



A Company and Product Overview



Company Background

LabWare, Inc. is a privately owned company with its worldwide headquarters in Wilmington, Delaware. The company specializes in the design, supply and support of enterprise-scale LIMS solutions. Since its registration in 1988, LabWare has continued to grow with no external funding or net borrowings. We are an exciting and innovative company whose robust growth is being achieved in a manageable fashion.

Laboratory automation is the core business of LabWare, and our primary focus is Laboratory Information Management Systems (LIMS). Our flagship product is LabWare LIMS, which includes an integrated instrument-interfacing module called LabStation. LabWare is not owned by any outside parent company or investor group, nor is LIMS a small sideline business for us. Furthermore, LabWare is not distracted by having to support multiple LIMS products. A company can only have one “top” priority. In LabWare’s case that priority is very clear; LabWare is focused exclusively on LIMS, and directs all of its effort toward a single functionally diverse product – LabWare LIMS v5.

LabWare is recognized worldwide as a marketplace leader. LIMS Administrators and end-users consistently rate LabWare, Inc. at the top of the industry in customer satisfaction, and as the company with the best and most innovative technology. LabWare LIMS v5 is differentiated by its rich functionality and by its configuration-driven approach to meeting customers’ business requirements *without resorting to customization*. Our company is founded on the philosophy of offering the most comprehensive LIMS features out of the box, and enabling these features to be tailored by the customer using configuration dialogs and editors, thus avoiding a reliance on customization and code development. LabWare believes that customization is fundamentally the wrong approach because it places the customer at significant risks. The short-term risk is in having its implementation delivered late and over budget due to the enormous design and testing burden, as well as the technology learning curve the project team must endure just to be productive. The long-term risks are in the difficulty of upgrading, the complexity of technical support and, for regulated companies, the difficulty of validation.

With LabWare LIMS, all of the configuration settings that define the way your systems will function are stored in the LIMS database and are completely audit-trailed by the application. Configuration does not change the base product or the source code in any way. With alternative LIMS products, business requirements can only be met by altering the product source code, or by creating programmatic extensions to the system that have source code dependencies. In many cases, these changes and additions are NOT stored in the database, nor are they automatically audited. They are stored in text files that must be compiled before they can be used, and even in cases where they are created as stored



procedures, they are not controlled or audited in any way within the application and must be managed. The LabWare approach greatly reduces risk, complexity and testing [validation] effort. In the long-term, LabWare customers are able to stay current with our technology because the product supports an automated upgrade process that can migrate all configuration settings to the new version.

About the LabWare LIMS Architecture

LabWare LIMS is an object-oriented Client/Server application designed specifically for the Microsoft Windows graphical user interface. From its original inception the product has evolved in its current development environment and with its current architecture, and there has never been a major product transition necessitated by technology (for example, the migration of pre-Windows legacy code). It is developed entirely in the industry's most functionally robust object-oriented programming language, for which a full ANSI standard specification has been available for over 20 years. Therefore it is not associated with or reliant upon any commercial vendor for its support, making its *long-term viability* assured and providing an unprecedented degree of stability and investment protection for our customers.

LabWare LIMS conforms to all applicable industry standards and protocols. LabWare LIMS uses standard ODBC 3.0 drivers for database communication, and operates over TCP/IP. Citrix technology is fully supported and is one of the most proven technologies for deploying LabWare LIMS across a wide geographic area. LabWare LIMS also includes full support for XML-based data exchange. All LIMS records can be imported and exported using XML format. XML viewers have been built into LabWare LIMS 5.0 that can parse XML documents and view information from XML data structures.

LabWare LIMS offers a Web-based interface using a J2EE compliant application server. The J2EE server and LIMS application server communicate using XML messages compatible with the Industry Standard SOAP protocol over TCP/IP.

