



## **ENTERPRISE MANAGEMENT AND SUPPORT IN THE LIFE SCIENCES INDUSTRY**

THE BEST-RUN BUSINESSES RUN SAP™



## **The Life Sciences Industry**

Three worldwide trends are driving increased consumption of pharmaceuticals and medical products: the aging of the baby boom generation, the lengthening of average life expectancy, and the rising incidence of chronic diseases. But despite these trends, success in the life sciences industry is far from easy. Fierce competition exists across industry segments, making it difficult for those first to market to capture market leadership, and complex medicines and medical devices require long research and development cycles with time-consuming and expensive discovery, engineering, and design phases as well as preclinical and clinical development. In addition, businesses must comply with complex, stringent regulations that vary from region to region. To succeed in this challenging environment, businesses in the life sciences industry need to find ways to do the following:

- Improve time to market by recognizing product pipeline gaps, identifying products with the best market opportunities, and efficiently running global R & D projects using timely information
- Ensure regulatory compliance by proactively managing product safety, improving product quality, and capitalizing on responses to regulatory and validation requirements throughout the value chain
- Speed time to value by decreasing the time from product launch to peak sales
- Make more efficient use of financial and physical assets

SAP has enjoyed more than 30 years of partnership with the life sciences industry. Currently, there are close to 1,500 installations of SAP® software worldwide among pharmaceutical, diagnostic, medical devices, and biotechnology businesses. mySAP™ ERP – a flexible, scalable, enterprise resource planning solution that increases productivity, insight, and adaptability – is a key element of SAP solutions for the life sciences industry. With mySAP ERP, organizations benefit from complete and integrated analytics, human capital management, financials, operations, and corporate services functions that have been tailored to the specific standards, processes, and challenges of the life sciences industry.

## **Enterprise Management and Support in the Life Sciences Industry**

mySAP ERP supports the important business processes of life sciences organizations and provides tools and best practices to help improve these processes. With mySAP ERP, organizations benefit from a scalable solution that can expand and adapt as requirements change over time.

### **Research and Development**

For life sciences companies, improving time to market requires highly efficient R & D programs. Businesses can realize significant competitive advantage by identifying products that address market opportunities; properly assessing budget, costs, risks, and resources; and efficiently managing R & D projects.

mySAP ERP includes R & D administration features that maximize the allocation of investments and resources. Businesses benefit from increased visibility into budget resources and project capacity, enabling better decision making for investments, while global project planning and scheduling tools accelerate R & D projects and provide a comprehensive overview of the development pipeline. mySAP ERP also ensures that key performance indicators, early warning indicators, and trend analyses are available to keep management

informed throughout the development process. Businesses can improve efficiency and speed development by capturing critical information during product development, optimizing the scale-up process, fostering collaboration, and reducing clinical trial cycle times.

### **Clinical Trial Supply Management**

For businesses in the life sciences industry, clinical trial supply management is crucial to the product development process. mySAP ERP helps optimize manufacturing processes, including planning, production, labeling, and packaging, to ensure that the right materials, such as patient replenishment kits, are at the appropriate clinical site at the proper time in accordance with study protocols. Companies benefit from reduced clinical-supply cycle time and improved on-time delivery. The solution also supports and streamlines patient recruitment and enrollment, aids management of investigator relationships, makes it easier to track costs, and simplifies monitoring and reporting on the status of clinical trials.

### **Quality Control**

As regulatory agencies charged with improving product safety continue their vigilance over manufacturing practices, life sciences companies must maintain exceptional focus on product quality, lot genealogy, compliance, and system validation. Comprehensive quality management functions within mySAP ERP help businesses enforce compliance throughout the manufacturing process, as well as deliver visibility into critical quality control and quality assurance processes throughout the organization. As a result, businesses can proactively monitor and manage manufacturing variability, track and trend product quality, manage nonconformance within the supply chain, and take corrective or preventive action when warranted. Key functions include the following:

- **Manufacturing compliance** – mySAP ERP supports all manufacturing strategies for the life sciences industry. The solution enables the development and horizontal integration of business processes that meet good manufacturing practices (GMP) requirements throughout an organization’s production operations. mySAP ERP also includes a document management system that supports standard operating procedure management and can be integrated into the manufacturing process.
- **Laboratory information management** – mySAP ERP helps businesses ensure product quality by offering a good laboratory practices (GLP)-compliant laboratory information management system (LIMS) that can be integrated with processes such as procurement, manufacturing, and shipping. The LIMS system, which is included with mySAP ERP, provides quality statistics and can be integrated into laboratory equipment and handheld devices. The application can also be Web-enabled for easy information access worldwide.
- **Equipment maintenance** – mySAP ERP supports enterprise-wide asset management that ensures all physical resources are operating and maintained at optimal efficiency. In addition, the solution provides maintenance scheduling and execution tools that are accessible via handheld devices and the Internet and can be integrated into manufacturing processes.

