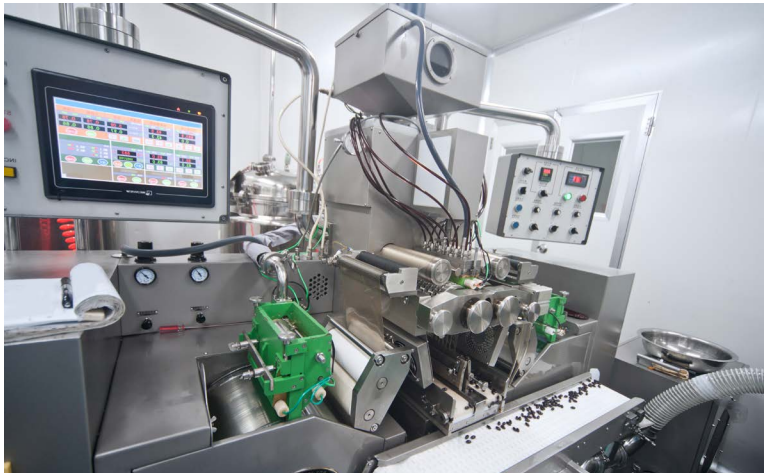
Broughton wanted to achieve higher specificity in the analysis of the e-cigarette products it was testing, and for this a chromatography data system (CDS) became a critical necessity in its labs. Broughton selected Thermo Fisher Scientific's Chromeleon 7.2 CDS to support its existing ultraviolet (UV) and MS instrumentation, enabling it to run tests in both modes simultaneously. Having multiple systems controlled by a single software solution simplified workflows and allowed Broughton to set even higher quality standards for its analysis.

Using a CDS also proved invaluable for helping Broughton keep up with the growing demands placed on its labs. Under TPD, e-cigarette manufacturers had until November of 2016 to have their products tested to comply with new quality measures. As Broughton's manufacturing partners prepared to meet the deadline in the second half of 2016, its e-cigarette testing workload increased significantly. As a result, Broughton was handling a huge surge in data.

The lab grew its team to keep up with the physical aspect of the data prep, but from an analysis perspective Broughton had no need to add headcount. Instead, it could rely on efficiencies in the CDS software to handle the increased demand. Over a few short weeks, using the new workflows developed with the help of the lab's chromatography partners at Thermo Fisher, Broughton doubled its data-processing throughput.

Preparing for Future Regulations

Current legislation regulates e-cigarettes as a consumer product buyers can purchase without a prescription. However, at least one device on the market has been approved as a nicotine replacement product (NRP), and other devices are now applying for the classification. To promote the use of e-cigarettes as a tobacco-cessation product, manufacturers will need to provide more detailed documentation to enable doctors to prescribe them for this purpose.



While we don't expect the revenue from e-cigarettes being sold as NRPs will surpass their sales as a consumer good, we do expect the industry to continue to move in this direction. Manufactured with high standards, it may not take much additional effort for a product to cross the line from consumer device to medicinal device. However, for manufacturers looking to market e-cigarettes as medical products, a CDS will be essential for achieving and documenting data integrity to the extent required to meet compliance standards, especially for regulated products used as a medical device.

As a pharmaceutical testing lab, Broughton has been working with the FDA in a highly-regulated industry for the past ten years, and is already implementing testing methods that are far more rigorous than current guidelines require. Where other tests provide a "not present" result on anything less than 100 parts per million, Broughton's tests report anything down to one part per million. Embracing rigorous testing and GMP ensures an extremely high level of quality in the tested e-cigarettes; consumers can be more confident in what they're buying. Furthermore, establishing best practices now positions Broughton to meet the increasingly stringent standards we expect to see as the industry matures.

The Power of Chromatography Combined with Mass Spectrometry

Recently, MS has been increasingly adopted for routine analysis in modern labs and production facilities, as it offers higher sensitivity and selectivity with less sample preparation giving more precise quantitative trace analyses for a wider range of samples. When combined with chromatography, MS is capable of even higher sensitivity and more effective and efficient separation and identification of components. Combining LC-UV and MS, however, can present a compliance and data integrity issue for the lab and reveal data processing issues if both UV and MS results need to be evaluated simultaneously and compliantly.

