thermo scientific

Thermo Scientific Integrated Informatics and Chromatography Software Solutions for the

Next

# Food & Beverage Industry

thermofisher.com/IntegratedInformatics

ThermoFisher SCIENTIFIC

# Introduction

Food safety is a global concern. Thermo Scientific Integrated Informatics and Chromatography Solutions enable food producers around the world to standardize and harmonize operations at all stages of food production, from the farm to the table and from the production of raw ingredients to the packaging that delivers the product to the customer. Our integrated laboratory software solutions can help laboratories achieve full compliance with even the strictest regulatory requirements. With the emphasis on improving food safety regulations in the US, Europe and around the world, traceability through all stages of production, processing and distribution is critical for food producers in their efforts to monitor quality, effectively manage recalls and limit product and revenue loss.

Now 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.

Having data readily available about a contaminated or imperfect food product can make the difference between batch destruction or a total product recall. That difference can have an enormous impact on your company's bottom line — and, more importantly, to your ability to preserve and protect your most valuable asset, your brand.


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

Request a Quote | Request a Demo | Please Contact Me

# Contents

# An Ounce of **Prevention** for Food Safety Labs

By Trish Meek, Thermo Fisher Scientific

As seen in *Food Quality & Safety*

Over $93 billion a year. That, according to a new Ohio State University study published in the *Journal of Food Protection*, is the estimated cost of foodborne illness in the U.S. alone. This doesn't look at the cost to industry, but rather it considers the cost to treat those affected by these illnesses.

What concerns those in the food industry most about staggering estimates like this is the increased scrutiny it brings from policy makers. In fact, the author of the study, Robert Sharff, hopes that his data, which looks at foodborne illness on a state-by-state basis, will "give policymakers a tool to determine whether a particular intervention they're using makes sense."

Increasing pressure from regulators is only part of the story for the food industry. According to "Food Safety in a Globalized World," a study done by global reinsurer Swiss Re, "52 percent of all food recalls cost affected U.S. companies more than $10 million each and losses of more than $100 million are possible." These estimates exclude any costs of reputational damage, so the ultimate number is much larger.

The significant costs of recalls and more onerous regulatory oversight are enough to justify even greater rigor for labs operating inside food manufacturers. But there's an obvious drawback to thinking only about recalls and other risks when outfitting and running a food industry lab—this is, after all, a for-profit business. Labs must balance their critical safety net role with a business imperative to drive higher and higher productivity and eke out larger margins wherever possible.

From a food safety and quality standpoint, there are many fail points within a typical food manufacturer that must be understood and closely tracked. This can quickly become overwhelming, and many labs soon become known for their bottlenecks instead of their benefits. From the way they accept raw materials to batch release speed, labs can have an outsized influence on production speed and efficiency.

The potential for labs to disrupt manufacturing productivity can put them squarely in management's crosshairs, which is why it's so important to leave nothing to chance, even the smallest process step. Yes, there's significant pressure to meet regulatory requirements, such as ISO 22000 and Hazard Analysis and Critical Control Points, and the specter of a recall is ever-present, but the answer isn't to slow operations to a more manageable crawl. That simply isn't an option.

The modern food industry lab must cast a wider net when it comes to safety and quality fail points, but technology can ensure that this happens with increasing alacrity. This isn't accomplished by relaxing standards and letting more pass by. In fact, it's quite the opposite: the best approach is to break down all the fail points, account for them in software and manage as if even the most insignificant problem could snowball into a costly issue.

While there are many places that labs could begin as they look for common fail points, three isolated common areas where an ounce of prevention could yield a pound of cure are inventory, standard operation procedures (SOPs), and traceability. These areas may seem obvious, but few labs approach them with the rigor believed is necessary, so let's explore them in greater detail.

## Inventory

Culture media, reagents, and even vials for gas chromatographs—just some of the everyday items in a food lab that often go out of stock. But why? Most labs operate fairly routinely, running the same workflow test after test with a normal cadence. It shouldn't be difficult to manage rotating stock with that information at your fingertips.

The problem is that it's not always at the fingertips. Inventory may not even be tracked electronically, so what looks to be in stock may actually be unavailable. This isn't something you want to learn as the product team is eagerly awaiting your approval to release a batch. Perhaps the batch is held, which stalls production altogether, or batches move through but eventually need to be discarded. In either case, a seemingly mundane issue—can't/don't track inventory in real time—jeopardizes productivity, and, in this case, blame falls squarely on the lab.

Inventory can be easily tracked and proactively replenished, but it requires commitment and technology that is capable of supporting high-throughput testing. A laboratory information management system (LIMS) can not only track inventory as it's used, it can also be programmed to generate alerts that warn of waning stock levels. Knowing that a reagent is almost out of stock seems trivial until hours into the latest stoppage when you realize how valuable that information would have been two days ago.

## SOPs

In writing about its most recent "Reportable Food Registry" annual report (2014), the FDA observed that

> "The most important lesson learned from this analysis of food allergen recalls and reportable foods is that many of these recalls were caused by simple problems and could have been easily avoided."

It advocated for regular reviews of processes, from raw material acceptance to packaging, to identify procedural changes that could help avoid future recall problems.

Nowhere are SOPs more important than in the lab. Increasingly, labs are going a step further, relying on electronic SOPs (ESOPs) as a defense against risk. Productivity also hangs in the balance, and inconsistency can lead to costly delays that erode trust that must exist between labs and the larger manufacturing enterprise.

But creating ESOPs is only part of the story and a LIMS, such as Thermo Fisher Scientific's SampleManager, can simplify this process, defining stepwise workflows along with technical corrective actions to ensure consistency and adherence to protocol. Beyond the discipline offered by software such as LIMS, labs must consider many things as they develop ESOPs including thoroughness, standardization, distribution, user compliance and, as the FDA assessment indicates, learnings.

This last consideration, learnings, reflects the fact that SOPs must always be part of a feedback loop. Yes, SOPs are standard, but regulations change and processes are updated—as this happens, the lab must reassess its procedures and then roll out changes effectively. With a LIMS, this happens rapidly and thoroughly with little if any disruption to production. In fact, there may even be opportunities to further streamline laboratory procedures by proactively identifying productivity gains through software.

Aiding proactive discovery in labs is statistical quality control (SQC), a capability that is now standard in some LIMS. With SQC, technicians can detect nonconformance trending before it reaches pre-defined thresholds. This gives labs real-time monitoring capability that relies on statistical algorithms: the lab is observing data trends while the analysis is running, not weeks later.


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



Think of this as a failsafe for SOPs, another way to catch errors that can cost thousands before they become productivity issues. If data goes out of spec—something that may be impossible for a human to detect—the LIMS can provide warning. The technician is able to address the issue proactively, and this could mean the difference between a rapid batch clearing result or a costly delay in production.

**Result Traceability**

Nothing can grind a lab to a halt faster than having to defend a result. Was there something wrong with the consumables or instrument? What was the source of the sample? Was the analyst recently certified on the gas chromatography? These are just some of the questions that must be answered if a result is questioned. Until that happens, productivity will likely suffer.

Without a documented and unbroken chain between data and sample, a result is indefensible, it's that simple. From barcoding through final reporting, each step must be recorded (according to SOPs) in a manner that makes it easy to trace the pathway of a sample. Now multiply this by hundreds, if not thousands of samples, and it's clear how onerous this process can be.

When a lab is holding up a batch release, for example, so much must fall into place for it to quickly test and confirm results according to strict formulation and safety parameters. If it still relies on paper-based systems, excessive time is likely required. Even if it has mostly automated data entry, it still must adhere to guidelines that if not codified in software will also require valuable time. And within a food manufacturer, time is always associated in some way with margin.

Without an integrated informatics solution, adhering to these procedures, defending the quality of the data, and making it usable would be nearly impossible. This is why data management through software isn't just about reporting for auditing purposes. It's about accelerating results delivery so that production can continue uninterrupted and efficiently, making the lab a demonstrable driver for higher productivity and margin, not an impediment.

**Small Steps Create Big Changes**

There are many fail points within a typical food manufacturer, and labs are a critical line of defense to ensure failure doesn't occur. But this can thrust them into a position of productivity impediment instead of driver. When it comes to product quality and consumer safety, some bottlenecks are inevitable, almost necessary. After all, regulation seeks to control certain points that are known to engender risk. But management doesn't want to hear that control must always equal productivity drain and revenue loss.

From the way they accept raw materials to batch release speed, labs can make demonstrable contributions to productivity and profitability. But only if they accept the notion that ounces of prevention—with data as the measure—can add up to pounds of cure, which in this case would equal more efficient operations and higher profits.

