

SAP Solution in Detail
SAP ERP



ENABLING AN INTEGRATED ENTERPRISE LABORATORY INFORMATION MANAGEMENT SYSTEM WITH SAP® ERP

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EXECUTIVE SUMMARY

Over the years, laboratory information management systems (LIMS) have evolved from custom-developed in-house systems used to track data in quality labs to proprietary commercial products. More recently, LIMS have evolved into standards-based systems. As a result, companies are beginning to think in terms of “enterprise LIMS” that not only support the full range of functions within the laboratory, but also are integrated with systems throughout the company.

The challenges labs face as they manage quality relate to turn-around time of lab tests, access to results data, accuracy of analyses, resource utilization, data exchange, record keeping, and productivity. The SAP® ERP application has a full range of quality management functions to address these challenges – in both commercial and industrial laboratories. In addition, SAP ERP offers an integrated LIMS as part of a larger, more comprehensive quality management solution, simplifying implementation and integration, as well as streamlining quality processes.

Because SAP ERP is the backbone of many companies, the integration of quality management functions into other logistical processes is seamless. To help your quality management efforts, SAP ERP provides open interfaces and leverages enterprise service-oriented architecture, enabling integration with other SAP and non-SAP solutions across the organization.

With the integrated approach supported by SAP ERP, companies are well positioned to embed quality-assurance endeavors into a variety of processes, from manufacturing to logistics to finance. This, in turn, stimulates efficiency in information sharing, data analyses, and reporting. Companies can cut costs and delays out of quality processes – both within the laboratory and across the company – and, ultimately, support improvements in product quality and customer satisfaction. As a result, the application can provide rapid ROI initially and lower total cost of ownership over time.

THE EVOLUTION OF LABORATORY INFORMATION MANAGEMENT SYSTEMS

A typical laboratory information management system (LIMS) is used to manage the complete testing routine – from logging the sample into the system, to testing, retesting, and final reporting. In today's global companies, the same laboratory can act as both a commercial and an industrial laboratory. Because of this, it is important that a LIMS can cover both cases.

To ensure effective laboratory management, it is becoming more important to have instant access to all relevant supply chain data. In an environment of globalization and outsourcing, companies need solutions that can work across company boundaries. As a result, instead of buying an isolated LIMS, companies are increasingly turning toward software that integrates the traditional LIMS functions into their other business processes. This results in added value for the company in terms of cost and time savings, and brings about improvements in data, process, and product quality.

Over the last few years, customer feedback and analyst reports indicate that a more integrated approach to LIMS increases operational performance, efficiency, agility, flexibility, and customer responsiveness. This can lead to significantly lower costs in the manufacturing process – a requirement in light of global competition that is forcing manufacturers to improve their return on assets and investments. In the end, there is a greater demand for a sophisticated LIMS that goes far beyond the traditional boundaries.

With a comprehensive and integrated enterprise LIMS, companies have an opportunity to greatly improve information sharing and link quality efforts. This will ultimately increase speed, efficiency, and accuracy across the organization.



SAP® ERP, QUALITY MANAGEMENT, AND LIMS

The SAP® ERP application includes functionality for quality management that supports many quality-related scenarios that are especially relevant to the process industry. The application is a vital tool to support analytical laboratories, as well as a means to open new options for companies that need LIMS.

Moreover, quality management with SAP ERP offers a comprehensive range of functions reaching far beyond the borders of traditional LIMS. These encompass processes such as inventory control and batch tracking, integrated problem solving and event handling, instrument calibration, and even audit management.