Most modern laboratories have adopted enterprise-level CDS to ensure they meet the current stringent compliance and data integrity requirements and can manage all their chromatography data under one system. However, this does not normally cover the MS instruments – this is particularly true for more advanced MS instruments (beyond single quadrupole) – leaving the GC-MS (/MS) or LC-MS (/MS) data outside of the compliant environment and the MS data disconnected from the data.

By choosing a CDS that supports full integration of the MS detector, it is easy to combine all data and eliminate manual, multi-step processes for data entry and analysis. The integrated system reduces user errors by simplifying workflows, keeping labs running during outages, and supporting documentation and validation to ensure data integrity and compliance for the whole laboratory.

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. With Thermo Fisher's integrated SampleManager platform, including LIMS, CDS and SDMS, 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.

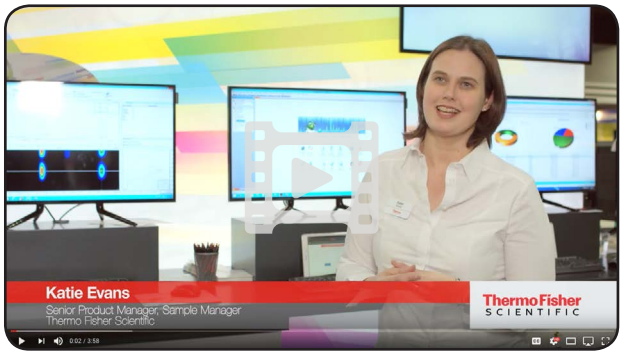
Business Benefits

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.



▲ **Leading LIMS Solution Bridges the Lab and Enterprise**
Katie Evans, Senior Product Manager, Thermo Fisher Scientific

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.

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Bioanalytical Labs
Don't Ignore Hidden Harbingers

by Matt Gruver, Thermo Fisher Scientific
As Seen in *Drug Discovery & Development*

Transforming the lab into a tightly integrated paperless environment gives users real-time access to information, automates processes and reduces manual data handling, and improves regulatory compliance and data integrity.

Those who work in preclinical and clinical labs know firsthand the rigor that's required. From a 10,000-foot view, bioanalytical labs are marvels of efficiency, especially when one considers the myriad quality and regulatory requirements that guide nearly every step.

But diving down below 10,000 feet, one can see small margins for error. Perhaps it's one of the sub-steps during assay validation. It could be something missed during sample tracking. It may be small, but that doesn't mean it is inconsequential, especially when these little problems snowball.

Operational inefficiency is analogous to seeing the forest but missing the trees – everything seems okay until it isn't. Small issues with sample prep, methods adherence and instrument sensitivity don't simply vanish. At some point, somewhere in the compound discovery and validation process, critical mass will be reached and there will be financial consequences.

Speed to market is paramount. Manufacturers can ill-afford wasted days and resources finding the root of problems they've allowed to mushroom. Failure to quickly rule out a compound, for example, isn't trivial when the costs of staying an improper course are added up. So, we argue, it's worth diving below 10,000 feet to see what's on the ground, to note the small problem signs that are easy to miss – until they become too big to ignore. Let's explore these hidden harbingers for bigger problems to come.

Poor traceability

A single laboratory may be responsible for hundreds of tests each week, and adhering to good laboratory practices (GLP) requires that labs break each test down into its component parts. This makes it much easier to defend results when technicians must painstakingly retrace steps that are often so embedded in the fabric of the lab. Combing through pages of handwritten notes, including those from colleagues, is time-consuming and often leads to inaccuracies. Yet many labs report that staff still spend a quarter of their productive time simply collecting data to defend a result.

Fortunately, laboratory information management systems (LIMS) are capable of handling more data and delivering more insight. A study director inside any drug developer can speak to this. From authorized and traceable access to instruments, methods and data, including audit trails, to maintenance, he or she must be 100 percent accountable. This is hard without a system designed for that purpose. That is what a LIMS is designed to do: everything required for traceability is continuously and purposefully organized for rapid retrieval, analysis and reporting. Nothing is hidden within a LIMS.