When a lab disrupts manufacturing, it should be to increase productivity, not impede it, and with LIMS and some added discipline this is possible. When this happens, a lab may still be in management's crosshairs, but this time it will be for all the right reasons.

# **The Case For Integrated Informatics:** Regulatory Compliance, Defensible Data, Traceability, Brand Protection

By Trish Meek

As seen in *Software & Technology*

To understand why an integrated informatics solution is important to manufacturers in the food and beverage industry, it helps to first consider the unique challenges this industry faces. Simply put, food production has scaled into a global business so rapidly that oversight has hardly kept pace. Even the stricter regulatory stances taken by the U.S. Food and Drug Administration (FDA) and the European Union in the past decade are effectively catch-up efforts.

The broader food industry, which for purposes of this article will also comprise beverage, has globalized quickly and, many would argue, haphazardly. It actually wasn't that long ago that the products we purchased in our local food store were produced locally or regionally. Seasons determined selections as well—if you wanted a tomato in November you'd pay a premium for that indulgence.

Seasons and geography no longer constrain what we can buy and when. By far the world's largest industry—with a combined revenue of more than $4 trillion, the food industry has used its massive scale to overcome historical limitations. We now take for granted that our grocery carts can be filled with fresh products that may come from thousands of miles away. And those products may have been grown, processed and shipped in multiple countries before they reach our local grocer.

The complexity and scale of this modern food supply chain is the industry's greatest challenge and regulators' greatest worry (on consumers' behalf). How can growers, producers, processors, packagers, shippers and others in the global supply chain secure a food chain that's so distributed? How can regulators ensure safety without restricting choice or inflating prices?

### The bits and "bytes" of food safety

The food industry—and its regulators—would likely agree on one thing: a system this massive cannot operate on trust alone, as it once did. The grower with generations of experience on the land, for example, is now too far removed from end consumers. A finished product may contain one farmer's product and those from five others, all from different regions worldwide.

Integrated informatics may seem like an unlikely fix for modernizing a highly distributed food chain, but it's actually perfectly suited. An integrated informatics platform provides access to massive amounts of information in a timely fashion, dramatically improving decision making. It does this by making information rapidly available to many stakeholders and by ensuring that it's reliable.

Consider this example. A hypothetical lab uses an analytical instrument to detect pesticides in barley, and regulation dictates that this data be compared to allowable maximum residue limits (MRLs). If the barley sample exceeds allowable MRLs, the manufacturer must identify everywhere that ingredient is being used, quarantine it and determine who produced it. All this must happen quickly and according to strict procedures.

Not only must the lab have a process for checking against current limits for a pesticide, for example, but also that analytical information must be tracked with the appropriate sample, and the method used to deliver the result must be consistent between different samples and users. Without an integrated informatics solution, adhering to these procedures, defending the quality of the data and making it usable would be nearly impossible.


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

## 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.

## The role of informatics

Gathering the bits and bytes of data, following procedures and making the data useful enterprise-wide is important, but regulatory compliance is where most industry attention is focused today. This is another area where integrated informatics provides significant benefits.

## The need arises

As noted, food industry growth outpaced regulatory oversight in the past decade or so. Globalization was rapid and inevitable, but so too were food safety breaches, and with progress came stories of tainted fruits, vegetables, meats, cereals, nut butters and more. Suddenly we had a trust issue. With a food chain that's distributed across many borders and jurisdictions, how is the public's trust best protected and by whom?

From the Food Safety Modernization Act (FSMA) to EU Regulation No. 178/2002, we've seen a heightened regulatory focus, and the most common themes are traceability, authenticity and risk-based approaches. The common denominator here is food chain security.

So what does all of this mean for food and beverage producers? It means having to conform to multiple regulatory requirements for each distribution market, and there are often many. And this is a data management and reporting headache. Fortunately, however, common standards such as ISO 22000, exist that enable companies to standardize their processes enterprise-wide, achieving levels of operational rigor and quality that satisfy multiple regulatory authorities at once.

So where do informatics fit into this regulatory compliance landscape? In a typical multinational food producer, a significant amount of the quality data is delivered by the laboratory. Raw materials are analyzed for pesticides, herbicides, nutritional content and so on. Packaged products are monitored for shelf-life compliance. Plant hygiene is monitored using microbiological samples taken from across the facility. Records from all of these distinct, but interrelated activities are critical for demonstrating compliance.

## Defending data

The shift in recent years has been toward prevention instead of crisis response. Regulators now focus on auditing food and beverage producers to assess their practices prior to any adverse event. For companies with good systems in place, time-consuming audits will be less frequent, so it pays to have systems in place that demonstrate that data is reliable and defensible.

Audits can be daunting. The producer must prove that activities were carried out correctly, that records are properly collected and that supporting information is accurate. Auditors typically pick a starting point in a process and follow the trail. They may start by looking at the data associated with a released batch of product; perhaps quality assurance samples; follow the trail to cleaning validation and then review individual laboratory results, including entire methods, instrument calibration, user training, etc. At each point of the audit, producers must show evidence of compliance—even the smallest details.

With an integrated informatics solution, all evidence resides in a single platform. Hierarchies and relationships within the data records are automatically recorded and retained. Everything—from relationships between lots or batches of material; the connection between methods, specifications and results; the history of an instrument configuration, maintenance and calibration; and user training records—is in one place for easy retrieval and reporting.

Having one system of record not only codifies data capture, it also helps labs create standard operating procedures (SOPs). Establishing SOPs does several important things.

It ensures that all lab users are following the same process—no personal preferences for carrying out a specific test.

It makes sure that all necessary data is collected—by enforcing a series of data entry steps, labs can prevent a method from being marked complete until everything has been entered.

Labs can roll out updates to their processes by updating the method for all users at the same time.

Managing lab execution activities in this way means that data is more consistent—it is being collected in the same way for all users. It is also prone to fewer errors because users move stepwise through each stage of the measurement process—they can stop a test whenever they encounter a problem.

**Achieving traceability**

Traceability, the ability to verify the history, location or application of an item using documented information, has become increasingly more important for the food industry. And traceability is closely linked to compliance and data defensibility as described above. Fortunately, traceability is another strength of an integrated informatics solution.

In practical terms, to demonstrate traceability we must be able to go either backward or forward within a set of process items and understand the complicated relationships. An integrated informatics solution lets us map relationships between "child" and "parent" batches, information that can also come from integrating ERP or PIMS systems. By integrating all this information, manufacturers can trace a product back through intermediate products and raw materials and then forward again to any resultant batches that may be contaminated. In other words, with an integrated informatics solution, traceability is built in.

**Brand protection**

Because of its size and fragmentation, the global food and beverage industry is a target for adulteration and counterfeiting.

While the risk to consumers of adulteration can be deadly, much of the impact comes in the form of trust erosion and fraud. An example is Manuka honey. The entry of fraudulent producers into the market affects legitimate producers by creating uncertainty about all products, depressing sales and lowering prices.

As it happens, however, honey has unique chemical markers that can be used to determine whether it has been adulterated. But isolating these markers involves complex analysis, including ultra- high-performance liquid chromatography (UHPLC) and methods that are highly specific, consistent and defensible.

For the honey producers, an informatics solution can automate processes so that no non-conforming product is missed, establish compliance rules and checks for instrument calibration so that results are defensible,

Thermo Scientific Integrated Informatics, the center of lab data acquisition, management and storage, 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.

and standardize methods through built-in laboratory execution system capability.

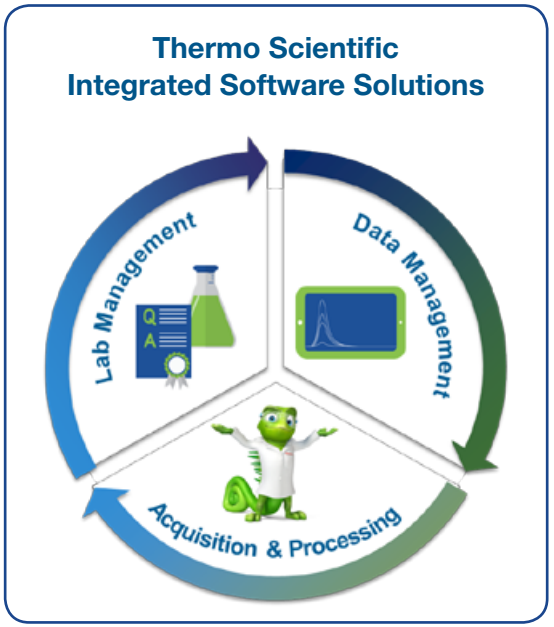
An integrated informatics solution is designed to address multiple business needs in the food and beverage industry, from compliance and data defensibility to traceability and brand protection. The complexity and scale of the modern food supply chain demands it.

