A Leading Solution for Automating the Laboratory and Integrating **LIMS with the Enterprise** 

# SampleManager LIMS™

Businesses Worldwide Count on Thermo Scientific Software for Their Informatics Solutions







# Our Commitment to the Customer

#### **A True Partnership**

Implementing an enterprise Laboratory Information Management System (LIMS) is a long-term business investment. Successful solutions combine leading technologies with world-class service capabilities that help analytical science companies lower operating costs and boost productivity. Thermo Fisher Scientific is the market-leading LIMS vendor with extensive resources and expertise to provide a comprehensive solution that meets your precise business requirements.

Thermo Scientific SampleManager LIMS<sup>™</sup> is a proven and time-tested solution with a continuous history of product innovation. The ongoing development process for SampleManager is driven by listening to you and incorporating industry advances and business needs into expanded functionality and capabilities. Thermo Fisher can also provide both the people and the processes to help you successfully deploy global LIMS projects, including the implementation, training and support that are essential to the long-term viability of an enterprise LIMS solution. Thermo Fisher approaches implementation projects as a partnership, involving and engaging the decision makers, users and subject matter experts from your business. The Thermo Fisher project team works to a defined project methodology that tracks project milestones, communicates progress reports, and enforces regular project reviews. A quality plan tailored for each project defines deliverables, roles and responsibilities for everyone involved.

Thermo Fisher's implementation services group is highly skilled, with backgrounds in laboratory software development and deployment, customer service, regulatory requirements and project management. Through Thermo Fisher's Professional Services and Global Partner Program, we have the world's largest and most experienced services team located in regional offices throughout Europe, the Americas, Latin America, South Africa, the Middle East and Asia Pacific.

Drawing on these extensive resources, Thermo Fisher provides experienced, dedicated and stable project teams who work in partnership with your organization to guide the LIMS implementation from start to finish. "The company's relationship with its customers matches that of its smallest and most nimble LIMS competitors," says Frost & Sullivan. "In fact, Thermo Fisher had leading competitive benchmarking scores for Brand Perception, Quality, and, most importantly, Customer Value Enhancement."

- Frost & Sullivan

#### The World Leader in Serving Science

Partnering with Thermo Fisher provides the security of working with a global, financially stable company committed to making laboratories more effective and productive with integrated informatics, services and instruments solutions. Thermo Fisher Scientific is the world leader in serving science, enabling our customers to make the world healthier, cleaner and safer. With annual sales of more than \$10 billion, we employ 30,000 people and serve over 350,000 customers. Our end-to-end workflows can outfit any lab from reagents, consumables, low-end and high-end equipment, to software and services.

Thermo Fisher has an extensive history of being recognized by world leading industry analysts in the LIMS market. A few examples include:

- 2008: Thermo Fisher was presented with two Frost & Sullivan Best Practices Awards in Market Leadership and Competitive Strategy Leadership.
- 2005: Thermo Fisher was named Company of The Year by Instrument Business Outlook (IBO) and was the market leader in LIMS.
- 2003: Thermo Fisher was named Life Sciences Instrument Company of the Year by Frost & Sullivan based on providing customers with total solutions.

### **The CARES Initiative**

The CARES Initiative (Customer Allegiance through Responsive, Excellent Service) encompasses all phases of product development, sales and service, and demonstrates the division's commitment to exceeding customer expectations across all operational levels. The CARES Initiative is built upon a platform of seven core principles, in areas such as product performance, order fulfillment, technical support, and sales and account management.

Our documented Quality Management System (QMS) is built into every aspect of the business and supported by all levels of the organization. Reliable and rigorous external product testing is also in place, including simulated multi-user environments and benchmarking to measure quality, performance and usability.

The eServices portal offers LIMS and CDS customers a wide range of support tools, including on-line incident logging, monitoring and resolution of support enquiries, as well as access to a comprehensive Knowledge Base.



Thermo Scientific LIMS and CDS customers also benefit from a sophisticated issue resolution system, which uses patented technology to capture a log of user actions and system events to quickly determine the cause of unexpected application behavior.

Around-the-clock support is offered, ensuring that customers have access to assistance wherever the business is located. As part of the CARES Initiative, we continuously communicate and seek customer feedback in order to improve products and processes. The CARES Initiative also ensures commitment from the highest levels of senior management.

# Leveraging LIMS Across the Enterprise

#### LIMS as a Strategic Solution

A successful LIMS implementation has traditionally helped to improve productivity and increase accuracy in the laboratory, enhancing efficiency and quality service. Today, global analytical science companies are standardizing on LIMS solutions that can be leveraged throughout their operations as an integral part of the enterprise computing infrastructure. This requires a LIMS that, in addition to providing the full range of functionality in the laboratory, can also be integrated with enterprise platforms and systems across the organization.