SAP ERP is more than just another LIMS. Unlike traditional LIMS, it offers seamless integration into the supply chain and other key areas within the enterprise. By enabling companies to take an enterprise approach to LIMS, SAP ERP does the following:

- Provides a standard basis for integrating quality management processes across the enterprise
- Enables visibility of quality data throughout the organization
- Enhances communication between quality groups and other departments

This integrated approach means that quality management functions can be embedded easily into business processes such as procurement, manufacturing, or controlling, helping to eliminate redundant data and increasing information transparency throughout the organization. On a more technical level, integration means having fewer systems and interfaces to maintain. Overall, the simplicity of SAP ERP as a LIMS can help companies reduce costs and increase profits and customer satisfaction through the following:

- Reduced workload for system administration, reduced training, and fewer upgrades by not using numerous fragmented systems
- Better process quality with standardization, increased efficiency, and ease of collaboration
- Better product quality, fewer defects, and less rework and waste
- Increased accuracy and security of data, which reduces costs associated with regulatory compliance
- Improved data quality and visibility because data is consistent, transparent, and available throughout the company

KEY FEATURES OF QUALITY MANAGEMENT WITH SAP ERP

Quality management with SAP ERP covers all common functions of a LIMS. A generally accepted definition says that a LIMS should support the full range of laboratory processes and include core functions such as the following:

- Master-data management (organization, samples, and methods)
- Inspection plan management (specifications and characteristics)
- Order management (work scheduling, status tracking, and quality-related costs)
- Results recording (validation, plausibility, and specification checks)
- Release (inspection results, samples, and batches)
- Laboratory statistics (certificates of analysis [COA], statistical process control [SPC], and key performance indicators)
- Data retrieval and archiving
- Work lists and workflow

For a comprehensive list of LIMS functions within SAP ERP, refer to Appendix 2.

SAP ERP offers an enterprise-wide quality management solution that provides added value through the following:

- Integration with SAP ERP (procurement, manufacturing, inventory and warehouse management, sales and distribution, plant maintenance, and controlling)
- Integration with other SAP software including SAP Product Lifecycle Management application; SAP Recipe Management application; SAP Collaborative Project Management application; audit management with the SAP NetWeaver® platform; SAP Environment, Health & Safety application; SAP Supply Chain Management application; SAP Customer Relationship Management application; and SAP NetWeaver Business Intelligence component
- Collaboration with business partners beyond company borders (Web scenarios for recording results, handling complaints, and issuing certificates of analysis)

Refer to Figure 1 to see how quality management is integrated into the different components of an enterprise.