Measurement traceability is hard, and if your staff are finding it hard to locate data and defend it, it could be a bad sign. When all that is taking place in the background, however, labs can dramatically reduce the time, expense and aggravation associated with defensibility. Managing data, now made much easier through software, is a pathway to immediate productivity gains, putting much of the 25 percent of time devoted to defending data back where it belongs, toward identifying breakthrough compounds.

Troubling analytical trends

If an experiment is out of spec or trending in that direction, how would you know? Would it be immediately clear from the liquid chromatograph (LC) data that something was wrong? To the human eye, perhaps not. Even the most experienced lab analyst would find it difficult to discern subtle patterns and trends in LC data, especially at the scale most labs operate. And for those that can – or do – the analysis is backward-looking, perhaps weeks after a result initially went out of spec.

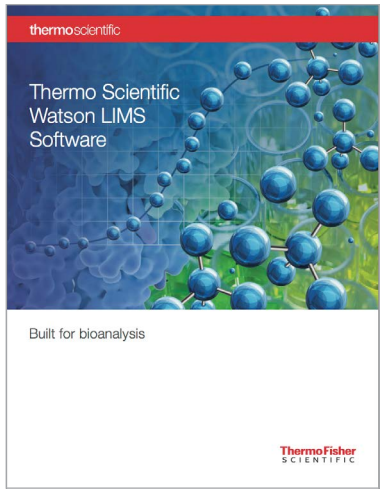
Focusing on errors after they occur is common, but far less effective than predicting and preventing errors, even small ones that seem insignificant. With QA/QC in bioanalytical labs, for example, systemic quality issues can create productivity gaps in the form of lost time and costly instrument/assay reconfiguration. In this case, allowing the problem to continue unchecked costs much more in the end than proactive monitoring as you go.

Sample mismanagement

GLP-compliant labs must track everything. This includes people, procedures, results, and, of course, samples. But tracking is not something that can be mostly or sort-of done. Labs must use rigorous methodologies and ensure user compliance, otherwise sample integrity is in doubt.

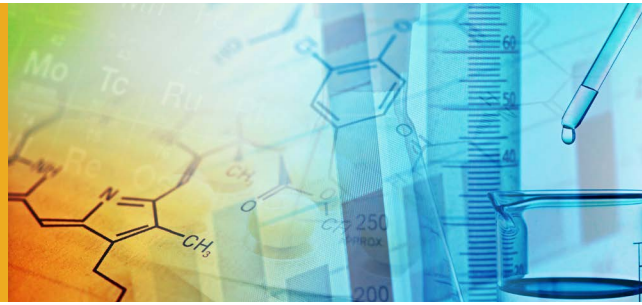
At any given moment, labs must know what's been received, where the sample is now stored, etc. And in bioanalytical labs, there are many interdependencies caused by unique experiment design that make the management of samples especially challenging. If a LIMS is not fit for this purpose, it's likely that months of customization will be required. And many homegrown systems simply cannot perform sample management reliably.

Sample management and chain of custody procedures are critical to GLP compliance, but they can be hard to enforce. Any discrepancies or missing information can disrupt an entire workflow, audit trails must be documented and even sample storage conditions must be monitored. A small problem anywhere in this process can be a big deal, making future defensibility nearly impossible and potentially derailing development.



▲ **Thermo Scientific Watson LIMS**

If there's one take-away from this article, let it be that there are indeed no small problems – everything compounds in the end. But not if you enable your LIMS to help you manage everyday problems, freeing you to focus on the next compound and the next wave of profitability for your company.



SOPs aren't standard

Inconsistent application of critical procedures in clinical and pre-clinical labs can put a company at risk with regulators and jeopardize progress toward development and commercialization. This is why standard operating procedures (SOPs) are critical to GLP compliance and other regulatory requirements.