# Take Your Lab Informatics to Another Level with SampleManager LIMS and Chromeleon™ CDS

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.

- Fully integrated LIMS, CDS, SDMS and LES/Procedural ELN
- 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.

Request a Quote | Request a Demo | Please Contact Me

# Data-Driven Food Safety Monitoring **Eases Regulatory Compliance and Delivers Opportunities**

By Trish Meek, Thermo Fisher Scientific

As seen in *Food Safety Magazine*

Government regulations often seem like a burden to the industry as they typically come with new and sometimes challenging reporting requirements. But new regulations also present opportunities because they help to establish clear benchmarks for accountability that can promote higher quality. In industries where regulation is pervasive—such as the food industry—the most successful companies are typically those that develop systems and practices that maximize these opportunities for process improvement, higher quality and ultimately greater insight into the data capture necessary for regulatory reporting and control over finished product.

Governments worldwide hold their food industries to a higher standard, and rightly so. Even small errors in food production can do serious damage to public health and consumer confidence. Numerous rules exist to enforce quality and safety, from voluntary standards such as ISO 22000 to mandatory regulations such as the U.S. Food Safety Modernization Act (FSMA) or the European Union Regulation (EC) No. 178/2002. Additional regulations exist for specific food and food production processes, such as the Federal Meat Inspection Act or the Egg Products Inspection Act. Most of these regulations are based on trusted quality assurance and quality control paradigms such as the Hazard Analysis and Critical Control Points (HACCP) methodology, which has been widely used in food production for several decades.

Managing this myriad of regulations and standards is hard work, but food producers that take a systematic and software-driven approach to achieving compliance with them can actually make all these rules work in their favor.

**Automating Compliance Data Management**

FSMA Section 103, entitled “Hazard Analysis and Risk-Based Preventive Controls,” outlines the structure of a “preventive controls plan” based on the HACCP methodology.

The main challenge of implementing these controls is dealing with the incredible volume of data they produce. A comprehensive HACCP program produces thousands of data points each day, and this data is only as useful as the system that manages them. One of the best solutions for managing this flow of data is a Laboratory Information Management System, or LIMS.

A LIMS collects and manages data over a food product’s entire lifecycle—from incoming ingredient shipments to finished product deliveries and all HACCP points in between. The LIMS helps food producers establish a new HACCP program or strengthen an existing one by guiding them through five critical steps: evaluating hazards, defining preventive steps, establishing monitoring controls, maintaining monitoring records and specifying corrective actions.

"an ounce of prevention is worth a pound of cure"

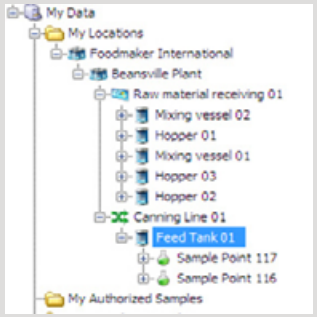



**Figure 1**

## Hazard Evaluation

Every food production process is different, so the first step in any compliance program is always identifying the unique HACCP points in a given facility. Food safety and food contamination risks most commonly occur where raw materials are introduced, vessels are opened, product is extracted, materials are added or finished products are packaged. Especially dangerous are the HACCP points that involve employee interaction—and by extension, the potential for human error.

Figure 1 shows a virtual facility map generated by a LIMS which lays out all hazard points within the production plant. Supplier data and outgoing shipments can also be mapped, allowing the facility to organize data by supplier, batch date, outgoing shipment or any other criteria. This capability makes it much easier to identify and manage the effects of process errors.

## Defining Preventive Steps

Nowhere is the classic adage "an ounce of prevention is worth a pound of cure" truer than in the food production industry. Though a comprehensive HACCP program may be expensive, its cost pales in comparison to the costs of a wide-ranging product recall.

Improper instrument maintenance is one of the most common causes of food production errors. A LIMS can help food producers prevent these errors by providing staff with automated maintenance reminders. The system can also keep track of operator competency records, which allows both management and external auditors to ensure that all staff have received the appropriate training. Lastly, the LIMS can monitor the quality of raw and processed materials as they move through the production facility, identifying out of specification materials at the earliest HACCP point possible.

**Are you looking for an easy application note finder tool?**

Check out the Thermo Scientific AppsLab Library of Analytical Applications – Methods, eWorkflows and more. Find the best solution to your separation challenges: easily download one-click workflows for use with Chromeleon CDS.

Go to AppsLab Library › appslab.thermoscientific.com/

Figure 3

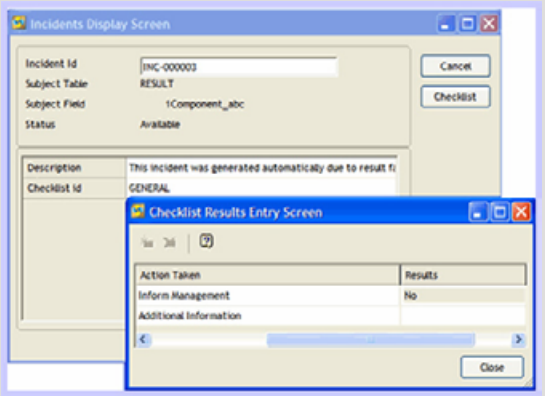



Figure 4

## Establishing Monitoring Controls

Identifying hazard points and defining preventive steps represent only the initial planning phase of the compliance process. The bulk of the work occurs once monitoring actually begins. Fortunately, a LIMS that catalogues all hazard points and preventive steps enables food safety professionals to simplify monitoring by scheduling measurements, setting alerts, applying control limits and analyzing data for each one of a facility's HACCP points.

All data generated by process monitoring instruments installed at HACCP points are stored in a relational database built into the LIMS. This makes it easy to present information in whatever way is most useful for the intended audience(s). Options include graphs, process map overlays, real-time alerts and more (Figure 3). Control points can also be organized into groups, enabling users to further segment the data and establish consistent sampling plans for each subset.

## Maintaining Monitoring Records

HACCP monitoring data are only as good as the system that manages them. Data lose most of its value if it's not organized into clear, comprehensive and easily understandable records. A LIMS simplifies record keeping and retrieval processes by enabling completely paperless data collection and reporting. Networking the LIMS with all HACCP monitoring instruments virtually eliminates manual data collection as well as the enormous potential for human error that manual work creates.

All records stored within the LIMS can be searched and organized according to many variables—including electronic signatures, origin and batch—making both internal and external audits much easier.

## Specifying Corrective Actions

A food production facility's error response time is often the difference between a controlled food safety incident and one that spirals out of control. A LIMS can significantly reduce a facility's response time by storing clearly defined corrective actions for every potential incident. When and if an incident occurs, the LIMS can provide automated standard operating procedures that walk staff through the actions necessary to contain and resolve the problem.

After the incident is contained, records stored in the LIMS can be used to determine the potential extent of the damage caused by the incident. This allows management to make more informed decisions about next steps, up to and including recalls. Once the incident has been fully resolved, detailed incident reports are stored within the LIMS for review by both internal and external parties (Figure 4).

## Conclusion

Solid data management systems are the catalysts that transform food safety regulations from burdens into opportunities. By handling as much of the facility monitoring, data collection and compliance reporting processes as possible, a LIMS allows food safety professionals to cut out much of the most time-consuming, error-prone and least value-added work as possible. By focusing on the beneficial consequences of meeting industry regulation, LIMS enables increased process efficiency and helps avoid product safety incidents altogether or minimizes the impact if any recalls do occur.

# **Informatics Delivers** Traceability and Data Management for Food Safety Monitoring

By Trish Meek, Thermo Fisher Scientific

As seen in *Food Science & Technology*


Food production is a highly regulated industry and for good reason: our system is based on trust. But while food regulations serve an important purpose, they do present significant challenges for the businesses that must comply with them.

Most food producers are subject to a broad range of regulations and standards, from industry-wide ones, such as ISO 22000 (which sets out several communications and system management guidelines), the 2011 United States Food Safety Modernization Act (FSMA) and the European Union Regulation (EC) No. 178/2002, to process-specific ones like the Egg Products Inspection Act (EPIA) or the Federal Meat Inspection Act (FMIA). Most of the industry-wide regulations require extensive application of the Hazard Analysis and Critical Control Points (HACCP) methodology, a systematic approach to preventing food safety hazards that has been in use for several decades.