Numerous mechanisms are available in LabWare LIMS to interface with other systems and databases. The system has the ability to issue any SQL statements against another database system, and also includes a full-featured built-in scripting language called "LIMS Basic", which enables the customer to implement fully supportable customer-configured extensions to the application's functionality. LabWare LIMS provides for the creation of flexible subroutines and triggered events allowing a sequence of steps to be automated. These subroutines are often employed to facilitate communication with other external information systems. LabWare LIMS also includes a Database Management Utility that allows records to be imported to or exported from the LIMS database via CSV formatted ASCII text files.



LabWare has collaborated to develop embedded LIMS functionality and features that enhance the level of integration with systems provided by strategic business partners such as Waters NuGenesis for its SDMS solutions as well as for the Millennium³² and Empower Chromatography Data Systems, SAP for R3 and R4, Northwest Analytical for its Quality Analyst OCX technology, and Documentum for its GxPharma EDMS. LabWare makes these integration features available as modules, available at no additional license cost.

Instrument interfacing is accomplished with our own integrated LabStation module, which is a built-in module of the LabWare LIMS application. This powerful software component makes it possible to interface with virtually any instrument or instrument data system, including RS-232 devices as well as software-controlled instruments such as chromatography data systems and other types of intelligent instruments.

About LabWare's Version Release Model

Since the product's initial release in 1994 there have been 5 major releases of LabWare LIMS, the most recent of which began shipping during February 2003. Customers are never forced to upgrade, and can continue receiving technical support from LabWare regardless of the release version that they are operating. LabWare's product release model is closely linked to its quality system, which consists of standard operating procedures governing the entire development life cycle, and which includes online systems that control and document all software changes. LabWare LIMS is extensively tested prior to each software release utilizing formal test plans and scripts. A traceability matrix is used to cross reference functional requirements and capabilities to user documentation, functional specifications, and test plans. To add further assurance that the software performs as expected and documented, LabWare engages an external validation consultant to execute the test plans and to sign off on the software prior to release. All LabWare products are released only when the external validation company certifies that all test cases have tested successfully, and that everything essential to product release is complete and in order.

The continual enhancements that LabWare makes to LabWare LIMS are provided to customers in the form of Modules that are released on an incremental basis. LabWare tries to release a new module every several months, based upon customer-driven input and enhancement requests. *These modules can be added to an existing LabWare LIMS environment without requiring the customer to upgrade to a new version of the system.* This minimizes the impact of adding new features to existing installations, and also aids in keeping our customers "current". If a particular customer does not require or desire an available module, then they don't have to load them.

All of our product development follows the LabWare Quality System, which includes a System Development Life Cycle (SDLC). The name for the approach is the “Spiral Model”. Major elements and deliverables of this model include:

- FRS – Functional Requirement Specification
- SDD – System Design Documentation
- User Manuals
- Training Programs & Manuals
- Test Plan & Scripts
- Test Records
- Traceability Matrix
- Installation Guide

LabWare has an SOP for coding standards, and they are followed during development. Code is audited and checked for compliance with the coding standards. SOP’s and on-line systems are used to control changes. Policies and procedures exist to control changes associated with the Quality System and Programs.

All program changes are tracked using on-line systems called DevTrack and LabTrack. These systems are available for inspection during a vendor audit. All customers that have an active software maintenance plan have access to these on-line systems and may use them to download new modules, and all other code made available by LabWare. The LabWare LIMS application includes upgrade and migration utilities that fully automate the transition from one major revision level of the system to the next. The installation of individual enhancements (or Modules, as they are referred to in LabWare terminology) is a comparatively minor undertaking. The module, which is packaged into an SLL file and “published” by LabWare (i.e. made available to customers through our on-line support service) can be downloaded by the customer and stored in a directory on their LIMS system. The SLL is then bound to the LIMS application, and when LabWare LIMS next launches, the file will be processed by the application and its features will be expressed in the system.