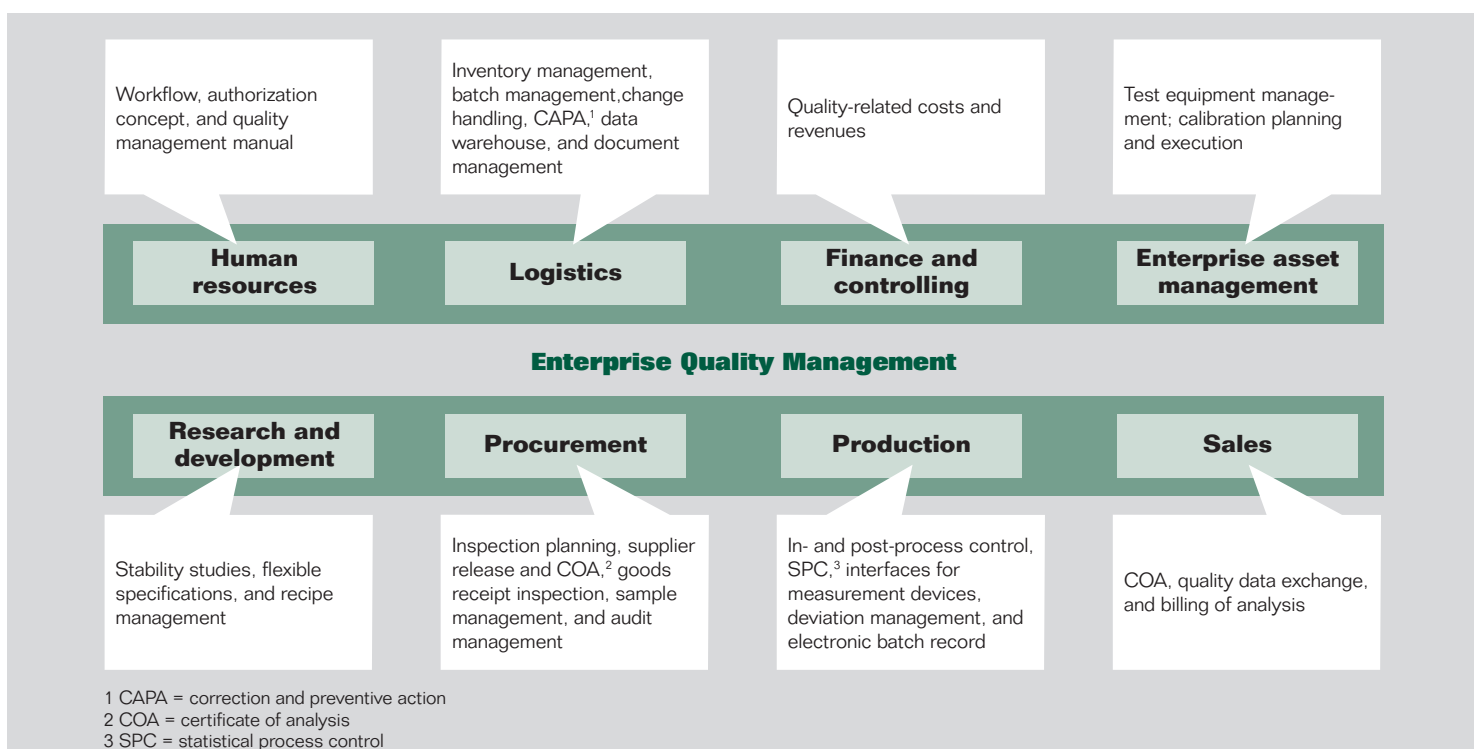


Figure 1: Integration of Quality Management into the Entire Enterprise

SAP ERP IN THE LABORATORY

By applying quality management functionality with SAP ERP, you are able to cover virtually all the functions of a traditional LIMS. Moreover, it supports processes in various types of laboratories, including industrial and commercial, adapting efficiently to the particular needs of each distinct laboratory process. In today's global companies, a single laboratory can act as both a commercial and an industrial laboratory.

An industrial laboratory is an organization within a company that focuses on analyzing raw materials, semifinished products, or products that are manufactured or processed by the company. It is a fixed element of the company's supply chain and supports other organizational units in the same company. Expenses for industrial laboratories are generally settled internally.

In contrast, a commercial laboratory acts as an independent service provider for both internal and external customers. Inspection specifications and methods can vary. Services and expenses for commercial laboratories are generally invoiced externally.

Supporting the Industrial Laboratory

The primary focus of an industrial laboratory is to ensure the quality of products produced by the company. It is typically involved in the entire product life cycle, from the inspection of incoming raw materials, to in-process and post-process control in production, to batch determination, and finally, to issuing certificates of analysis in sales and distribution. In an industrial laboratory, systems must support master-data maintenance and inspection planning, particularly the maintenance of specifications, methods, and inspection characteristics.

With isolated LIMS, you must maintain inspection plans and specifications separately in various individual systems. In an integrated system, you maintain master data in one location. Additionally, you can integrate problem management into all processes. This makes it possible for quality managers to use workflow functions to easily notify the appropriate processor if results are "out of spec," and to automatically execute follow-up actions.

The integrated approach of SAP ERP can help industrial laboratories in the following key processes:

■ Stability studies

Shelf-life studies provide a means of testing and evaluating products during various stages of the product life cycle. This process determines how a product will hold up under controlled environmental conditions over predefined periods of time.

■ Incoming inspections

When procuring raw materials, it is vital for purchasing departments to select vendors that have received a positive evaluation in terms of price, reliability, and quality. With the quality management functionality of SAP ERP, the purchasing department can issue technical delivery terms or quality assurance agreements on the purchase order and automatically initiate inspections when goods are received. After a sample has been drawn and the inspection completed, the company can decide how to proceed. Goods can be released, blocked for the rest of the production process, or sent back to the vendor with a complaint. If there are problems, the application can notify the logistics group directly and block the processing of purchase orders and invoice receipts for the vendor in question. The application can also assist in inventory management efforts by separating the inspected goods according to the usage decision (options include unrestricted-use stock, stock in quality inspection, blocked stock, and return delivery).

