

# LIMS: AN EXECUTIVE PERSPECTIVE

NGP talks with **Dave Champagne**, Vice President and General Manager of Thermo's Informatics Business, about the future of laboratory information management systems.

**T**hermo Electron Corporation is the worldwide leader in laboratory software and related services, providing enterprise-wide, multi-laboratory solutions that have become the corporate standard at leading organizations. The company's LIMS and CDS are facilitating laboratory data in the world's leading pharmaceutical companies, petrochemical and chemical plants, food and beverage manufacturers, and other major industries. To support its global installations, Thermo provides implementation, validation, training, maintenance and support from the industry's largest worldwide informatics services network.

**NGP. What is a laboratory information management system (LIMS)? How is it used?**

**DC.** First developed nearly three decades ago, LIMS have evolved from individual laboratory computing solutions to store and provide access to laboratory data into enterprise-wide systems that drive business decisions. Today's LIMS yield real-time analysis and reports, monitor regulatory compliance and product quality, integrate with a company's broader network, provide secure access to data throughout the organization and provide much more functionality than merely storing and retrieving results.



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**NGP. Thermo's Informatics business places a special focus on creating and implementing LIMS tailor-made to the needs of the pharmaceutical industry. Why is that? What is so special about that industry?**

**DC.** The combination of global regulatory compliance, long-term data traceability and complexity of laboratory testing, as well as the emphasis on batch versus continuous process manufacturing, have, for decades, forced pharmaceutical companies into lengthy, costly adaptations of generic LIMS to meet their specific needs. Extensive customization and implementation periods – in many cases taking 36 months or more – have become commonplace. And the increased system complexity created by extensive customization can result in decreased productivity.

**NGP. What is the future direction of LIMS and how do Thermo's solutions fit in?**

**DC.** According to the 2005 Worldwide LIMS Survey by Strategic Directions International, Inc., the LIMS market was over US\$325 million in 2004 and growing at approximately 8-10 percent over the next five years. Growth drivers include consolidation and standardization that will replace numerous, smaller existing LIMS installations at large pharmaceutical companies, as well as aftermarket support and service. The survey further reveals that: “The more a user needs to

deviate from an ‘out-of-the-box’ LIMS solution, the greater the investment is for custom software, implementation and validation.”

Thermo believes that the special challenges facing the pharmaceutical industry can be ideally addressed using commercial off-the-shelf (COTS) solutions that provide as much application-specific functionality as possible – out-of-the-box – to meet the particular needs of various laboratories. When the required functionality is built into the base system as standard, it eliminates the need for user-specific customizations during implementation. This, in turn, results in reduced validation, shortened deployment and easier ongoing support.

Additionally, global deployments are more consistent and more rapid, while system upgrades are simplified, project risks are minimized and compliance is enhanced. Furthermore, COTS solutions facilitate enterprise-wide application and training. These multifaceted benefits help lower the total cost of ownership of the solution, which is critical to pharmaceutical customers because the industry is under ever-increasing pressure to contain costs and increase efficiency, in part through global harmonization of business processes.

In an attempt to relieve some of this pressure, Thermo provides four distinct COTS LIMS solutions for the pharmaceutical industry to support early stage R&D, particularly in biotechnology, *in vitro* ADME/Tox research, bio-analysis, and manufacturing R&D and quality control. Each system is built specifically to address as much as 85 percent of the user requirements for a particular laboratory or application, significantly reducing project risk, implementation time and cost, and future upgrades and validations. A generic LIMS typically provides 30-40 percent of required functionality out-of-the-box.

### **NGP. What functionality makes Darwin, your latest LIMS, specific to pharmaceutical development and quality control?**

**DC.** Thermo has built extensive pharmaceutical functionality into Darwin to deliver rapid deployment, validation and training in a fraction of the time generic systems require. For US Food and Drug Administration (FDA) and International Conference on Harmonization (ICH) regulatory compliance, there are activity- and event-based system privileges that better correspond with users' work responsibilities. Furthermore, Darwin can be delivered with the flexibility to be used in non-GMP mode for analytical development, allowing researchers greater flexibility during exploratory work, or GMP mode, to enforce adherence to company standard operating procedures (SOPs) and regulatory guidelines.