Increasingly, electronic SOPs (ESOPs) are a lab's defense against violation of procedures. With SOPs defined electronically in a LIMS, for example, a rigid workflow exists with clearly defined technical corrective actions that ensure consistency and adherence to protocol. If these don't exist – or the paper SOPs aren't handy, clear or widely understood, it's too easy for an analyst to err and the experiment to go off track and be out of compliance. Worse, it can compound small problems and affect the entire development timetable.

Structuring how SOPs are created, distributed and tracked for productivity and compliance purposes is an important, but overlooked step. Many labs still use paper, and that puts them at a distinct disadvantage. The good news, however, is that technology has evolved to a point where managing SOPs is easier and more efficient than ever. A LIMS turns those SOPs into steps that must be undertaken, ensuring quality, consistency and accountability are built into the process.

Instrument incompatibility

Incompatibility with instruments, including issues with calibration, maintenance and other factors can compromise the entire development process. This starts with costly delays, but can soon escalate into much larger problems that impact compliance. Incompatibility isn't trivial and it cannot be fixed by clever work-arounds or temporary fixes.

Because drug development today is more decentralized than ever, incompatibility is becoming a larger issue. Lab analysis is increasingly spread across different geographies and partners, including contract research organizations. Managing development across a complex networks of instruments, SOPs and methods can be challenging, if not impossible.

LIMS are designed to expose and help overcome potential issues with instrument incompatibility. Instruments used to prepare and measure samples and interpret data must meet specific and uniform requirements. They should adhere to existing SOPs, handle high throughput, send/receive information to/from the LIMS and, equally important, be on predefined routine maintenance schedules that ensure consistency and data integrity. Where instrument incompatibility exists, so too does the opportunity for errors and development delays. If it exists, it's a problem, and labs are wise to address it using all means possible.

There are no small problems

In their haste to accelerate drug discovery and commercialization, many drug companies overlook the small problems that affect many labs. But in the bioanalytical lab setting, small problems can be magnified, even more so than in other industries. Too much is at stake. Fortunately, LIMS were designed expressly for the rigors common to pre-clinical and clinical labs. These systems are built for purpose, designed to address the demands of high quality, onerous regulation and controlled costs. If there's one take-away from this article, let it be that there are indeed no small problems – everything compounds in the end. But not if you enable your LIMS to help you manage everyday problems, freeing you to focus on the next compound and the next wave of profitability for your company.

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.

▲ **Chromeleon Enabling Seamless Data Flow from Lab to Enterprise**
Darren Barrington-Light, Product Marketing Specialist, Chromeleon CDS
Thermo Fisher Scientific

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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 (SMDS), and Laboratory Information Management Systems (LIMS).

Lab Execution System/Procedural ELN

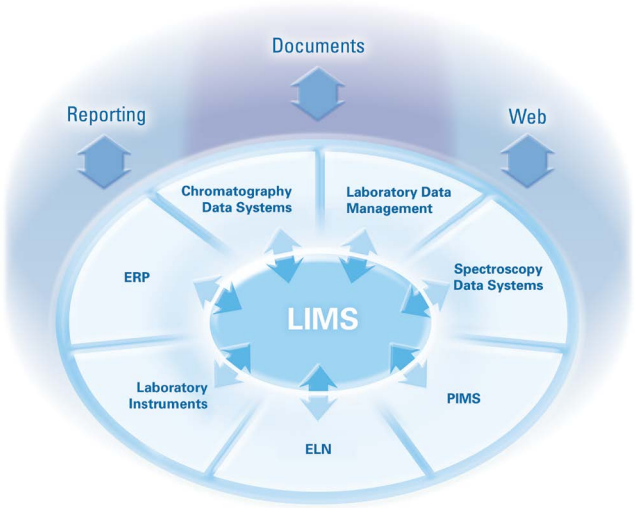
An LES/Procedural ELN has become a critical component of today's paperless lab, ensuring that quality processes are followed in the laboratory and that the methods built on QbD principles are followed in day-to-day laboratory operations. LES drives users through any laboratory procedure in a stepwise 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.

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.