■ Inspections during production

The application can automatically trigger an inspection (in-process control) when a production order is released. In this case, control charts can be used for SPC, and test equipment can be linked to the application. Inspection activities (time) and quantities (yield, scrap, and rework) can be confirmed when recording the results to calculate production costs. If required, another inspection can be triggered at the end of the production process. For these inspections, the application can support legal requirements, such as the Good Manufacturing

Practice (GMP) data security requirements (see the “GxP Requirements and 21 Code of Federal Regulations Part 11 Compliance” section below), or multilevel release. Digital signatures can be added when drawing samples, recording results, or when deciding whether to use incoming goods or produced batches. Batches can be classified according to the inspection results.

■ Sales and distribution

In sales and distribution, products can be selected according to their suitability for various customers through a process known as batch determination. For example, a company can locate and deliver batches of products with water content of less than 2%, or select batches that meet the regulatory requirements of target-market countries. When a product shipment is ready for delivery, an inspection can be triggered automatically and if needed, a certificate of analysis can be created in a variety of formats – paper, fax, Adobe PDF, or XML. In general, quality data can be exchanged easily between the inspection laboratory and the vendor or customer. With the integrated nature of the application, data can be transferred directly from one system to another, eliminating the need to write out results manually and reducing the number of errors typically associated with reentering data.

■ Gauge calibration

Due to close integration with SAP ERP asset management functionality, it is also possible to keep track of all types of test equipment, manage and monitor these test devices, and schedule and conduct inspections to calibrate instruments used for quality inspections.

Supporting the Commercial Laboratory

Commercial laboratories must remain flexible since customer requirements for analyses vary constantly. The focus in these labs is not on the product or batch, but rather on the specific sample that was brought in for analysis. Both routine inspections and special analyses must be processed efficiently – even on short notice.

For routine planned analyses, the customer determines the scope and time frame of the inspection. Such analyses typically focus on ensuring food quality or examining water and soil in accordance with regulations. Quality management with SAP ERP can support planned analyses by generating inspection orders automatically at predetermined times according to the testing schedule. When the orders have been assigned to laboratories or inspectors on the basis of capacity requirements planning, the physical sample can be drawn and prepared for inspection.

Unplanned analyses are often required when a lab customer needs to test for particular pathogens, or when effluent, soil, or air must be tested after a breakdown of a machine, production line, and so on. With SAP ERP, a lab technician records the number of samples; flexibly selects the inspection specifications, such as the inspection characteristics and methods; and assigns these to the samples.

At times, analyses must be performed at the customer’s site. Some test materials, such as well water, could undergo changes while being transported to a laboratory. Since quality management functionality within SAP ERP is based on the SAP NetWeaver platform, it supports a number of open standards (interfaces) and technologies (for example, XML-based enterprise services) to enable offline and online inspections. Additionally, it is possible to calculate inspection results using sophisticated formulas and rounding rules – or to transfer measured values directly from a coupled test device.

When inspections have been completed, certificates of analysis that address the customer’s requirements can be issued. Customers have the option to download these certificates from distinct vendor-owned pages on the Internet. This means a company can give customers access to quality data about a shipment before it arrives, reducing the customer’s administrative costs.

At the end of the inspection process, the software calculates charges for each customer, based on the analyses performed and methods used, and issues an invoice.

GxP REQUIREMENTS AND 21 CODE OF FEDERAL REGULATIONS PART 11 COMPLIANCE

GxP is an acronym for Good Clinical/Laboratory/Manufacturing Practice (GCP, GLP, and GMP) and refers to exacting requirements for regulated industries, such as pharmaceutical, food, and beverage industries. For example, the U.S. Food and Drug Administration (FDA) requires companies in the pharmaceutical industry to introduce their products into the U.S. market with a detailed, complete, and traceable description of their production process. This includes all operations affecting product quality performed during the manufacture and distribution of a particular drug. The requirements for computerized systems with respect to electronic records are described in the *U.S. Code of Federal Regulations (CFR), volume 21, part 11*.