Darwin also features a comprehensive test library that includes complex pharmaceutical testing methods for dissolution, dosage unit uniformity, product assays and a stability module that simplifies the process of designing, implementing and managing stability studies. All this functionality is supported by the helpdesk, covered in the user manual, which can be seen in the demo and is incorporated into Thermo's upgrade process.

As a built-for-purpose solution, Darwin provides functionality to address aspects of the pharmaceutical industry such as:

- Pharmaceutical workflow.
- ICH guidelines.
- Pharmaceutical methods (dissolution and content uniformity).
- Enhanced stability study management.
- A detailed, pre-configured test library including tests for assay (HPLC, GC, GC/MS, LC/MS, TLC, etc.); pH; percentage loss on drying (%LOD); and dosage unit uniformity (content uniformity or weight-based uniformity), with integrated USP 3 stage test limits and automatic scheduling of subsequent stages when required.
- Dissolution testing, with integrated USP 3 stage test limits and automatic scheduling of subsequent stages when required.
- Appearance (supports multimedia for direct comparisons with stored images).
- An advanced n-tier system architecture based on XML and Microsoft .NET to allow complete scalability and system extensibility to add custom functionality and integrate with external systems.
- Sample management and facility management to allow sample tracking to be as basic or as detailed as desired.

### **NGP. How did Darwin emerge?**

**DC.** Darwin was designed based on the proven concepts of SampleManager LIMS, Thermo's flagship enterprise system that is a corporate standard at leading companies in multiple industries. However, Thermo's development strategy has been extended to make use of open standards and Darwin's development is based on the Microsoft .NET framework, using n-tier architecture and web services. This allows users to extend the system using open industry-standard tools rather than proprietary programming languages or scripts. SampleManager customers in the pharmaceutical industry are eligible to migrate their SampleManager application to Darwin, saving on future customizations to their existing systems.

### **NGP. As a COTS solution, is Darwin flexible?**

**DC.** Absolutely. Darwin can be configured to address the specific workflows of any pharmaceutical company. For example, users can modify screens and develop reports to meet their unique needs without custom coding or IT involvement. If more complex special needs are required, such as integration with a custom in-house system, Darwin is completely extensible. It does not rely on

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proprietary tools from the LIMS vendor, but rather uses industry standard Microsoft Visual Studio tools and skill sets that are readily available in the marketplace or in the internal IT department.

### **NGP. What geographic territories does Darwin address?**

**DC.** Darwin is designed to comply with ICH guidelines, supporting regulations in North America, Japan and Europe, as well as other leading regulatory bodies around the world. Darwin is sold globally through Informatics local offices and via Thermo-preferred distributors in other parts of the world.

### **NGP. What role will SampleManager play in the future?**

**DC.** We will continue to develop and support SampleManager. Over the next couple of years, we will systematically upgrade certain architectural elements of the product to fit into our unified informatics technology platform. 2006 will see the release of the latest version of SampleManager as the basis for COTS functionality for industrial laboratories. This new version will also support the .NET framework and will share common components with Darwin while continuing to support VGL code for existing customers.

### **NGP. What is the importance of automation?**

**DC.** Thermo has a very broad and deep portfolio of analytical instruments, scientific equipment, automation tools and software to serve the life and lab science marketplace. We are uniquely qualified in providing 'whole product' solutions to the market that combine LIMS and chromatography data systems (CDS) with instrumentation, detector technology and automation (e.g. robotics). Our open, unified architecture will share an XML-based middleware layer that will be performance-tuned to communicate and work seamlessly with all major instruments and automation available in the marketplace, whether they are Thermo's or a competitors. This initiative is currently well under way in our product development group.

### **NGP. What is Thermo's strategy regarding open standards?**

**DC.** Thermo will continue to be an open systems supplier. We understand that all customers operate in a heterogeneous technology environment and their success, as well as ours, is dependent on ensuring that all these technologies can work together as seamlessly as possible. Customers will continue to put pressure on those vendors who maintain a proprietary stance with their technology. The trend is to open up to cooperation with other vendors who provide other key software and hardware essential to the user's businesses. ■

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