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

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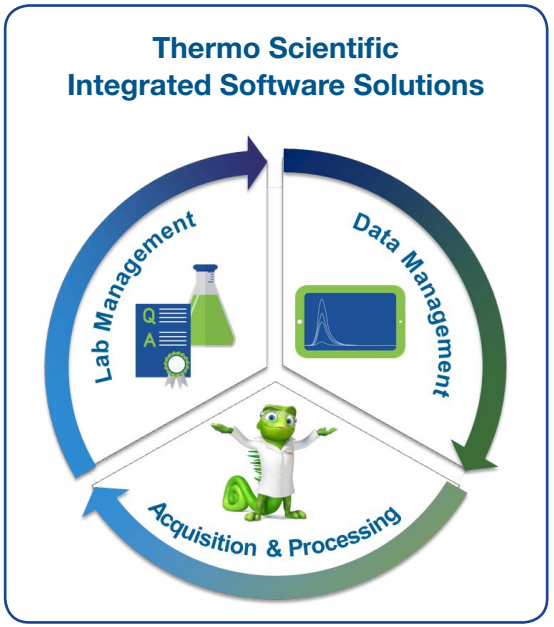
- Workflows to drive the laboratory process
- Comprehensive multi-vendor instrument support
- Centralized data management
- Advanced search and data mining with SDMS
- Monitor chromatography queue status and Instrument Health from the LIMS

With Chromeleon CDS linked to SampleManager LIMS, users have complete control of all chromatography and mass spec instruments, combining two of the most common analytical techniques into a single system. SampleManager LIMS then allows you to turn that data into actionable knowledge by providing sophisticated data processing, visualization, search and data mining capabilities.



Thermo Scientific Chromeleon CDS is a leading chromatography data system, unifying workflows for chromatography and routine quantitative MS analysis Chromeleon CDS allows you to run your analyses in an enterprise environment – from method creation to quantitation and library-based compound identification and offers industry-leading multi-vendor control, supporting over 400 different instrument modules from over 15 manufacturers. With the SampleManager LIMS and Chromeleon CDS link built onto one platform, users will have complete control of all chromatography and/or mass spec instruments, combining two of the most common analytical techniques into a single system. SampleManager LIMS then allows you to turn that data into actionable knowledge by providing sophisticated data processing visualization, search and data mining capabilities.

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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.

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). 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.

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.

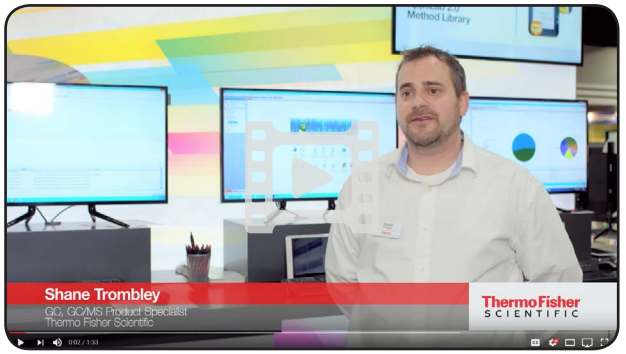
The single-system requirement leaves only two real options: either buy the entire system from a single vendor or ensure that all systems can share data via digital interfaces or utilizing integration tools that can translate and communicate data. The system must enable bidirectional data flow, including 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.



▲ **Chromeleon Combines LC, GC, MS Instrument Control as well as Method and Data Management**
Shane Trombley, Product Specialist, Thermo Fisher Scientific

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

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.

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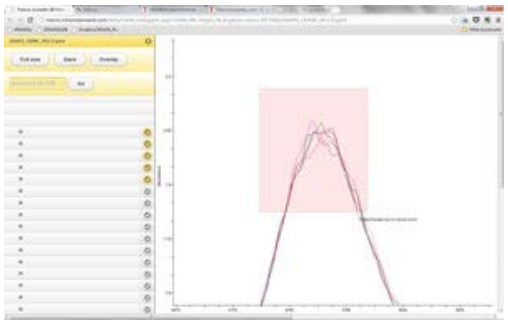
Christoph Nickel, Senior Director for Informatics and Chromatography Software, Thermo Fisher Scientific

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.