GxP compliance plays a decisive role in data acquisition and validation, especially in analytical laboratories. Accuracy and clarity of data, as well as consistent change documents (who did what, when, where, and why), are crucial for regulatory compliance.

Quality management with SAP ERP supports these GxP requirements, providing complete audit trail functions and digital signatures in results recording, sample or product release, and notification processing. These functions also support change management, electronic batch records, and integrated document management to store all relevant documents, such as standard operating procedures.

One added benefit is the optimized data flow that results from eliminating interfaces between systems. The use of SAP ERP as an integrated enterprise LIMS can lead to improved data accuracy and consistency, which, in turn, can lead to better – and easier – regulatory compliance.

For more information about compliance of SAP ERP with GxP requirements in general, refer to the SAP white paper *Complying with U.S. FDA Title 21 CFR Part 11 for the Life Sciences Industry*.¹



OPEN INTERFACES

Quality management with SAP ERP provides the following standard open interfaces:

- Inspection data interface (QM-IDI) linking subsystems or external devices
- Statistical data interface (QM-STI) connecting statistical programs

The QM-IDI interface enables companies to link the application to measurement devices. It can also be linked to third-party systems for highly specialized applications, such as lab automation systems, chromatography data systems, DNA sequencers, or other niche applications.

The QM-STI interface links quality management functionality within SAP ERP to external evaluation systems. As a result, you can perform evaluations that are not supported by the statistical functions in SAP ERP for results recording (control charts, histograms, and process capability indexes). You can use a format defined by SAP to transfer recorded inspection results from the quality management function to the external evaluation system. You can use QM-STI for manual statistical analysis of inspection results from SAP ERP or for an automatic start of predefined statistical analyses.

For integrating systems, databases, or other external applications (especially on the shop floor), SAP offers the SAP xApp™ Manufacturing Integration and Intelligence (SAP xMII) composite application. SAP xMII integration templates provide content-based examples of how to integrate SAP ERP business processes with shop floor-related processes using SAP xMII transactional techniques (see Figure 2 for an example).

In addition to this, SAP xMII provides a connector framework to establish or develop connectivity to various production and test devices. SAP is also building a partner ecosystem around SAP xMII. For more information on SAP xMII, go to www.sap.com/solutions/xapps/xmii.

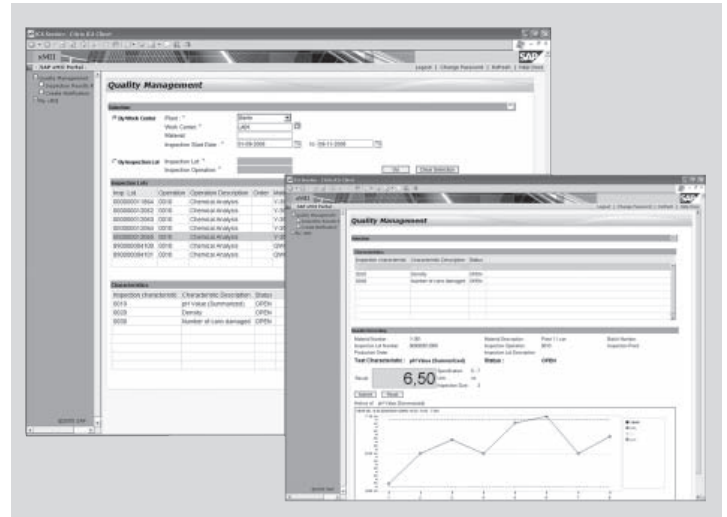


Figure 2: Results Recording Based on SAP® xApp™ Manufacturing Integration and Intelligence Composite Application

Figure 2 shows an example of an easy-to-use, Web-based results-recording application based on SAP xMII. Shop-floor operators would use it for in-process control. To download this sample application, go to the SAP Developer Network (SDN) site www.sdn.sap.com/irj/sdn/downloads. Then select *Manufacturing* from the *Available Downloads* link and download *Manufacturing Composite Applications/xMII Sample Application*.

