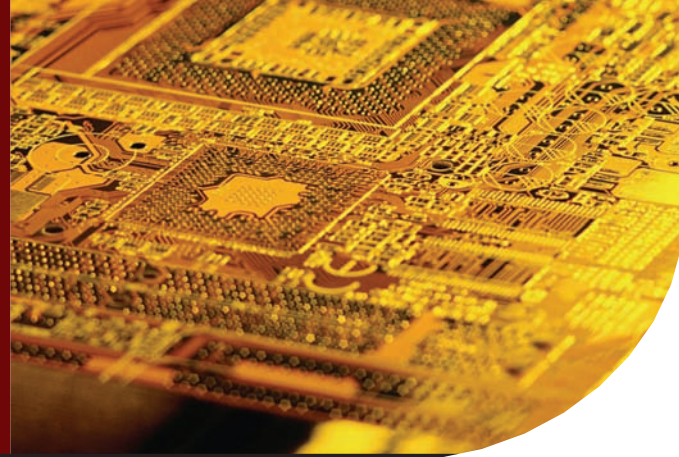# Continuous Focus on Sample Management. Improving Productivity via LIMS

The Food and Environment Research Agency (Fera) is an executive agency of the UK government's Department for Environment, Food and Rural Affairs (Defra). It supplies goods and services to public and private sector customers. Fera was founded by bringing together the Central Science Laboratory (CSL), the UK Government Decontamination Service (GDS), the Plant Health and Seeds Inspectorate (PHSI), Plant Variety Rights Office and Seeds Division (PVS) and Plant Health Division (PHD). Fera adopted a laboratory information management system (LIMS) as part of its continuous focus on sample management across its entire site. To improve efficiencies, productivity and sample integrity Fera needed to invest in a data management solution that would enable to organisation to integrate laboratory processes and data.

> *" Fera wanted to maintain its reputation as one of the best units in the world, and ensuring that all samples are well managed is a crucial part of this objective...*

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PROFILE

Fera provides robust evidence, rigorous analysis and professional advice, underpinned by world class research, to help Defra, other government departments and many other customers support and develop a sustainable and secure food chain, a healthy natural environment and protect the global community from deliberate chemical, biological, radiological and nuclear (CBRN) or major accidental Hazardous Material (HazMat) incidents. With almost 900 employees across four main sites, Fera provides operational policy and oversees regulation in support of these activities, particularly in respect of plant and bee health, crop varieties and seeds. In addition, it undertakes and delivers high quality support and input into other regulatory issues relevant to its expertise to other public and private sector organisations on a commercial basis. Fera has responsibility to support government in responding to and recovering from emergency situations, by providing capacity, scientific evidence and advice. Fera has over 40,000 customers and 1,000 collaboration partners spread over some 100 countries. This stakeholder base is made up from Government, academia, industry and commerce and, while a significant proportion of Fera's work is UK-based, it has global reach across Europe, and five of the other six continents, the exception being Antarctica. Fera manages over 600 research projects, analysing over 50,000 plant and food samples a year and is the National Reference Laboratory for chemicals in food, pesticides, veterinary drugs, dioxins and polychlorinated biphenyls (PCBs) in feed. CSL, as it was, before becoming part of Fera on 1st April 2009, invested in a data management solution to improve efficiency and key parts of sample management across the laboratory.

BUSINESS CHALLENGE

Fera's main laboratory facility is located on a 32-hectare site at Sand Hutton near York in the United Kingdom. The laboratory has specialist areas of analysis and testing using in-house LIMS developed by scientists on site. In 2003, with the aim of establishing both best-in-class practice and laboratory-wide consistency of approach, what was then CSL outlined a requirement to invest in a corporate LIMS. Its stated aim was to deploy a central numbering system for samples across the entire site to ensure sample integrity. The intention was simply to ensure that there was only one #1 sample on site, and not multiple samples with the same number in the different areas of work. Being a government organisation added additional pressure to display a level of professionalism—Fera specified that in order to have credibility it required robust processes and that investing in a LIMS would support this objective.

Fera wanted to maintain its reputation as one of the best units in the world, and ensuring that all samples are well managed is a crucial part of this objective. A A Laboratory Information Management System (LIMS) would dramatically reduce the amount of error-prone paper work, minimise mistakes and expedite sample management. Fera initially created and operated an in-house LIMS, however there was too much pressure on one in-house member of staff to support the needs of the laboratory, both in terms of back-up support and also in terms of professional future proofing. Fera required a LIMS to manage all samples on site within a single repository. An automated system was also required to manage the issue and reconciliation of laboratory worksheets across the laboratory. Analytical trend data was being recorded and assessed manually, so there was a need for a LIMS system that would readily generate trend data in an acceptable format to support internal investigation and reporting functions.