In a recent study on the worldwide LIMS outlook, the ARC Advisory Group points out that productivity and cost reduction programs will not be enough to sustain increased profitability goals, and that manufacturers will need to improve efficiency and increase yields by integrating the laboratory with the production process and management at the highest levels of the organization<sup>1</sup>.

Organizations are striving to guarantee tight quality control throughout their business processes as well as compliance with strict regulatory requirements – from early product development, material delivery through production, packaging and distribution, to worldwide customer service. As a result, Laboratory and Quality Managers need to deliver analytical data and results to a growing number of stakeholders across the organization and world. Integrating LIMS with enterprise applications can provide the means for efficiently exchanging data and effectively sharing information throughout the enterprise.





# Standardization and Harmonization in the Multi-Lab Enterprise

### The Value of a Corporate LIMS Standard

Laboratories within an organization will usually differ in their LIMS requirements. Production labs, for example, are set up to monitor product consistency, while research labs tend to be less structured to foster discovery and innovation. Yet the advantages of standardizing on a single LIMS for both the lab and the organization are significant:

- Reduced total cost of ownership due to lower support and maintenance
- Reduced workload for system administration, simplified training
- Fewer systems and vendor relationships to maintain
- Increased accuracy of data, reducing regulatory compliance costs
- Improved data quality and visibility. Consistent, transparent data become available for easier collaboration on a company-wide basis
- Faster integration with laboratory instruments and enterprise applications

"Thermo Fisher's leadership position in the market is widely recognized by LIMS end-users and LIMS vendors."

- Frost & Sullivan

# A Strategic Business Solution

### Proven LIMS Technology, Predictable Deployment

Organizations standardizing on an enterprise LIMS are best served by a total solution of proven technology, dependable implementation and reliable maintenance. SampleManager has evolved from the sample and report management tool introduced years ago into a strategic solution utilized today as a corporate standard by major life and analytical sciences organizations. Web-based capabilities and advanced configurability provide the flexibility needed for the multi-lab enterprise, and full integration with other applications and instruments is easily accomplished both in and out of the lab. Scalable and multi-lingual, SampleManager easily accommodates workflow, lab types and user communities throughout the organization,

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SampleManager's Thermo Scientific WebAccess<sup>™</sup> provides 100% of the desktop client's functionality in a browser. It is supported on any browser and with any operating system. and Thermo Fisher is ranked the top selling LIMS vendor in numerous studies conducted by independent analysts, such as ARC Advisory Group and Frost & Sullivan.

Customers choose SampleManager for its proven track record and smooth, predictable multi-lab deployments, as well as its consistent performance that boosts productivity and minimizes downtime. Since this often requires coordinated activities across multiple geographies, an important requirement for an enterprise LIMS vendor is a global professional service operation with broad industry experience and deep technical expertise. As part of a comprehensive laboratory informatics solution, Thermo Fisher provides extensive professional services for planning, implementing and supporting enterprise LIMS systems.

### Simple Deployment

SampleManager reduces the administration workload by requiring only a browser on the end-user desktop to fully access 100% of the functionality of the application.

SampleManager can be deployed with a mix of any of the three types of clients:

**Desktop Client:** Suitable for smaller deployments or deployments where the customer is comfortable rolling out software to all of the PCs that will access the LIMS.

WebAccess<sup>™</sup>: This provides 100% of the desktop client's functionality in a browser. It is supported on any browser and with any operating system.

**Citrix Client:** For customers who prefer Citrix, we test and validate SampleManager on Citrix.

All client modes provide an identical experience to the end user. This also makes mixed deployments viable since no additional training is required for WebAccess<sup>™</sup>.

An added benefit of WebAccess<sup>™</sup> is that the server stores the session. Even if the connection to the server goes down, the session will be maintained on the server and no work will be lost – which is particularly useful for remote access situations.

# Web Services Technology Based on XML

Web services architecture dramatically simplifies and reduces the cost of integrating SampleManager with other laboratory and business systems. Web services are based on XML (eXtensible Markup Language) for complete platform independence and open communication with lab and enterprise applications. Web services, being neither server application nor program language specific, offer flexibility and increased access to information across the organization.

Thermo Fisher's strong business partnerships with leading providers of complimentary technologies such as Microsoft, Oracle, etc. ensure that the needs of our mutual customers are met through standard integration solutions. SampleManager can drive the enterprise-wide transfer of scientific data at the heart of an organization's computing infrastructure.