**Ensuring compliance**

Establishing a 'preventive controls plan' (as described in FSMA Section 103 – Hazard Analysis and Risk-Based Preventive Controls) based on the HACCP methodology is the best and simplest way to achieve enterprise-wide compliance. This route is not without its challenges, however HACCP, when properly practiced, generates a significant amount of instrument data and records.

Managing this information is key to success, which is why many food producers put a Laboratory Information Management System (LIMS) at the core of their regulatory compliance system. A LIMS enables producers to monitor and record the progress of all product batches as they enter into, travel through and are shipped from production facilities. In addition, it also guides producers through the five steps for establishing a preventive controls plan: evaluating the hazards, specifying preventive steps, specifying how the facility will monitor its controls, maintaining monitoring records and specifying corrective actions to correct problems.


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

The Chromeleon™ 7.2 CDS enterprise support for MS gives you the ability to control, process and report MS data from remote PC's or even from another building, another site, or even in another country! The sharing of data has never been so easy!

**Request a Quote** **Request a Demo** **Please Contact Me**

# LIMS and preventive controls plans

**1. Evaluating the hazards.** The first and most important step in managing food safety hazards is identifying them: one cannot minimize a hazard without being aware of it. Contamination risks are commonly found where materials are added, product is extracted, vessels are opened, raw materials are introduced, finished products are packaged or, most pernicious of all, where employees are most unlikely to follow operating procedures.

A LIMS can help food safety professionals by generating a software map of these hazard points. In addition to locations within the facility, the LIMS can also store supplier data for all incoming shipments. Using this map, the manufacturer can then use the LIMS to group data by batch, supplier, date or any other relevant parameter, allowing management to easily identify potentially contaminated or out-of-spec materials.

**2. Specifying preventive steps.** With food safety, prevention is always better than hazard response. This is why defining preventive measures is one of the most critical parts of a controls plan. Hazards can be introduced to the production process in many ways, including equipment failures, human error, poor environmental or site-specific conditions, as well as the use of non-conforming materials. A LIMS can play a role in preventing all of these hazards.

When a LIMS is integrated with all laboratory instrumentation, it can provide automated maintenance reminders for those instruments to relevant staff members in the lab. In addition to maintenance records, detailed operator competency and training records are stored so that management can verify whether staff have received the appropriate training and so that untrained personnel are prevented from performing critical tests and procedures. This safe-guard will be particularly important if the organization is audited for any reason, or has to deliver reports proving full traceability of processes and materials to a regulatory agency.

Finally, a LIMS can be used to monitor the quality of raw and process materials as they pass through quality checks during processing, helping manufacturers detect non-conforming materials as early as possible, ideally before they leave the facility.

**3. Monitoring controls.** The hazard points identified in the first two steps require regular monitoring – as a result, they generate significant amounts of data. Using a LIMS, food safety professionals can schedule measurements, apply control limits, set alerts and analyze data for each control point in the facility.

Sampling plans for control points can be managed as a group, which means that producers can use a consistent protocol for each type of product moving through the facility. This capability allows management to compare data from one batch to those from another. All data generated by process monitoring is stored in a relational database and can be presented in the way that is most useful to each user, including graphs, real-time alert messages and process map overlays.

**4. Maintaining records.** Food safety regulations require extensive record-keeping for use in regular compliance audits. A LIMS greatly simplifies the process of record-keeping and retrieval by enabling entirely paperless data collection and reporting. All records stored within the LIMS are searchable, secure and authenticated by electronic signatures and audit trails, making audits much easier by capturing and organizing all data necessary to demonstrate compliance and producing it in report formats either required or easily recognized by auditors or regulatory authorities.

**5. Specifying corrective actions.** When a food safety incident occurs, clearly defined corrective actions – developed in advance – must be known by all relevant staff. The records housed within a LIMS play an important role here: by analyzing the data pertaining to the affected batch, food producers can know in real time the extent of the problem and what corrective actions are required. Detailed incident reports are then stored within the system for critical review, driving continuous process improvement and streamlining any regulatory review.

## Conclusion

What all food regulation has in common is data – producers must collect, store and present massive amounts of it. This is why LIMS are now so prevalent in the food industry: proven data collection, analysis and recording capabilities can help producers monitor product quality at every step of the process, enabling them to account for full traceability of all processes and materials. From low-tech loading docks to high-tech packaging cleanrooms, a LIMS can continuously monitor an entire food production process and make demonstrating regulatory compliance much easier. More importantly, a LIMS can help ensure that the trust customers place in their food is supported by the most advanced technologies available today.

# ISO 22000 and Integrated Informatics: Business Best Practices to **Meet Global Food Safety Regulatory Challenges**

By Trish Meek, Thermo Fisher Scientific
As seen in *Lab Manager*

In KPMG'S 2014 *Food, Drink and Consumer Goods Industry Outlook Survey,* 22 percent of the senior managers questioned said that "staying ahead of or navigating changes in the regulatory environment" would consume most of their time in the coming 12 months. Nearly 20 percent said that geographic expansion would be one of the primary areas of investment in the coming months. Taken together, these two data points echo a common food industry refrain: we want to expand internationally, but we're increasingly aware of the difficulties and costs of doing so from a regulatory standpoint.

Navigating regulations and requirements on a country-by-country basis is fraught with challenges: some countries are exceptionally strict and onerous while others are developing and the regulatory framework is far from mature. So what's the best path forward? While there's no single formula for success, one path forward for participants in the global food supply chain is to rely on accepted international standards such as ISO 22000 as best practices for their lab operations.

Derived from the ISO 9000 family of quality management systems, ISO 22000 incorporates principles from the Hazard Analysis and Critical Control Points (HACCP) methodology and other proven food safety systems. It is widely considered the gold standard globally for food safety monitoring. In fact, the US Food Safety Modernization Act (FSMA) has modeled much of its recent requirements legislation around the ISO 22000 and HACCP guidelines. As such, ISO is an ideal starting point for companies like those in the KPMG survey that are eager to grow but that also fear "staying ahead" will consume too much of their time.

## Data Management for Global Compliance

While some food and beverage companies still rely on manual data capture in some parts of their laboratory operations, spreadsheets and manual data transcription will prove incapable of handling the large volume of data that must be discoverable and auditable for ISO 22000 compliance – or as evidence to any other regulatory authority, such as under the European Union Regulation (EC) No. 178/2002, or US FDA Food Safety Modernization Act. Only an enterprise-level integrated informatics solution can handle the volume of data required of the latest food safety regulations in a secure and defensible manner. Laboratory Information Management Systems (LIMS) have an established track record across food and beverage laboratories for helping manage

Connect all of your labs with the Chromeleon™ 7.2 Chromatography Data System (CDS). Now you can take advantage of new import and export options, which means transferring data between other laboratory systems is now easier than ever.

HACCP and ISO 22000 process and compliance efforts in particular. This makes a LIMS an essential part of any food or beverage company that markets and sells its products around the world.

With a LIMS managing workflow and process, and serving as the central source of data for all sample testing, from raw materials through to the final packaged product, food and beverage companies can be assured that the data will be defensible to regulatory authorities, management will have the data necessary to routinely reduce the risk of contamination or to effectively manage a food recall if that should prove necessary. Most important, the money invested in building the brand will be secured and the consuming public will continue to have confidence in the quality and safety of the food products being sold. The adherence to regulatory requirements is one very important part of the ongoing efforts to build and support a brand. If processes are not in place to capture non-conforming product before it reaches the public, then a recall is a very real possibility and one which is badly managed or widespread will have dramatic impact on the value of the brand and shareholder confidence. HACCP guidelines can introduce another layer of data management, with five critical steps in the process (Hazard Evaluation, Defining Preventive Steps, Establishing Monitoring Controls, Maintaining Monitoring Records, and Specifying Corrective Actions) each adding their own level of complexity to the lab's data management challenges, but ultimately improving the consumer trust in the brand.

### Enterprise-Level Integrated Informatics—Built-In Best Practices

For food producers, the main benefit of using LIMS to manage ISO 22000 compliance is its ability to address compliance needs in multiple geographies – meaning both "everywhere in the world" and "at every step of a process." In the sense of "everywhere in the world," a standard ISO/LIMS strategy can be implemented in any country without sacrificing regulatory rigor or compliance. At the individual process level, "global" means that a LIMS collects and manages data over the entire life cycle of a food product, from incoming ingredient deliveries to finished product shipments (and all HACCP points in between).

No matter how many laboratories are involved in a company's manufacturing processes, or where in the world they may be, the LIMS is capable of managing the levels of relationship complexity and connectivity with multiple sites and manufacturing environments. Enterprise-level LIMS can build all the ISO 22000 and HACCP steps into their workflow structure so that adherence to these regulations are routine not only in the lab but across the entire organization.