SAP has established a process to certify third-party software, ensuring that it works properly with the interfaces offered by SAP. You can find more information about that process on the SAP Integration and Certification Center (ICC) location of SDN at www.sdn.sap.com/irj/sdn/sdnservices/icc?rid=/webcontent/uuid/970b0473-0501-0010-d5ad-8b1d94abd33d.

Note: Technical certification on the QM-IDI interface is a prerequisite for a software vendor to apply for the SAP software partner program. For more information, refer to *SAP Software Partner Program* at www.sap.com/partners/howtopartner/.

SAP maintains partnerships to provide direct interfaces with instrument links that are essential to supporting laboratory processes. Though the LIMS functionality of SAP ERP is dynamic and complete, making integration with third-party LIMS unnecessary, partnerships in particular regions and industries complement the functionality of SAP ERP quality management.

In addition to the standard interfaces listed above, SAP ERP provides enterprise services that expose the functionality of quality management business objects in SAP ERP. You can use these enterprise services to integrate external quality management systems or composite applications with SAP ERP.

The enterprise services bundle for the integration of quality management systems (IQM) helps you exchange inspection lot data, inspection results, and quality notification data between the quality management functionality in SAP ERP and external quality management systems. Benefits of IQM compared to QM-IDI include the following:

- New XML-based technology (Web services)
- Greater flexibility (you can deploy a subset of services)
- Enhanced functionality (for example, quality notifications and unplanned inspection points)

For more information on this enterprise services bundle, please review the Wiki tool on SDN at www.sdn.sap.com/irj/sdn/wiki (select *Enterprise Services WIKI (ESpackages)* from the *Topics* list) and check out the Enterprise Services Workplace site at www.sdn.sap.com/irj/sdn/esworkplace (requires a login).

CONCLUSION

With the comprehensive, integrated quality management functions of SAP ERP, companies can handle traditional LIMS tasks in the laboratory, while integrating quality processes across the organization. Using SAP ERP as an enterprise LIMS, companies can do the following:

- Keep future options open with a scalable and flexible system that supports an open infrastructure
- Decrease costs and expedite operations through more efficient, standardized quality processes throughout the enterprise
- Collaborate with internal and external partners throughout the entire product life cycle
- Minimize system complexity through integration into other applications, thereby reducing costs

The LIMS functionality of SAP ERP introduces the comprehensive approach of a complete, fully integrated LIMS – with a lower total cost of ownership. At the same time, it allows companies to create a flexible foundation for allowing a true enterprise-wide approach to LIMS and quality management.

Customer Comment

“We were able to replace our stand-alone LIMS with the functions delivered by SAP PLM [SAP Product Lifecycle Management] quality management. We now use this solution as our global LIMS.”

Viola Meisterling, Head of Process Teams, Core Competence Center, Clariant Verwaltungsgesellschaft mbH, Germany

Note that quality management was formerly supported by the SAP® Product Lifecycle Management application.

APPENDIX 1: ADOPTING AN INTEGRATED APPROACH

Today, a number of companies in the process industry are using the SAP® ERP application as their laboratory information management system (LIMS) without the need for specialized third-party products for additional LIMS functions.

Customer Comment

“With the quality management functionality of SAP PLM [SAP Product Lifecycle Management] as our enterprise LIMS, we have managed to fully integrate our business processes. Eliminating interfaces has given us a considerable advantage when it comes to the performance and consistency of our work processes.”

Heinz Rammer, Enterprise Resource Planning Consultant, DSM Fine Chemicals Austria Nfg GmbH & Co KG

Note that quality management was formerly supported by the SAP® Product Lifecycle Management application.