# Shared Access to Data From R&D to Manufacturing

SampleManager offers a modern technological platform with integration capabilities to support all key enterprise processes and systems. Its open architecture and client/server capabilities provide the tools to connect isolated laboratory data islands into a global knowledge platform. This strategic LIMS approach recognizes laboratory data as a valuable business asset that is best leveraged when visible to the wider organization. Shared access to data is a particular advantage within R&D environments as it accelerates the discovery process and the development of new products.

In the manufacturing environment, SampleManager's effective data sharing and mining capabilities can foster innovative ways of analyzing samples, with new algorithms to extract information from the large body of lab data. Modern analysis tools can construct models for 'closed loop' control and process optimization, increasing product yields and accelerating production. As manufacturing efficiency, quality control, and product development timelines are improved, both profits and customer satisfaction increase. The result is a rapid return on investment upfront and a lower total cost of ownership over time – with future technological options kept open.

#### Multi-vendor Integration Solution

- Instrument Integration
   ERP Integration
- PIMS Integration
- · Phylo integration

### SampleManager LIMS Product & Services Solution

#### Add-on Modules

- Statistical Quality Control
   Water Industry
   Compliance
- Stability Studies

# • Web Deployment

- Role-based Access
- Electronic Signatures
- Auditing
- Lot Management
   Specification Checking
- Incident Management

#### Services Portfolio

- Project Consultancy
   Requirements Definition
- Implementation Services
- Compliance and
- Validation
- Training
- Helpdesk Support

# Integrating LIMS with Enterprise Systems

## A Foundation for Enterprise-wide Quality Infrastructure

LIMS integration can be the foundation for an enterprise-wide quality infrastructure. Collecting parameters from disparate enterprise applications – throughout a twenty-hour cycle, for example, from raw materials to the finished product – results in shared knowledge throughout the entire process. Standardized, integrated systems provide flexibility and lower operational costs, while LIMS integration with plant control systems can help eliminate bottlenecks in the production process.

#### **ERP Integration**

SampleManager offers flexible, user-friendly interfaces with ERP systems such as SAP, to facilitate the distribution of consistent quality information throughout the organization and enhance operational efficiencies. Data flow between the laboratory and manufacturing is expedited, data handling is streamlined, and data collecting and reporting is integrated. User-driven mapping functions offer SampleManager users easy access to required information from the ERP in a familiar LIMS format. Advanced functionality allows the creation of inspection points within SampleManager so that recognizable data objects can be sent to the ERP. As SAP customers upgrade or customize their system only a simple reconfiguring of the SAP objects in SampleManager is required.

#### SampleManager LIMS Meets Enterprise Requirements

Architecture: N-tier architecture using Microsoft .NET and supporting industry standard database technology

**Configurability:** Flexible for different lab types without timely and costly coding

**Functionality:** Robust, stable and reliable to ensure smooth, large-scale deployments

**Integration:** Web Services for integration with different instruments and enterprise applications

Internationalization: Available in multiple languages

**Reporting:** Flexible reporting, providing even casual users outside the lab access to pertinent data

**Scalability:** Able to support a large, growing number of users and labs

**Security:** Sophisticated access controls to ensure secure access to data across the organization

**Standards:** Industry-standard tools, languages and databases

**Support:** Offered across the world and in multiple languages

User Access: Full web browser and desktop client access to all functionality

"Stand alone LIMS are slowly disappearing in favor of solutions that can be integrated with higher level MES and ERP systems.

– ARC LIMS Worldwide Outlook

#### **MES and PIMS**

Companies rely on Process Information Management Systems (PIMS) and Manufacturing Execution Systems (MES) to continuously monitor and control their production processes. Traditionally these systems have operated independent of LIMS – functioning as separate islands of information. SampleManager interfaces with PIMS from leading vendors, such as OSIsoft, Honeywell, Yokogawa and AspenTech, providing real-time delivery of quality-related data for plant- and enterprise-wide monitoring and analysis purposes. Making validated analytical information immediately available directly to the systems and managers involved in the manufacturing process leads to better control of plant operations; increasing yields, reducing product loss and boosting productivity. Data can also be transferred from PIMS to SampleManager, allowing it to be more easily accessed by other corporate systems, such as ERP.

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SampleManager offers tight PIMS integration with leading vendors.