### Conclusion

Regulations are increasing every day and in every region of the world now. With our global food culture, we want to experience what the world has to offer and it is imperative that no matter where we live, and no matter where our food comes from, we can be assured that our food is safe from contaminants or impurities of any kind. An enterprise-level integrated informatics solution makes this possible. In fact, choosing to comply with a standard as comprehensive as ISO 22000 is actually a smart decision for global players in the food industry. Following ISO 22000 and HACCP guidelines is a business best practice which guarantees that processes and quality parameters meet even the most onerous requirements. The LIMS eliminates burden by automating compliance and leaves only the benefits: increased efficiency, improved product safety and reduced, well managed recalls.

# Using Your Laboratory to **Protect Your Brand**

The cornerstone of the Food Safety Modernization Act is prevention. This will require facilities to place greater emphasis on traceability, creating urgency for them to take the lab to the field and deploy laboratory information management systems.

By Paula Hollywood *ARC Advisory Group*

**Summary**

The food supply chain has become a complex global system consisting of small to large domestic and foreign manufacturers, processors, packers, distributors, and transporters with few common business practices. Consumers now expect year-round supplies of fresh fruits and vegetables as well as more exotic foods. This has increased the risk of a major food safety incident. Compliance with differing government regulations and enforcement policies adds to the complexity. With such a convoluted value chain with multifaceted reporting requirements, how can consumer-facing suppliers demonstrate regulatory compliance and protect their brands? Laboratory technology can play a key role in brand protection by efficiently managing test samples. Laboratory Information Management System (LIMS) facilitate end-to-end traceability of samples and products and all associated laboratory processes; providing a central repository for data and test results for increased traceability and regulatory compliance.

**What's at Risk?**

While consumer brand preference is subjective, product safety is not. The implied contract between producer and consumer is that products are unadulterated and will not cause harm. According to the Grocery Manufacturers Association (GMA), the voice of the consumer packaged goods industry in the US, ensuring product safety is the industry's single most important goal. While this may be true, for producers, brand protection is also critical. Recall costs can range from tens to hundreds of millions of dollars and lost sales due to damage to the brand can be devastating.

The Peanut Corporation of America (PCA)—a supplier of peanuts, peanut butter, peanut meal, and peanut paste—provides a case in point. In 2008, the US FDA determined that one of the company's processing facilities was the source of the worst salmonella outbreak in US history, killing nine and sickening hundreds. Not only was PCA forced into bankruptcy, sources estimate the cost of the incident to the peanut industry at $1 billion in lost product and sales. The domino effect throughout the food industry involved the recall of about 1,000 different products. This single incident wreaked havoc with not just one company, but an entire industry.

This incident alone demonstrates the expression that "an ounce of prevention is worth a pound of cure." In other words, it is far better to avoid problems in the first place than to have to fix them later. Experts cite the PCA incident as the impetus behind the Food Safety Modernization Act (FSMA).

## Major Elements of the FSMA Food Safety Plan

- Prerequisite programs are in place to ensure food is produced in a safe and sanitary manner
- Hazard analysis that identifies all potential risks throughout processing
- Preventive controls that are implemented to mitigate risks
- Monitoring of preventive controls to ensure they are properly implemented
- Verification that the preventive controls have the intended reduction in risk
- Re-analysis of the hazards and preventive controls when there are significant changes in the process or every three years

### FSMA Emphasizes Prevention

The cornerstone of the FSMA is to prevent incidents based upon risk assessment, as opposed to rapid response to an incident. The Act will require facilities to write, implement, document, and demonstrate a food safety plan. It will likely require facilities to go deeper into the supply chain than the current "one up and one down" regulations. This deeper penetration of the food chain will impact several hundred thousand foreign and domestic facilities registered with the FDA.

For food processors, more stringent controls will be required, enabling a more proactive approach to quality. At minimum, preventive controls will require new practices with more control points and additional requirements for Corrective Action and Preventive Action (CAPA), root cause analysis, and more continuous documentation. Producers must also demonstrate crisis management preparedness, product traceability, batch coding, and Hazard Analysis and Critical Control Points (HACCP) plans. To improve effectiveness, these systems must interact with many applications throughout manufacturing and its supply chains such that the information can be quickly accessed to contain the scope of a recall in the event of an incident. Plans will differ from facility to facility based upon the level of risk to food safety.

### Taking Lab Technology to the Field

Globalization of the food supply chain has not only increased the availability of more exotic foods, it has also increased the number of pathogens. The FDA has reported that there are five times more identified pathogens today than 50 years ago. Traceability of each product from raw material through production and packaging dictates that more pervasive use of laboratory technology in the field will be necessary.

To minimize risk, food processors must be able to produce detailed and accurate records that identify the quality, quantity, disposition, and handling of products at each handover point. Raw material testing and identity verification at each handover point are critical to traceability and quality management. Portable optical analysis tools, such as those available from Thermo Scientific, bring the laboratory to the field for fast, accurate material identity verification. Handheld Raman, NIR, and FTIR spectrometers can help users quickly verify raw material identification to determine suitability for further processing. These handheld devices require little to no sample preparation, enabling technologies previously restricted to laboratory use to be used in the field to speed raw material identification and data synchronization. The ability to locate the source of a problem through good traceability can minimize the time to recover and avoid extensive damage to the brand and company reputation.

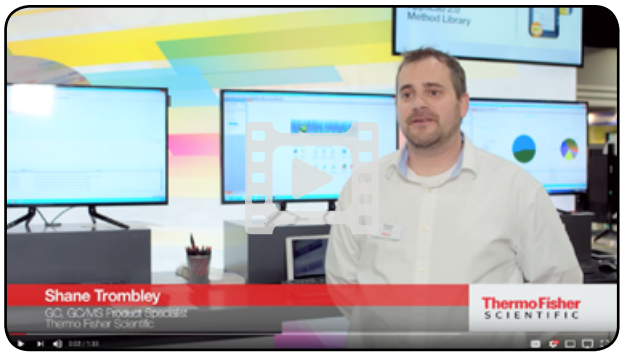
## LIMS Secures the Data Environment

The increased traceability requirements mandated by FSMA not only require greater amounts of data, but also require turning that data into useful information. A laboratory information management system, like Thermo Scientific™ SampleManager LIMS™, can manage samples, act as a repository for records data and test results, and provide increased traceability and full chain of custody to help ensure regulatory compliance. For producers, a LIMS can help verify that product quality meets regulatory standards while recording that data for subsequent inspections, if required. For auditors, a LIMS facilitates review of compliance reports and related certificates of inspection stored with the LIMS to verify safety. Integrating LIMS with enterprise systems such as ERP, PIMS and MES enables organizations to share information throughout the enterprise for faster and improved decision making.

FSMA increases the stakes to the point where home-grown systems and paper-based tracking methods could place food producers and processes at greater risk for non-compliance, which in turn could jeopardize not only the brand, but the entire operation. Commercial LIMS such as Thermo Scientific SampleManager LIMS that are specifically designed to help organizations comply with regulations such as GMP, GLP, HACCP, CO-DEX, and 21CFR Part 11 are likely to prove indispensable under the FSMA, since they provide a secure audit trail and document corrective actions. While the emphasis is on prevention, the ability to quickly react to a contamination incident minimizes recall costs and potentially protects brand reputation.

## Conclusion

The current food supply chain not only increases consumer access to year round supplies of fruits and vegetables, it also increases the number of pathogens that could cause contamination. The FSMA requires tools that focus on prevention and provide a framework for regulatory compliance. LIMS provides a secure environment for monitoring batch relationships between raw materials, processed materials, and packaged goods in the complex food supply chain. As the centralized system for collecting, storing, processing, and reporting all food lab-generated data, LIMS provides a complete overview of product quality in accordance with regulatory requirements.




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

**Streamline your laboratory workflow using Thermo Scientific™ Chromeleon™ 7.2 Chromatography Data System (CDS) software. This software delivers superior instrument control, automation, data processing, and more. The first CDS to unify the workflows for chromatography and routine quantitative mass spectrometry (MS) analysis, Chromeleon software provides full integration of Thermo Scientific gas chromatography (GC-MS/MS) and liquid chromatography (LC-MS/MS) instruments. Run your analyses in an enterprise environment—from method creation to final report.**

Request a Quote | Request a Demo | Please Contact Me

# How to **Transform** Your Lab and Business

The biggest challenges many elite enterprises face are actually external forces completely out of their control, from geopolitical and economic macro trends to global threats to health and the environment.