The following companies use SAP ERP as their LIMS:

■ Life science industry:

- Merckle GmbH, Germany
- Roche Diagnostics GmbH, Germany
- Sanofi-Aventis Deutschland GmbH, Germany
- B. Braun Melsungen AG, Germany
- 3M ESPE AG, Germany
- Solvay Pharmaceuticals B.V., Netherlands
- Schering Mexicana S.A. de C.V., Mexico

■ Chemicals industry:

- BASF AG, Germany
- Röhm GmbH, Germany
- Clariant Verwaltungsgesellschaft mbH, Germany
- DSM Fine Chemicals Austria Nfg GmbH & Co. KG, Austria
- Sasol North America Inc., United States

■ Food/consumer industry:

- Dr. August Oetker Nahrungsmittel KG, Germany
- Döhler GmbH, Germany
- Arla Foods amba, Denmark
- McCormick & Company Inc., United States

■ Laboratory service provider: SGS INSTITUT FRESENIUS GmbH, Germany

APPENDIX 2: QUALITY MANAGEMENT FUNCTIONS WITHIN SAP® ERP

The SAP® ERP application supports all essential functions in a laboratory information management system, including the following:

Note that this paper does not discuss all the functions listed here.

- Audit management
- Bar coding and labeling
- Batch management (batch traceability and electronic batch record)
- Calculations and formulas
- Calibration of instruments
- Certificates of analysis
- Change management (audit trail)
- Complaint and problem management, and corrective and preventive action
- Data retrieval and archiving
- Digital signatures
- Document management
- Engineering change management (audit trail)
- Flexible inspections
- Goods receipt inspections
- Information system and reporting
- In-process control
- Inspection plan maintenance
- Interfaces (inspection data and statistical data)
- Inventory control
- Invoicing and billing of analysis
- Laboratory statistics
- Master-data maintenance
- Multiple specifications
- Nonconformance reporting and processing
- Notification processing
- Order management
- Post-process control
- Problem solving and event handling
- Quality assurance
- Quality planning
- Quality data interchange
- Recurring inspections
- Results recording and copy
- Returns inspections
- Sample management (unplanned and planned samples)
- Skip-lot functionality
- Specification management
- Stability (shelf-life) studies
- Statistical process control
- Statistical quality control
- Test equipment interfacing
- Quality cost tracking
- Vendor evaluation
- Web services
- Work lists and workflow

APPENDIX 3: REFERENCES

1 *Complying with U.S. FDA Title 21 CFR Part 11 for the Life Sciences Industry*, SAP white paper (material number 50 050 628, April 2005)

SAP® xApp™ Manufacturing Integration and Intelligence composite application Web site: www.sap.com/solutions/xapps/xmii

Download area of the SAP Developer Network (SDN) site: www.sdn.sap.com/irj/sdn/downloads

SAP Integration and Certification Center area of SDN: www.sdn.sap.com/irj/sdn/sdnservices/icc?rid=/webcontent/uuid/970b0473-0501-0010-d5ad-8b1d94abd33d

SAP software partner program Web site: www.sap.com/partners/howtopartner/

Wiki tool on SDN: www.sdn.sap.com/irj/sdn/wiki

Enterprise Services Workplace site on SDN: www.sdn.sap.com/irj/sdn/esworkplace (requires a login)

APPENDIX 4: FOR MORE INFORMATION

To find out more, refer to the following:

- For general information about the SAP® ERP application, visit service.sap.com/erp (login is required).
- For general information about the quality management (QM) functionality within SAP ERP and QM as an enterprise laboratory information management system, visit service.sap.com/qm (login is required).
- For online documentation (SAP Library) for SAP applications, visit SAP Help Portal at help.sap.com. The following link is an example of the online documentation available for quality management: help.sap.com/saphelp_erp2005vp/helpdata/en/a0/df293581dc1f79e10000009b38f889/content.htm.
- For information about electronic records (SAP audit trail functions, table logging, and change documents), refer to SAP Library at help.sap.com/saphelp_erp2005vp/helpdata/en/7c/fb0f3a57b38c0fe10000000a11402f/frameset.htm.
- For more information about laboratory information management systems, refer to the following:
 - “It’s your choice,” *SAP INFO* article (www.sap.info), December 2002 (no. 101)
 - Andreas Hagenow, “Enterprise LIMS – Process-Oriented Applications Save Time and Money,” *G.I.T. Laboratory Journal*, 5/2003 (to order a reprint of the article, go to the GIT VERLAG Web site at www.gitverlag.com/index.html?lang=en).

To coordinate visits or phone calls with companies using SAP ERP, contact your SAP sales representative.

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