To help our pharmaceutical customers manage the most complex data management challenges, we're introducing the latest evolution of our integrated laboratory software platform – Thermo Scientific Integrated Informatics, the center of lab data acquisition, management and storage, and designed for data integrity and compliance.

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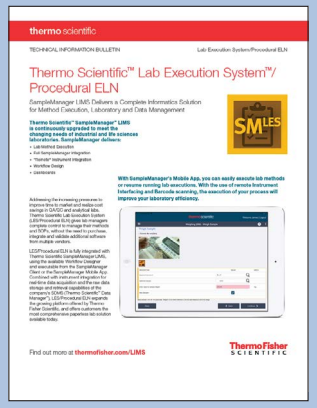
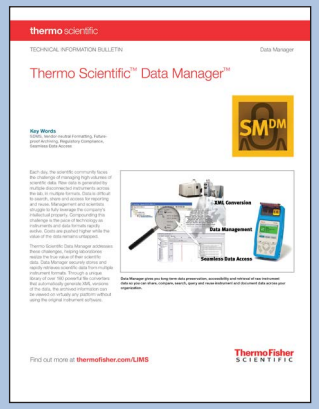
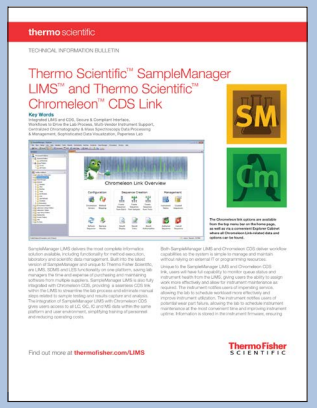
Thermo Scientific SampleManager LIMS



Thermo Scientific Lab Execution System/ Procedural ELN

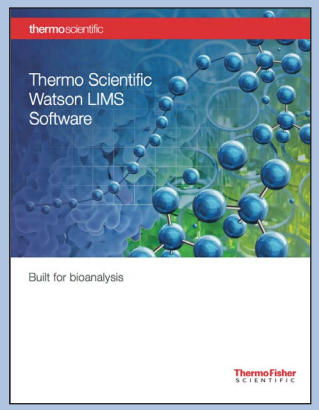


Thermo Scientific SDMS – Data Manager



Thermo Scientific SampleManager LIMS and Chromeleon CDS Link

Thermo Scientific Integration Manager



Thermo Scientific Watson LIMS

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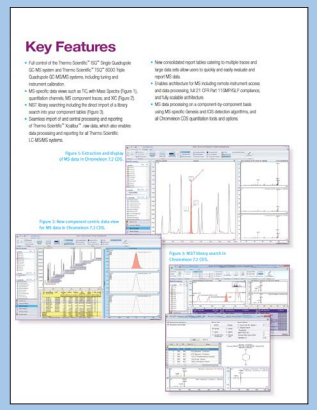
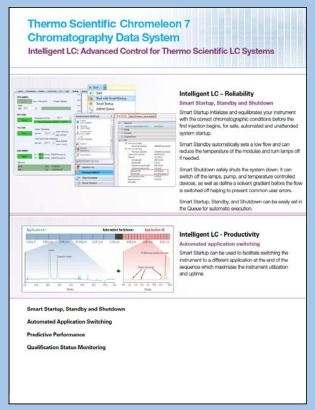
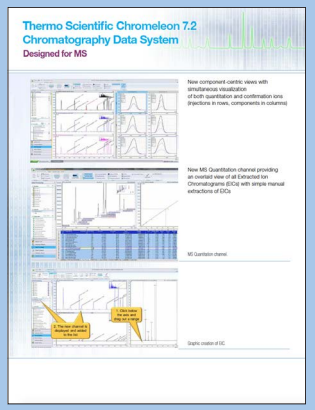


Thermo Scientific™ Chromeleon™ Chromatography Data System (CDS) Software Combining Separation (GC/IC/LC) and Mass Spectrometry (MS) in an Enterprise (client/server) Environment