# Integrating LIMS with Laboratory Instruments

### A Flexible, Scalable Solution

Integrating LIMS with analytical instruments not only automates laboratory functions, but also provides data sharing benefits that add value to the informatics investment. Traditional instrument integration products designed for single PC operation struggle with today's networked operations, which require a more flexible, scalable solution.

SampleManager offers a highly-configurable instrument integration solution that doesn't require extensive custom coding. Data is automatically and securely captured from instruments, eliminating potential transcription errors and improving the flow and management of laboratory data. A standard interface is used within the lab and around the organization to integrate all the types and brands of instruments, simplifying and streamlining the operation, and offering all the benefits of increased automation.

# Easily Configured for Disparate Instrument Types

Setting up an instrument interface is simple and can usually be completed within a day. The configuration process requires only an understanding of the instrument's data format, with no need for complex programming or extensive training. The user is able to map any instrument file to any data field within the LIMS.

SampleManager's instrument integration architecture divides the collection and processing of instrument data into appropriate software components. In organizations where high levels of data processing and modern, reliable networking are required, these components can be deployed in a distributed configuration so that no processing of data needs to occur at the instrument workstation.

A series of instrument file collectors is installed at the instrument workstation. The function of these collectors is configured at a central server, which instructs each to look for either a data file from a network or hard drive, or a stream of data via an interfacing port, and then to transfer the instrument data to the server.

#### A Proven Sample Testing Tool

SampleManager is a proven tool for the efficient testing of samples that routinely pass through a typical lab – whether process testing, quality assurance, or R&D – by sorting test information and organizing it into specific report formats to meet regulatory requirements. The complete testing routine is managed, from sample login to testing, re-testing, and final reporting.

#### Sample Login

Sample registration can be done in a variety of ways both manual and automated. For environments where there is regularly scheduled sampling, automated pre-scheduled login will register samples at user-defined time intervals. In addition to the standard login functionality, SampleManager also supports the use of Sample Plans. The Sample Plan ensures that the correct tests and specifications are assigned to samples based on a decision tree workflow. This functionality is used heavily for raw material testing and supports skip lot testing.

# Automating the Laboratory

#### **Sample Tracking**

SampleManager tracks, displays and reports samples by any criteria that are required by the user. A typical multi-criteria request would allow review of all the current day's samples that have results entered, are within specification, have a high priority and require authorization.

#### **Result Entry**

Entry of results into SampleManager can be fully automated from all leading laboratory instrumentation. The Incident Management functionality allows users to record, track, and manage the unforeseen events that inevitably occur in a busy laboratory.

#### **Calculations**

SampleManager features advanced tools to create complex calculation formulae across different samples. An already extensive library of mathematical functions can be extended with users' own calculations and formulae to meet the most complex of situations. Calculations are automatically carried out as soon as the appropriate data is available within SampleManager.

#### Reporting

Reports in SampleManager can be configured to precisely reflect user requirements; report templates are built using a graphical environment and can include statistical calculations, graphs, pie charts, bit maps, or OLE objects. Additional reporting formats include Microsoft® applications, PDF, XML and CSV outputs. The production of reports can be triggered automatically and sent to multiple destinations including printers, email or other mechanisms to notify operators in the event of an alarm.



SampleManager's reporting tools provide key performance measures such as the number of samples analyzed per month.



SampleManager's comprehensive lot disposition report provides organizations with detailed product information and results.

# Purpose-Built for Your Laboratory

### **Specialized Functionality**

A series of specialized functional and industry modules have been developed for SampleManager to meet the business needs of each customer:

- Advanced SQC trend analysis to track over a period of time the performance of products, standards, methods, etc.
- ERP interface
- PIMS link module providing standard interfaces to OSIsoft, Honeywell, Yokogawa and AspenTech platforms
- Pre-configured water management testing regimes and reports to support compliance with the latest regulatory requirements
- Stability studies with powerful inventory functionality to monitor and control stock levels of raw materials, in-process and finished products

#### **Compliance with Regulations**

SampleManager supports GxP requirements and offers comprehensive functionality to facilitate compliance with standards such as 21 CFR Part 11, GAMP and ISO17025. A wide variety of standard functionality is available to help meet regulatory and security requirements and support standard operating procedures, including:

- Full control of data review and approval
- Timeouts
- Password checks
- Extensive versioning capabilities
- Sophisticated sample custody and incident management
- Ability to configure secure electronic signatures for any system operation

SampleManager also provides complete audittrail functions to ensure data accuracy which in turn leads to better regulatory compliance.

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SampleManager maintains records of the relevant competence, education and professional qualifications, training, skills and experience of all technical personnel in accordance with ISO 17025.