REQUIREMENTS

The initial decision to purchase a LIMS was a corporate decision made in 2003 by what was then CSL. The team posted an OJEU (Official Journal of the European Union) notice and created a user-group committee, consisting of chemists, laboratory managers, laboratory technicians, QA, etc. to evaluate tenders. At the time of decision, one work area alone was processing 10,000 samples with 100,000 results (this number has now grown five-fold to 50,000 samples). The LIMS was a fit with Fera's stated objective to expand capacity and has provided the ability to move up to millions of data rows. The Oracle database allowed Fera to scale up to meet future unknown requirements. LIMS provide a flexible solution that can be tailored to different projects—for Fera this was key. Fera wanted a system that could be tailored to their multiple diverse requirements.

IMPLEMENTATION

The original usage of the LIMS was standard and followed basic laboratory requirements. The LIMS was required for: package receipt for chain of custody; sample login and storage; bar-coded labels; and results and reporting.

The opportunity was also taken to simplify some of the existing working practices wherever possible and build new processes to take advantage of the flexibility and functionality provided by the LIMS. Today, samples are logged into a central repository, which includes the following steps: setup, sample receipt, login, numbers, barcodes, and ship to labs. Fera set up a central sample reception facility that was secure and allowed in-situ login to the LIMS and storage of the samples. Login of samples is site-wide. There was an immediate mandate that the Fera laboratory had to use the LIMS to login samples across the entire site, from day one. Since original selection, the Fera LIMS team has been
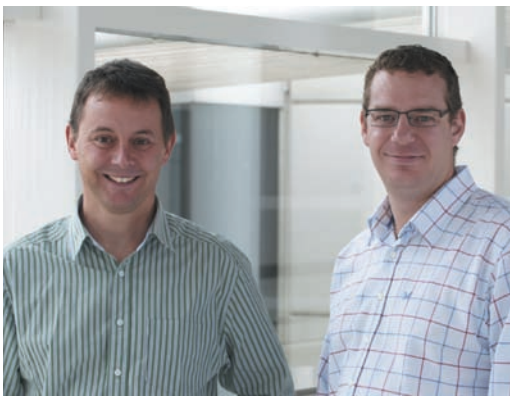
consistent and is still 75% as it was at the outset in 2003. The team consists of former scientists who have moved into the LIMS role. The LIMS does not just support the sample handling; Fera also uses the LIMS to help generate income for the business. The project has grown, so the selection of a flexible LIMS has given Fera the ability to grow with the business, and has allowed Fera to be more competitive. Fera's use of the LIMS has expanded as the organisation has changed. Fera has had some major success using the features of the LIMS to enable the organisation to help win and deliver new work and projects.

POST-IMPLEMENTATION BENEFITS

The LIMS has been in use at what is now Fera's Sand Hutton site since 2004 and is used by over 200 staff. The major benefit realised at Fera since the installation of the system is improved operational efficiency. The LIMS solution provides Fera with a full sample recording, management and reporting system. Since its implementation, the LIMS has operated efficiently and has proven a significant benefit to Fera. Data is entered one time only and is shared among all departments as necessary. At sample intake, the LIMS has improved the efficiency and security of data entry and has greatly assisted sample identification and tracking by printed and automated label generation. As all samples are now recorded on a single electronic database, the LIMS has provided Fera with a means to retrieve and report data in a way that would never have been possible previously. Laboratory personnel can easily configure the LIMS to suit the individual workflows of the very different laboratories. For example, Fera's Molecular Testing Unit has seen significant time savings since the implementation of the LIMS. Before the system was installed, 384 plate-well values had to be recorded manually by hand which could take over an hour to complete. With a LIMS, this step can be completed within minutes. In the Food Analytical Services area there also have been substantial improvements in laboratory efficiencies. Using the LIMS, the laboratory is now 95% paperless and saves 25-30% of lab time. As there is no manual recording of data, transcription errors are eliminated. With regards to commercial benefits, the LIMS offers Fera the ability to communicate efficiently and effectively with its customers. All reports can be published online via Fera's existing secure web applications so clients can quickly and easily obtain relevant information about specific samples and download data electronically. Communication and data transfer between Fera and its customers is totally seamless and secure.

Fera has undertaken large microbiological projects using LIMS-generated sampling forms and labels to allow staff at Fera to take meat samples from butchers and supermarkets all around the country. These were then received back into the LIMS via their barcodes. The customer used Fera's secure web portal to check the status of samples and could review the results after the lab had completed the testing. Final reports were unnecessary because the customer had the ability to download the data themselves. The laboratory staff found the best savings came from the automatic generation of over 7,000 labels a week via the LIMS during the project. In addition, the LIMS has the potential for integration with other business systems. With this LIMS in place, Fera is confident that they can meet any future challenges.
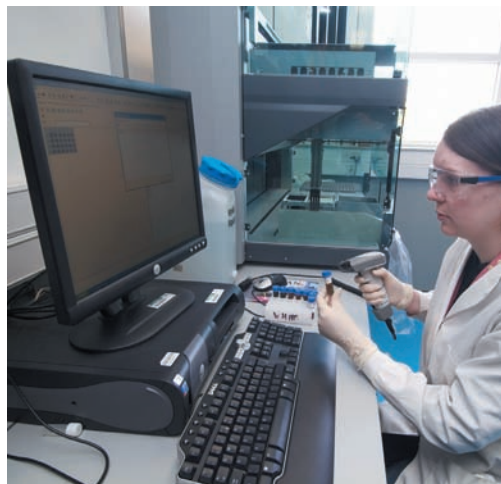
FUTURE PLANS