By Trish Meek, Thermo Fisher Scientific
As seen in *R&D Magazine*

This lack of control creates a tumultuous global business climate that conspires to unravel even the most well-thought-out strategic plans. Businesses can no longer adopt a wait-and-see approach. To have any chance of sustained success, today's enterprises must be more agile and aggressive than ever.

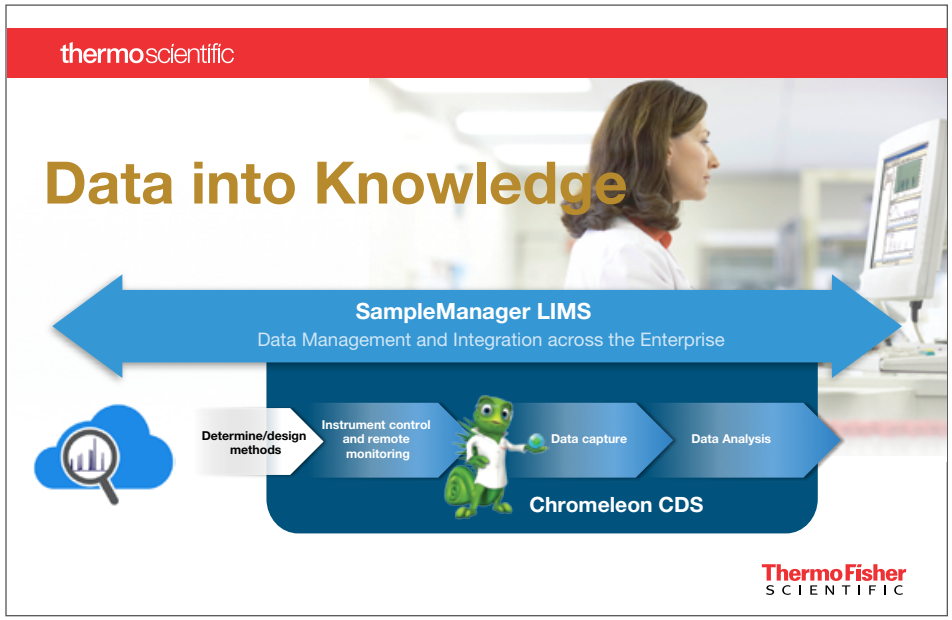
In many industries, from pharmaceuticals to food, business agility is dependent on a well-funded, efficient and prolific R&D function. Successful companies tirelessly monitor performance and quality, and are psychologically and structurally ready to capitalize on every new opportunity to transform and grow. These successful enterprises have discovered that four drivers are critical to sustained business transformation: business intelligence, innovation, automation and integration. When all four drivers are in sync, business transformation isn't just a strategy anymore, it's a state of being.

For those businesses unfamiliar to the four drivers, all is not lost. In fact, many established businesses are closer than they think to transformation because they've spent more than two decades methodically adding technology in the business version of "keeping up with the Joneses". But all this investment will be for naught unless corporations strategically align non-integrated, often disparate technology and resources in ways that enable maximum agility, and there's no better place to start realignment than with research and development.

## Drivers of transformation

The pull of technology is a constant when advancing your business. And for a R&D laboratory of any size, new technologies go well beyond analytical instrument advancements alone. Yes, technology is an enabling catalyst that can accelerate transformation, but it can also distract by putting constant pressure on laboratories and their management to stay ahead.

Technology is simply a means to an end: data. Data is the true currency of business, especially in the laboratory, and business transformation is unsurprisingly linked to effective data management. Even with the best laboratory instruments and information technology infrastructure in place, there may be little difference between one point solution and another. It is how the data is used across the enterprise to enable business intelligence and decision making that becomes the distinct competitive advantage.




**To help our food and beverage 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.**

A flexible data management solution, such as a Laboratory Information Management System (LIMS), is designed to enable business intelligence and decision making. A LIMS is an invaluable tool that can be configured and integrated to transform any organization, allowing activities, both inside and outside the enterprise environment, to be automated and monitored for greater efficiency, productivity and data integrity.

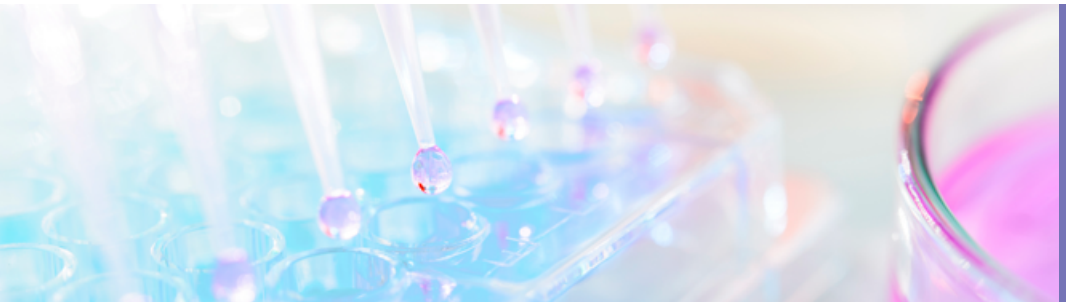
Because LIMS are so tightly integrated with other enterprise operation systems, insights from a LIMS-enabled R&D laboratory are infinitely more important to businesses seeking true enterprise-wide agility than previously realized. Enterprises aren't only capturing and collecting data; they are making data actionable, positioning management to transform their companies into nimble enterprises capable of responding quickly to new regulations or market trends and flexible enough to know and capitalize on cost-saving or margin-growing opportunities in the future.

## Implementing the four pillars

To be business transformation ready, a company must rely on a platform that is reinforced by four pillars: business intelligence, innovation, automation and integration. The good news is that many R&D functions have already invested in some aspects of these pillars, so implementation is less burdensome than many realize.

## Business Intelligence (BI)

Many organizations declare success once they've acquired the ability to quickly and efficiently collect, store and organize knowledge. To be truly business transformation ready, however, companies must use BI to do more than organize; they must insist on action. In many enterprises, if a manager or executive wants to see laboratory progress or productivity reports, for example, the IT department has to step in. This extra step discourages many executives from taking advantage of the rich data that surrounds them. Thanks to more mature BI approaches enabled by cloud computing, however, laboratory personnel can now create real-time dashboard reports that managers and executives can access continuously via desktop, tablet or mobile device. They are a few clicks away from being able to make a decision. Analytical data, so critical for quality assurance, consistency and compliance, is now more useful today and it can be used to drive profitable product innovation in the future.



From laboratory instruments to software systems and mobile devices, nothing in an enterprise should exist in isolation, unable to inform decision making and support rapid business transformation.

**Innovation**

Innovation is tightly aligned with information. A laboratory driven by data insight—not just instrumentation—is able to discover avenues for innovation that exist only in a macro view. From improved food or drug quality, for example, to more efficient ways to manufacture consumer products or oil and gas, liberating laboratory data in dashboard form turns it into a catalyst for continuous change. And the ability to recognize and exploit pathways for innovation is as much cultural as it is process-oriented. When employees become accustomed to seeing a bigger picture—through data—business transformation becomes a cultural norm, not a discrete initiative.

**Automation**

Time is an ally of discovery. When staff can devote more of it to innovation, great things happen. Automating time-consuming tasks, such as instrument calibration, compliance, reporting, user training and maintenance, liberates more time for new ideas and improved decision making, investing this perishable intellectual capital back into business transformation. As businesses turn to new markets and just-in-time product innovation to compete, the ability to automate processes will become one of the most important characteristics of a business transformation-ready company.

**Integration**

When people, processes, technology and data are stuck in silos, business agility is impossible. From laboratory instruments to software systems and mobile devices, nothing in an enterprise should exist in isolation, unable to inform decision making and support rapid business transformation. From tracking raw material shipments at the loading dock to assimilating data from different laboratory instruments, true visibility—to inform business decisions—is only possible when an executive dashboard is built from comprehensive, near real-time data in open digital formats.

A plan now exists for constructing an enterprise transformation-ready R&D department. When data is presented to decision makers logically and intuitively, it fuels new strategic growth, and it does so with unprecedented ease. Step one is liberating hidden insights that are stored in laboratories around the world, enabling more smart people to proactively query and use vast stores of knowledge. When that happens, R&D is truly transformed, its laboratory is a growth driver, management is fully engaged and the entire business couldn't be happier.


▲ **Introducing AppsLab — Your Online Access to Thousands of Apps & Experts**
Christoph Nickel, Senior Director for Informatics and Chromatography Software, Thermo Fisher Scientific

Request a Quote | Request a Demo | Please Contact Me

# Traceability is Key in Food Safety: Europe Leads the Way

For more than a decade, European authorities and producers have been held to higher standards for food quality than any other region worldwide, and the results have matched the regulation: Europe has one of the lowest levels of food contamination in the world.