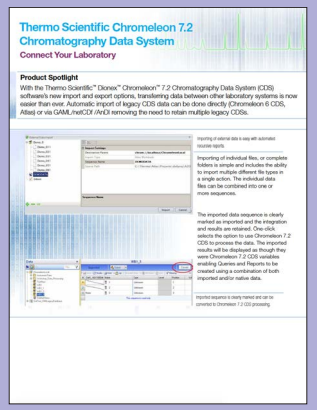


Thermo Scientific™ Chromeleon™ 7 Chromatography Data System Intelligent LC: Advanced Control for Thermo Scientific LC Systems

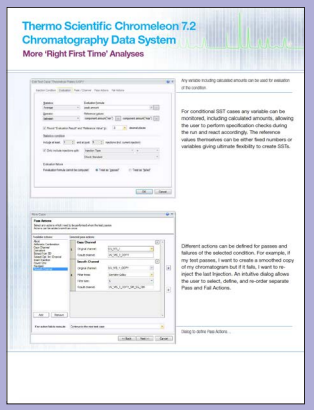


Thermo Scientific™ Chromeleon™ 7.2 Chromatography Data System Designed for Mass Spectrometry (MS) Instrument Control and Data Processing

Chromeleon CDS Specification Sheets



Thermo Scientific™ Chromeleon™ 7.2 Chromatography Data System (CDS) New Import and Export Options for Transferring CDS Data Between Multiple Systems



Thermo Scientific™ Chromeleon™ 7.2 Chromatography Data System (CDS) New Intelligent Run Control (IRC) for Complete Control Over Your Running Sequence

Chromeleon CDS Case Studies

Thermo Scientific™ Chromeleon™ CDS Reports Provide Significant Time and Cost Savings for New Zealand Pharmaceuticals Manufacturer

Thermo Scientific™ Chromeleon™ CDS Software Integrates High-Volume Contract Manufacturing Operation at Regis Technologies for Significant Efficiencies in Pharma/BioPharma Manufacturing

Sigma-Aldrich CMO Helps Customers Comply with 21 CFR Part 11 Using Thermo Scientific™ Chromeleon™ CDS Software

Chromeleon CDS Handy Web Links

Thermo Scientific AppsLab Library of Analytical Applications – Methods, eWorkflows and more

Thermo Scientific Chromeleon™ Chromatography Data System

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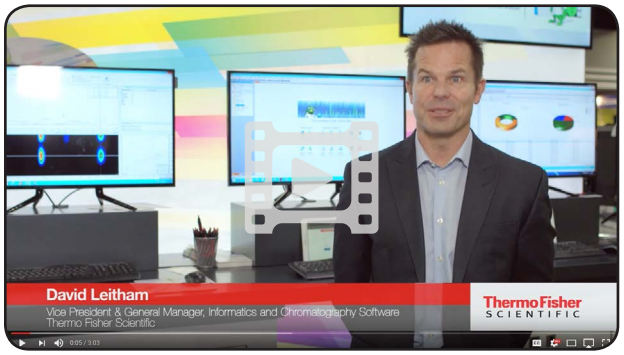
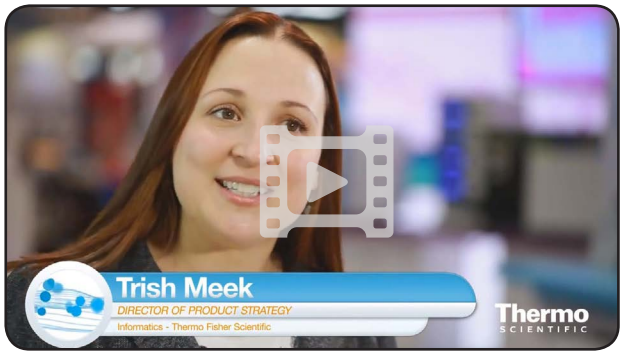
Videos