About Customer Involvement in the Product Enhancement Process

LabWare responds positively to requests from customers to participate in pre-release field-testing, and from time to time, makes requests for volunteers from among the customer base, depending on the functionality of the individual module or the overall revision. In order to best understand this area, it is helpful to understand LabWare’s overall product enhancement model. LabWare solicits input regarding required new functionality from its customer base. If a customer submits and sponsors a request for a new feature, and if the decision is made to



undertake the development of that feature, then LabWare normally engages that same sponsoring customer to assist in the design of the feature and also to act as “alpha” tester. “Beta” testing is more applicable to new release versions of the overall product. Commonly there are up to 10 customer beta testers. As one would expect, LabWare approaches this testing in a structured manner, recording all test activities and outcomes in our internal tracking database.

A good example of how LabWare has worked very closely with a customer is a case involving one of the world’s largest manufacturers of heavy machinery and industrial engines. Collaboration began during 2002 with a specific focus on deployment of LabWare functionality via a web browser interface. The solution that resulted from this effort has led to the evolution of LabWare’s current LabWare Web LIMS capability. This same customer also participated as the primary alpha tester of LabWare’s Interpretation Manager Module, and as a beta tester of the current LabWare LIMS v5 product. As a result of these activities, LabWare LIMS has been very rapidly deployed at multiple sites within this customer’s enterprise employing a combination of both served thin client and browser-based user interfaces, and at the same time has included enhanced features that were not previously available in the software.

About Regulatory Compliance

Because of the manner in which LabWare LIMS is configured rather than custom-coded, customers never waste valuable time re-implementing functionality when upgrading to a new version. This benefits all customers, but is of particular value to customers whose LIMS systems are subject to FDA regulation or oversight by other regulatory agencies. LabWare LIMS v5, as well as LabWare’s business processes, are designed to surpass compliance regulations and to exceed auditor’s expectations. LabWare LIMS was one of the very first applications to become 21 CFR Part 11 compliant when Version 4.0 shipped in June 2000. Since that time, LabWare has been working with numerous customers in the pharmaceutical industry and experts on Part 11 to enable our product to meet the various company-specific interpretations of Part 11. Our configurable approach to LIMS enables a customer to adjust the security settings and Part 11 specific business rules in LabWare LIMS in order to tailor the system to meet its regulatory requirements. We are the very first LIMS provider to embrace Public Key Infrastructure (PKI) technology and Digital Certificates & Signatures. This technology allows digitally signed Part 11 electronic records to be reviewed and used outside of the LIMS environment that originally created them. We believe this technology represents the future for how Part 11 compliance will be achieved by multi-site laboratories that must inter-operate together in a synergistic fashion.



LabWare's company mission and vision for the future is to provide technology and solutions that will enable pharmaceutical laboratories to move towards a more paperless environment. To this end, LabWare has developed a novel solution that allows laboratories to replace their paper-based Analysis Worksheets with an all-electronic equivalent. The Electronic Worksheets feature of LabWare LIMS brings together all of the supporting analytical data for a series of similar samples or tests, such as sample preparation data, standards & reagents, and processed chromatograms or instrument reports placing them together in a single secure PDF document. Because LIMS assigns each Electronic Worksheet a unique identification number, they can be instantly recalled and displayed. During the review cycle, appropriate individuals within the organization can digitally sign the Worksheet. Working with our strategic software partners, such as Waters NuGenesis (CDS and SDMS), Documentum (EDMS), and SAP (MRP) we have built interfaces to allow analytical workflows to occur between these systems without the need to generate extra disk files. For example, the Waters Millennium³² and Empower Chromatography Data System can be seamlessly operated directly from within LIMS, and data can be shared between LabWare LIMS and these systems in a programmatic and Part 11 compliant manner.

LabWare is very confident that our business approach and momentum in the marketplace make us the best LIMS partner for pharmaceutical and consumer product companies.

About Deployment Options

LabWare LIMS supports a wide range of deployment options, which are briefly described in the following paragraphs. It is important to note that these may be used in combination, and need not be system-wide approaches. This will enable you to choose the approach that best suits each part of your business.