By Trish Meek, Thermo Fisher Scientific

As seen in *Food Safety Magazine*

What makes Europe's success so remarkable is how complex the system is: Despite strict regulations enforced to protect more than 500 million people, compliance takes place without interfering with the independence of the EU's 27 sovereign nations. Such a structure would be impossible without a massive technology infrastructure and investment in state-of-the-art data management technologies, including laboratory information management systems (LIMS), which are widely used by industry and governments to structure laboratory sampling, analysis and reporting tasks, and integrate food quality data across vast enterprise systems.


**What Makes Europe Different?**

Europe hasn't always been the world standard for food safety. Several food crises, including outbreaks of mad cow disease (formally known as bovine spongiform encephalopathy or BSE), salmonella and botulism, led to the establishment of the European Food Safety Authority (EFSA) in 2002. The organization's mission is straightforward, but ambitious: "to deliver independent, high-quality and timely scientific advice on risks in the food chain from farm to fork in an integrated manner and to communicate on those risks in an open manner to all interested parties and the public at large."

If achieving this goal wasn't challenging enough, EFSA must do all this while respecting the sovereignty of the EU's member states. The dramatic rise in international trade over the last 20 years, coupled with increasingly complex supply chains in food manufacturing, means that new rules must be all-encompassing without being stifling. While Europe needed stricter regulations in 2002, EFSA had to promulgate them in concert with the food safety authorities of individual nations within the EU.

The same law that established EFSA – Regulation EC/178/2002 – laid the groundwork for implementation guidelines, principles and procedures. For example, any food produced in Europe or imported is now subject to some of the strictest traceability requirements in the world. The regulation requires that manufacturers and distributers have "the ability to trace and follow food, feed, and ingredients through all stages of production, processing and distribution."

To date, EFSA's massive undertaking is working. The organization cooperates with more than 400 organizations within the EU to carry out food testing,

One of the key contributors to successful monitoring of food safety “from farm to fork” is the application of consistent practices to the laboratory environment.

and since 2002, EFSA has published more than 2,500 “scientific outputs”—pieces of research used to institute new regulations or modify existing rules. The number of cases of BSE has fallen from thousands each year before the institution of EFSA to only 44 in 2010, and now only two percent of EU residents consider mad cow to be a possible food risk. Salmonella contamination has fallen off even more dramatically, decreasing by 50 percent from 2004 to 2009.

One of the key contributors to successful monitoring of food safety “from farm to fork” is the application of consistent practices to the laboratory environment.

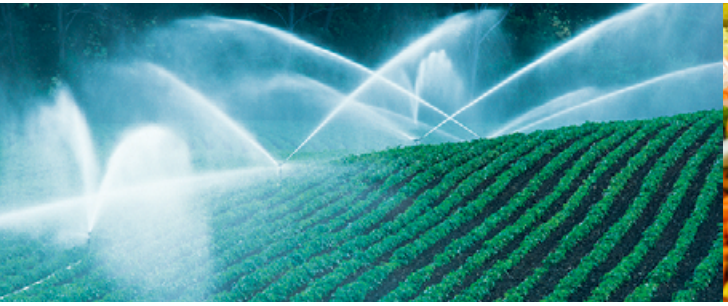
Since 2010, EFSA has required that laboratories generating data that will be used as a part of any traceability record must be accredited under the ISO/IEC Standard 17025, which demands that labs keep records not just of the samples tested and their results, but of supporting data such as instrument calibration status, staff training records, reagents and standards, etc. Having this universal accreditation requirement for all food-related analysis means that it is possible to compare data sets from different sources, which in turn leads to faster and more accurate monitoring of food-related incidents that may impact EU citizens.

**LIMS Plays a Starring Role**

As well thought-out as the EFSA approach is, the system would be impossible to administer without sophisticated data management, like today’s enterprise-level LIMS. From 400 independent organizations, individual manufacturers and national authorities within the member states to the EFSA itself, the massive sampling operation hinges on consistent, reliable laboratory testing, management and integration. LIMS monitor instrument calibration and maintenance schedules, ensure proper training records for personnel, manage workflow and testing requirements inside labs and store all records related to sample testing and report generation. A LIMS also provides a secure data management environment for monitoring batch relationships between raw materials, processed materials and packaged goods in an increasingly complex food supply chain. Having a LIMS also ensures that the external accreditation program for ISO 17025 is significantly less burdensome for the laboratory by having online searchable access to supporting records—something that is both time consuming and tricky if the data is kept as paper records.

Across many individual labs, LIMS aggregate and analyze the massive data sets from throughout Europe, helping authorities identify potential outbreaks before they happen. Consider the Department of Agriculture in Ireland, where agrifood remains one of the country’s most important industries, accounting directly for more than eight percent of both GDP and employment and exports of more than €8.1 billion.

These Irish Department of Agriculture’s duties require timely and accurate flow of information and research results across all locations, and the Irish Department of Agriculture uses Thermo Scientific LIMS to ensure accuracy and gather new epidemiological insights. The solution allows for improved sample tracking through automated label generation and electronic transfer of data to third parties, including European authorities.



The ability of the LIMS to retrieve, analyze and report data—with speed and efficiency impossible in a paper-based system—also allows authorities to use the system as a database for animal disease surveillance. This information is ultimately compiled with data from across Europe to model potential trends and prevent contamination issues before they become serious.

The ability of the LIMS to retrieve, analyze and report data—with speed and efficiency impossible in a paper-based system—also allows authorities to use the system as a database for animal disease surveillance.

**Conclusion**

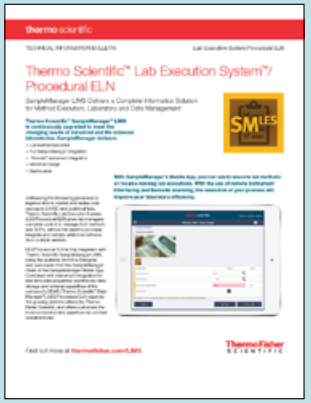
Anticipating the steps needed to fully comply with the Food Safety Modernization Act, leading food and beverage brands can look to experience in Europe for guidance. After all, many manufacturers globally are already complying with the strictest food testing regulations in the world because they're distributing in Europe. And while Europe's regulations are indeed stringent—from traceability to handling and so much more—they are also best practices that help food companies protect their brand reputations by offering a product that is uniform in quality, safety and taste every time.

Adopting best practices and achieving compliance isn't simple, but it's far easier today thanks to the advancing technology of today's LIMS. Navigating and thriving in a system as complex as EFSA's requires more than instinct and hands-on experience. With LIMS behind the scenes automating data aggregation and analysis, equipment calibration and maintenance, technician training and more, the global players in the food supply chain are united in a common goal: ensuring that everything we eat and drink is tasty, nutritious and, most importantly, safe.

# The Resource Center

## Technical Bulletins: LIMS, LES, SDMS, and CDS


Thermo Scientific SampleManager LIMS




Thermo Scientific Lab Execution System/ Procedural ELN


Thermo Scientific SDMS – Data Manager

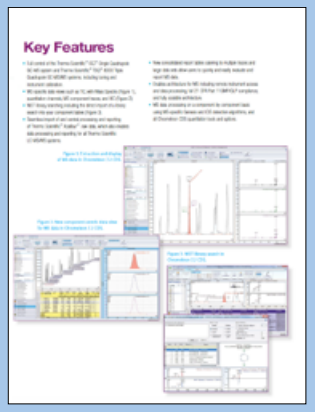

Thermo Scientific SampleManager LIMS and Chromeleon CDS Link


Thermo Scientific Integration Manager

## Infographic

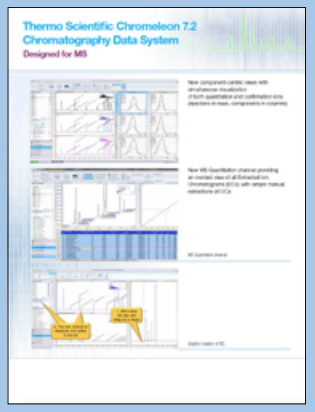

Download Free Infographic

## Chromeleon CDS Brochures



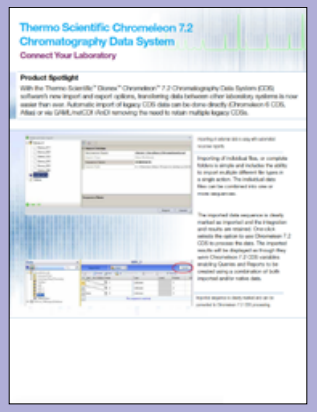

**Thermo Scientific™ Chromeleon™ Chromatography Data System (CDS) Software Combining Separation (GC/IC/LC) and Mass Spectrometry (MS) in an Enterprise (client/server) Environment**


**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 Handy Web Links


**Thermo Scientific Chromeleon™ Chromatography Data System**

**AppsLab Library: Find your Methods, eWorkflows and more**

The AppsLab Library of Analytical Applications is a fully searchable online, analytical method repository where you can find applications with detailed method information, chromatograms and related compound information.