Some work areas currently use LIMS for sample login only. The LIMS team has a two-year program ahead to roll out the LIMS into other areas of the laboratory for everyday use. Fera is also looking at ways to incorporate handheld PDAs to improve the efficiency of sample management and data collection. Data can be transferred directly between a geographic information system and the LIMS database, meaning that in the event of a contingency situation data would appear in the central server within seconds of it being captured in the field. Fera is currently evaluating an upgrade for use in a new work area. The LIMS upgrade continues to demonstrate the success of the LIMS implementation at Fera, with added functionality in a number of key areas including user interface, workflows, plate handling and data management.

In the future, the team plans to integrate the LIMS with additional laboratory instruments (several laboratories have already integrated instruments, such as balances, in their LIMS workflows). Integrating the LIMS with as many pieces of laboratory equipment as possible will allow for automated data transfer and additional efficiencies. Fera is working in an enhanced commercial environment. Its customers are under increasing financial pressure to outsource projects with minimum cost, which drives pressure onto Fera to deliver professionally, on-time and within budget. Having invested into a LIMS for its organisation, Fera uses the system as a tool for operational sample management making the laboratory more efficient. Fera reduces costs by eliminating paper reports, working electronically and involving its customers in the project by giving them access to their results electronically in real-time. Only with a LIMS can Fera continue to manage so many diverse projects across such a large laboratory.

THE ROLE OF LIMS IN FOOD SAFETY TRACEABILITY EFFORTS

Colin Thurston, Director of Product Strategy, Process Industries, Thermo Fisher Scientific

Globalisation of the food supply chain is one of the main driving factors of the ever increasing number of alarming food safety incidents. In order to ensure finest product quality and compliance with food safety legislation, producers and importers must perform precise, real-time product safety testing at all stages of production, processing and distribution. Each step in the food chain is associated with certain safety challenges to be addressed. Laboratory Information Management Systems (LIMS) play a critical role in the work-flow of food producers, ensuring that test data from all parts of the delivery chain, is captured and analysed so that the safety of the consumer is guaranteed.

Major food producers importing and exporting from/between the U.S. and Europe are guided by the U.S. FDA and the European Food Law. Batch traceability is key in the effort to monitor product quality, effectively manage any recalls and limit product loss. The term traceability in European Food Law (178/2002) is defined as the ability to trace and follow a food, feed, food producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution.

Ideally, any substandard components should be detected during the crop growing, raw materials collection or processing stages, preventing unfit products from reaching the public. In cases when substandard products have been released, the traceability of the product batches affected can lead to a much more effective recall and prevention program, thus limiting the manufacturer's exposure to costs and possible litigation.

Sophisticated LIMS solutions are designed to efficiently manage batch relationships between raw materials, processed materials and packaged goods enabling analysts to identify which batches are affected by any contamination and automatically suspend release of a product during investigation. LIMS are designed to manage and control the quality assurance process, organising and storing analytical data and facilitating the conversion of data to information. This process is fully automated, ensuring that the majority of sample results will be within acceptable limits and filtering and highlighting failures to initiate follow up investigation. The LIMS workflow schedules analytical work up for samples with positive results addressing the need for fast screening techniques to identify potential contaminants.

Food analysis techniques produce large quantities of different types of data. LIMS are used to automatically gather, store, manage and report on these data including sample preparation data, instrument generated data, standards, reagents and media, reference data for users and management and metric reports.

Food samples used for safety testing are often time and condition sensitive requiring fast turnaround or storage in suitable conditions. LIMS are capable of identifying each sample, uniquely generating labels, barcodes and hazard data and storing metadata and sample lifecycle transactions. Freeze thaw cycles and preparation steps are logged, sample inventory is maintained and work for laboratory staff is prioritised. Overall, the use of LIMS in the food safety workflow ensures that samples are handled correctly and processed within allowed timeframes.

Food producers and importers face strict penalties for non-compliance with food safety legislation. At the same time, food recalls are very expensive to carry out both in terms of financial costs and reputation. The ability to trace the components used at any point in the food manufacturing and supply chain is a critical function in ensuring product quality and regulatory compliance. Batch traceability can be easily and effectively achieved using a LIMS solution. LIMS controls the sample chain of custody, automates data collection from instruments and analysers, manages data by exception and facilitates certification. The LIMS collects results directly from instruments and determines whether they are within acceptable limits, making it an ideal tool to manage quality data for food producers and importers alike.