Stand-Alone:

All files are installed on the client, including a Microsoft Access database. All software runs on the client without requiring any network connections. This option is useful for development, training and evaluation purposes. (LabWare does not support the use of Microsoft Access in a multi-user environment.)

Thick Client:

All files are installed on the client. The software runs on the client and accesses a database using ODBC.

Served Client:

Most files are installed on a file server and a small number of files are installed in the client's working directory. The executables are served from the file server to

the client, and they then execute on the client. The local files are configuration files that are static in nature and are not altered during system upgrades. The client accesses a database using ODBC.

Thin Client:

Most files are installed on a file server and a small number of files are installed on a terminal server (e.g., Citrix). No LIMS files are installed on the client. The software runs on the terminal server and accesses a database using ODBC. The communication between the terminal server and the client consists of keystrokes, screen information, and traffic to any mapped ports for printing or instrument data capture.

Web Client:

All of the files are installed on an application server in the same manner as they would for a Thick Client or Served Client installation. The web interface software is installed on a J2EE compliant application server. The J2EE server and LIMS application server communicate using secure XML SOAP messages over TCP/IP. The LabWare WebLIMS initiative exposes substantially all of the end-user functionality of LabWare LIMS, and may co-exist with any other deployment scheme described here. This enables the LabWare LIMS customer to deploy the application using the web, as it deems appropriate, but does not force the customer into a “web-only” deployment strategy. LabWare WebLIMS runs on any J2EE-based web application server without requiring the use of any applets or plug-ins. This option also places the customer in a position to exploit the power of Web Services in their enterprise. The web user interface reflects the system’s underlying LIMS configuration and therefore honors all business rules, template configurations, and security settings that have been established.

About Technical Support

LabWare provides technical telephone-based support services via a technical support hotline. Support services are provided from Wilmington, DE; Manchester, England; Sydney, Australia; Johannesburg, South Africa and Almaty, Kazakhstan permitting “follow the sun” support around the world. Many of LabWare’s customers prefer to use email-based communication for technical support, and that mode of interaction is fully endorsed within LabWare. The support desk operates during standard business hours on normal working days, and identical best practices are followed at each of the regional support locations. In addition, LabWare offers extensive on-line support services that allow 24-hour instantaneous access to LabWare’s knowledge bases, its technical white papers, a defect tracking system, a feature request system, and a system to download LabWare’s extensive list of LIMS software modules. Upon receiving a support call, LabWare will initially attempt to answer questions and resolve problems over the telephone or (in kind) via email. Calls are registered, and



support procedures and tracking systems are utilized, to promote efficient interaction with the customer and to bring about rapid resolution to problems. Additionally, the LabWare LIMS product has the ability to create a "Support Log" that creates a snapshot of the customer PC client configuration and the contents of other LOG files that can be used to diagnose a particular problem. In the most difficult to troubleshoot problems, LabWare may request the customer to make a copy of the LIMS database configuration and FTP this file to the LabWare Secure Support Website. LabWare provides a tool with the software that allows customers to migrate the LIMS database from one vendor's RDBMS to another, and this enables LabWare to assist the customer regardless of what RDBMS platform that customer has chosen for its LabWare LIMS system. With prior planning and sufficient notice, LabWare is very willing to assist your company with any appropriate "over the weekend" support activities, such as a product upgrade performed during weekend hours, etc. One of the most popular support services LabWare offers is the LW-LIMS email-based discussion list server. This is a 24x7 email discussion group that all LabWare customers, our implementation consultants, and all LabWare employees participate in. A LabWare customer can post a question "to the list" and get rapid feedback, opinions and help from other customers, our worldwide consultants, and of LabWare's development staff.

LabWare customers enjoy the instant accessibility of the our online support mechanism, and can also call any of LabWare's offices for support, essentially providing a "virtual" all-day window of coverage that meets even the most active and extensively deployed customers' needs.