Discover the latest applications from Thermo Fisher Scientific for LC, IC, GC, GC-MS and LC-MS instruments. Search by compound, column, instrument or any other method parameter and view key method parameters.

Download one-click eWorkflows, created and tested by Thermo Fisher Scientific application scientists, which can be directly executed in your chromatography data system.

All the information needed to run, process and report the analysis is available in ready-to-use eWorkflows.

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

Request a Quote | Request a Demo | Please Contact Me

# 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.

Request a Quote | Request a Demo | Please Contact Me

Case Study:

# Thermo Scientific LIMS **Helps Müller's Yogurt Production at UK Quality Control Laboratory**



Making the transition from a manual system that's essentially paper-based to one which automates almost every quality control (QC) sample check and reporting process is a major undertaking for any company. With UK production over 1.8 billion pots of yogurt per year, the time was ripe for change at Müller and Thermo Fisher Scientific was the clear solutions provider.

**Profile**

Molkerei Alois Müller (UK) is a market leader in European dairy products. The Müller UK site specializes in yogurt products; from low-fat yogurt offerings to yogurt and cereal combinations.

Müller UK sales have been increasing annually since the company entered the UK market due to a focus on quality and innovation. In fact, the state-of-the-art production facility at Market Drayton that was opened in 1992, has been significantly expanded several times to add more manufacturing, warehouse and distribution capability. Now, Müller produces more than a third of all yogurt eaten in the UK from the Market Drayton factory.

**Focus on Quality Control**

The Müller UK labs are mainly focused on production QC. "But we test product from the start," Shaheen Adatia, Müller UK's Laboratory Manager explains. "Milk from farms arrives by tanker and is passed by pumps into silos, then separated into skim milk and cream, and some skim into concentrate. Yogurt mixes are made in tanks and batch sterilized. If the batch meets specifications, it is processed through a heat exchanger, cooled, and placed in an incubation tank where culture is added. Every step in the process undergoes quality checks. During incubation, the pH is monitored and checked every two hours. After eight to nine hours of incubation, the pH has dropped and a final pH check is made when the yogurt is cooled."

With the checks being performed and recorded manually, there were many places a LIMS could be used to automate and expedite the QC tasks.

**Efficiency Expectations**

The decision to implement a LIMS was driven by the increase in production demand, and justified by the need to increase the lab's efficiency. Müller UK's paper-based system for tracking and reporting QC data was supplemented by Microsoft's Excel spreadsheet program. A LIMS would dramatically reduce the amount of error-prone paperwork and expedite testing.

The LIMS was also expected to assist significantly in real-time monitoring of Müller's production processes and play a pivotal role in ensuring quality control for finished product. By using a LIMS, Müller would be able to trend all data and make decisions and necessary improvements much faster.

**LIMS Selection**

Müller UK selected Thermo Scientific LIMS to manage QC data for raw materials, in process, and finished dairy desserts. One of the reasons Müller selected the LIMS was that it could map easily to their business processes via the LIMS' Workflow functionality. The ease of implementation was also attractive and drove the decision to implement and configure the solution without any significant help from Thermo Fisher.


"The LIMS is ideal as its flexibility allows us to expand and develop the services provided by the Laboratory," he continues. "The LIMS also enables us to do more with the data, such as create trend analyses."

Integrating the LIMS with as many pieces of the lab equipment as possible allows for automated data transfer and additional efficiencies.

"The work processes were reviewed and the LIMS team asked, "What are we doing?", "Why are we doing it?", and "Can it be done better?" Adatia recalls. "From November to May, methods and workflows were input, systems were set up, and the layout of the lab and equipment reorganized to streamline operations."

Workflows for milk reception, separation and pasteurization were developed, along with workflows for other products and areas of manufacture.

The milk reception processes managed by the LIMS were developed to include barcoding samples from the tankers upon receipt, checking the milk for antibiotics, and checking the milk composition for fats, protein, lactose, and solids. Any out-of-specification parameters can be reported automatically. For instance, if a tank fails antibiotics, it gets rejected outright, the LIMS flags the result as being out-of-spec and creates a report automatically.

## IT Involvement

Müller UK's Information Technology (IT) team was actively involved in the LIMS selection and implementation, and worked closely with the lab team to select and implement the LIMS. In fact, there's a dedicated IT person to ensure the integrity of the solution.

IT reviewed distribution of all the QC information, people were asked what they wanted, and then they were provided with the appropriate reports.

With the LIMS, IT determined the access privileges to the data, which included sample reports, daily averages, and moving averages. These are all read-only and certain reports such as sales are restricted to a for-your-eyes-only status that can only be accessed by certain levels with authority to do so.

The reports are more accurate and stay consistent within the system. Interfaces to various instruments and lots now ensure that there are no input or copying errors.

## The Importance of Training

The implementation team had to overcome training personnel on the new system. The majority of people were only used to the paper-based system of recording results.

Basic PC training was arranged at the very start for everybody. This was followed by an introduction to the LIMS, and training on the first workflow.

"A one month transition was scheduled to test the LIMS and ensure that everyone used it correctly," Adatia states. "Then, once we were comfortable with using the system, the system went live."

After the implementation of a couple of workflows, workshops were held so that everybody could further explore the system and ask questions in a more informal atmosphere. This proved to be a valuable tool in the implementation of the system.

## Summary

Implementing a Thermo Scientific LIMS has helped Müller UK's lab to not only meet production demands with equanimity but will also position them to meet future challenges.

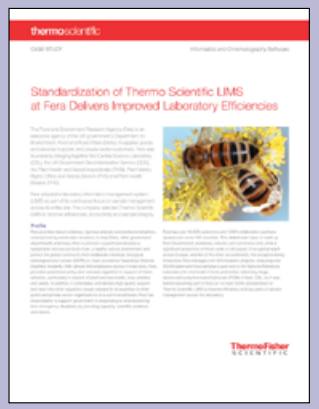
At the time of the LIMS installation, incoming and outgoing milk products, storage silos and separator workflows were tracked by the LIMS, however a lot of product had yet to be incorporated. The goal for future phases of this installation is to enable automatic release of finished product.

Adatia also anticipates changes down the line with the roll out of corporate-wide solutions. In addition, the LIMS has the potential for integration with other business systems. With a Thermo Scientific LIMS in place, the lab is confident that they can meet these and other challenges.

**Integrated Informatics Solutions Built for Industry**

Today's data management challenges are more complex than ever. Laboratories worldwide seeking a single, integrated informatics platform can now standardize on one comprehensive laboratory information management system, encompassing LIMS, LES and SDMS functionality. You can rely on our Integrated Informatics solutions to deliver the flexibility you need to meet changing regulatory requirements and your business objectives. Built with workflow and dashboard driven technology and enterprise integration tools, our Integrated Informatics Solutions will reduce your total cost of ownership and deliver a faster return on your Informatics investment. Thermo Scientific Informatics solutions are relied on at food and beverage companies around the world. To support our customers, we provide implementation, validation, training, maintenance and support with the industry's largest worldwide Informatics services network.

## Additional **Case Studies**




**Standardization of Thermo Scientific LIMS at Fera Delivers Improved Laboratory Efficiencies**


**How LIMS Helps Labs in Processing Achieve Food Hygiene and Safety**


**The Irish Department of Agriculture Gains Improved Efficiencies and Strategic Information Management with Thermo Scientific LIMS**


**Chr. Hansen Standardizes on Thermo Scientific LIMS to Ensure Optimum Quality Control in Starter Culture Production**

Request a Quote | Request a Demo | Please Contact Me

ThermoFisher SCIENTIFIC

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.


thermofisher.com/IntegratedInformatics

**Are you looking for an easy application note finder tool?**
Check out the Thermo Scientific AppsLab Library of Analytical Applications – Methods, eWorkflows and more. Find the best solution to your separation challenges: easily download one-click workflows for use with Chromeleon CDS.
Go to AppsLab Library › appslab.thermoscientific.com/

BR80041EN 0524S

Request a Quote | Request a Demo | Please Contact Me