# **Ongoing Education and Support**

### **Flexible Training and Education**

Equipping your project team, IT staff and end users with the knowledge they need to use, deploy and support a global solution will ensure a successful project. Thermo Fisher's expert trainers offer a variety of education solutions, to ensure our customers are able to obtain the most value from their investment. Thermo Fisher's education consulting services range from training needs assessment to final training delivery. Scheduled training courses and workshops are provided either at the customer site or a nearby location, or at one of Thermo Fisher's regional facilities. Alternatively, a customized training solution can be tailored to your specific needs.

### **Expert, Reliable Support**

Global LIMS solutions are typically highly integrated mission-critical systems. Customers need to be able to ensure the availability of these systems, and have expert help on hand to deal with incidents should they occur. Through a global network of experienced support professionals, Thermo Fisher offers dedicated, local language help desks to ensure SampleManager deployments continue to operate efficiently and smoothly and that customers continue to realize maximum benefit from their informatics investment over time. Thermo Fisher support services provide access to the latest software updates ensuring customers benefit from the latest informatics technology and applications.

# LIMS Validation and Compliance Services

Thermo Fisher's professional validation and compliance specialists combine laboratory expertise with a deep understanding of regulatory requirements to help companies in regulated industries address issues with LIMS validation and 21 CFR Part 11 compliance. Services include validation consulting and planning, test development and execution, and validation training. Thermo Fisher offers an integrated LIMS implementation approach with a well-defined validation methodology based on GAMP. "Thermo Fisher's service has always been great, but the new eService has really been awesome! The tracking of tickets is helpful and the response has been fantastic."

> - Joe Vorderbrueggen, IT Specialist, Shell Oil Products





# **Count On Us to Understand Your Industry**

At Thermo Fisher Scientific, we have a unique understanding of your industry's specific laboratory informatics requirements. Over 30 years of industry leadership across a variety of global industries has allowed our company to grow with your business and to design and build industry-specific functionality throughout our LIMS and CDS product lines. Understanding your challenges is our first step in developing the purpose-built software solutions you can count on.

#### **Chemicals Manufacturing**

Chemicals manufacturers operate using either a continuous production process or a batch methodology. Since raw material prices can be volatile, Thermo Scientific LIMS are deployed to contribute fully to the efficiency of the organization by controlling specifications and maximizing the margin achieved on each finished product.

#### **Drinking and Wastewater Treatment**

Drinking water and wastewater analysis labs have to monitor the quality of both potable water and effluent on a regular basis in order to maintain public safety and ensure contents satisfy regulatory requirements. Above-limit determinations need to be reported rapidly, and trigger increased testing frequencies to monitor any potential health hazards. Thermo Scientific purpose-built LIMS are routinely used to most effectively manage the collection, storage, reporting and scheduling of these highly regulated activities.

#### **Environmental Regulations**

Environmental labs work under the auspices of national and international regulators such as the EPA or EU, and therefore need to have stringent control of the analytical techniques used to determine chemicals found in the environment. Integrating LIMS and CDS with a variety of analytical instrumentation to support the analyst in making determinations is critical to carrying out this activity efficiently. We deliver highly configurable integrated software solutions designed to meet the specific needs of environmental laboratories.





### Food and Beverage Testing

Scrutiny over imported food sources and increasing regulation facing the food industry has meant a new focus on quality control operations in order to support compliance and public safety. Since the raw materials in food products are much more variable than other industries, food testing labs need to have flexible software solutions that can accommodate changes based upon the materials used for each manufactured product so that traceability and batch genealogy is assured. Thermo Scientific LIMS are instrumental in the day-to-day operation of food and beverages laboratories.

#### **Metals and Minerals Production**

Metals and minerals production require a fast turn-around of quality data from a laboratory information management system, particularly in refining and extraction operations. Our LIMS allow for fast analysis of instrument data, which means process decisions may be made as quickly as possible and process parameters may be adjusted based upon what is often an inconstant raw material for the operation. Count on us to provide the necessary process control to maximize output and margins.

## Petrochemical, Oil and Gas Production

Producing oil and gas at the world's refineries requires that the production laboratory is able to monitor the quality of production on a regular timed basis. Thermo Scientific purpose-built LIMS is easily integrated with the onsite PIMS to ensure that all sample analyses are delivered when needed and production efficiencies are optimized.

"Thermo Scientific LIMS solutions allow us to provide our customers the opportunity to bring their products and services into the market quickly and efficiently while strictly respecting their deadlines and budgets."

 Troy Bradley, Director, Algorithme Pharma

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