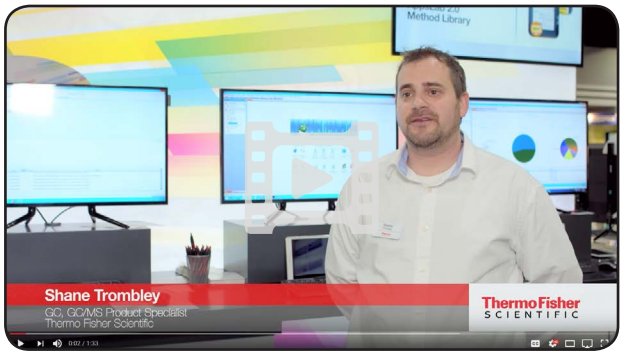
The Age of Informatics In and Out of the Lab
David Leitham, VP/GM Informatics & Chromatography Software, highlights the need for robust software and LIMS solutions to harness the power of data in and out of the lab and how Thermo Fisher Scientific can be a partner to customers. Learn about our leading LIMS and other software solutions, including Chromeleon CDS, and unleash the power of your data across your enterprise.



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.

Leading LIMS Solution Bridges the Lab and Enterprise
Katie Evans, Sr. Product Manager, talks about Thermo Scientific SampleManager LIMS, the leading LIMS solution, and how Thermo Scientific software solutions bridge data gaps in the lab and across the enterprise with leading laboratory management technologies.

Chromeleon Enabling Seamless Data Flow from Lab to Enterprise
Darren Barrington-Light talks about Thermo Scientific Chromeleon CDS and the latest release of the leading chromatography software from Thermo Fisher Scientific. Learn how our CDS solutions link into Laboratory Information Management to unleash the power of data in your enterprise and across your research.



Chromeleon Combines LC, GC, MS Instrument Control as well as Method and Data Management
Thermo Scientific Chromeleon CDS software combines the control of, and data collection from your chromatography (GC & LC) and MS instruments. Unifying workflows for these analytical instruments means that different sources and types of data can be overlaid, compared, backed up, and processed in one application. Chromeleon combines method creation and quantitation, and performs library-based compound identification. Streamlining data collection and experimental management liberates time for scientists so they can focus on science instead of logistics. This increase in efficiency is invaluable in an enterprise or other high-throughput environment.

Introducing AppsLab — Your Online Access to Thousands of Apps & Experts
Whether you need to find a solution to a new separation challenge or just want to optimize your chromatography – the AppsLab Library gives you access to Thermo Scientific application notes and methods online. It already holds more than 1,900 applications for GC, HPLC, IC, GC-MS, IC-MS, and LC-MS and continues to grow. Search, filter, and download complete applications and one-click workflows for immediate execution.

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On-Demand Webinars

Data Integrity Issues in Regulated GxP Labs

Data integrity is not just confined to emerging markets — it is a global issue. This Fundamentals Series presentation will provide: an introduction to data integrity; definitions of data integrity; criteria to ensure data integrity in lab records; discussion of GxP regulations and guidance for data integrity, focused on GMP; and 10 most common data integrity problems and how to resolve them.

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Managing Pharmaceutical Lab Data Management to Ensure Compliance

Join Stacey Brown and William Leonard, Senior Validation Analysts for Informatics at Thermo Fisher Scientific, to understand more about the complex requirements of pharmaceutical data management: key concerns in implementation and validation; ongoing system management; how to ace your audits.

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If your lab is challenged by increasingly complex data management, let us show you the power of Integrated Informatics & Chromatography Solutions.

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DATA INTEGRITY COMPLIANCE

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This eBook has been developed to give you a comprehensive resource when searching for the data management solutions that can help your business meet the challenges of ever-increasing regulatory requirements, as well as product quality and pressures to improve production efficiencies. You can rely on Thermo Scientific Integrated Informatics – a complete package of integrated software solutions – to help you unlock the value of your data and leverage that data for business optimization.

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To help our pharmaceutical customers manage the most complex data management challenges, we're introducing the latest evolution of our integrated laboratory software platform – Thermo Scientific Integrated Informatics, the center of lab data acquisition, management and storage, and designed for data integrity and compliance.
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