### **Sales Order Management**

Life sciences companies can accelerate the order-to-cash cycle by decreasing the time between drug launch and peak sales. But doing so requires improving sales and marketing performance and effectively managing increased chargeback and rebate volumes. mySAP ERP supports these activities with superior insight into sales back-office processes, including inquiry handling, quotation preparation, order generation, and order processing, as well as contract and billing cycle management. Key processes supported include quotation and order

management, contract management, and billing management. Businesses benefit from a complete overview of the customer life cycle, including order status, billing, payment, and credit management. In addition, complementary applications are available that enable mySAP ERP to support Internet sales, sales entered through mobile devices, and call center functions.

### **Regulatory Compliance and Corporate Governance**

Manufacturers in the life sciences industry are subject to a variety of regulations that may impact nearly every area of the enterprise, including purchasing, product development, manufacturing, sales, distribution, service, and maintenance. mySAP ERP offers proven compliance tools to help companies comply with U.S. FDA requirements – which are the most stringent in the world – as well as good laboratory practice/good manufacturing practice (GxP) guidelines; the Prescription Drug Marketing Act (PDMA); and 21 CFR (U.S. Code of Federal Regulations) Part 11 (U.S. FDA guidelines that mandate specific controls for the use of electronic records). These far-reaching requirements regulate the use of computerized systems, e-signature and e-record technology, lot and serial traceability, audit trails, change control, archiving, and security. In addition, support for environment, health, and safety within mySAP ERP makes it easier for organizations to produce safer products, create safer workplaces, reduce risks to employees, protect the environment, and comply with all relevant national and international regulations.

Effective corporate governance and compliance with regulations such as the Sarbanes-Oxley Act require accurate, detailed tracking of billing, revenues, and project status. Support for “whistle blowing” includes a complaints form that can be configured according to an organization’s own requirements – for example, to address specific federal laws and internal policies. Available support for compliance and governance within mySAP ERP includes management of internal controls capabilities, which centralize the documentation of internal controls as well as assessments of control design, efficiency, effectiveness, and management reporting. In addition, the audit information system supports internal and external auditors with online controls and facilitates the export of data to specialized auditing software.

### **New and Enhanced Capabilities for the Life Sciences Industry**

mySAP ERP offers several new and enhanced capabilities designed to improve operations for businesses in the life sciences industry.

#### **Collaboration**

Efficient management of enterprise financials and assets often requires the development of products in multiple locations, including offshore facilities. However, for geographically distributed personnel and partners to participate in the product development life cycle at appropriate times, companies must provide support for collaboration and information sharing. mySAP ERP ensures that all internal and external team members and partners have immediate access to relevant data, enabling rapid response to changes or issues. Effective program and project management helps improve collaboration and communication among internal and external participants in the product development process, resulting in efficient processes that speed time to market and satisfy customer demand. And new and enhanced collaboration functions, including support for real-time collaboration mechanisms such as online meetings, chat, instant messaging, and application sharing, drive dynamic communication through permanent and ad hoc groups and communities.

### **Quality Assurance and Control**

New quality assurance and control enhancements in mySAP ERP provide improved sample management capabilities, including extended selection options for sample work lists, extensions to the master record, and archiving of sample data in alignment with the overall SAP archiving concept. In conjunction with an available laboratory information management system, mySAP ERP supports the archival functions that are essential quality management features for life sciences companies that handle large numbers of samples and drawings. mySAP ERP also supports current GxP guidelines for pharmaceutical manufacturers and other life sciences companies .

### **Radio Frequency Identification Support**

mySAP ERP supports radio frequency identification (RFID) technology, which supplements or replaces bar codes with electronic tags that store unique identifying information for individual items, cases, or pallets and transmits this information to readers deployed at warehouses and distribution facilities. RFID speeds product and order handling, reduces hands-on processing, and minimizes errors. In addition, companies can easily track the location and disposition of products to final destinations, which helps prevent products from being stolen or tampered with while in transit. In conjunction with the SAP Event Management application, RFID support within mySAP ERP also improves visibility of stock levels and execution status throughout the supply chain, enabling the identification of quality and process improvements.

### **Documentary Batch**

Life sciences companies often face legal requirements to document where a product was produced, what components were used, and whether quality standards were met, particularly during product recalls. They also face legal and customer requirements to store data pertaining to materials procured from vendors, used in production, and delivered to customers. To address these requirements, mySAP ERP supports batch tracking, eliminating the need to manage batch inventory. Comprehensive search features facilitate the traceability of products – an important legal requirement. mySAP ERP can also manage all required data, such as material tracking numbers, in support of legal regulations, and can trace the flow of materials to significantly reduce total cost of ownership.

### **Trials in Recipe Management**

New trial capabilities in mySAP ERP integrate trial definition, planning, execution, and monitoring during development in laboratories, pilot plants, and handoffs to production. All data related to recipes and formulas, research and development, production, and environmental health and safety can be included in a single environment. Enhanced support for pilot plants and production lines allows fully automated transformation to production planning-process industry recipes. These enhanced development functions enable faster product development and improved product consistency.

## **Why mySAP ERP in the Life Sciences Industry?**

To succeed, life sciences businesses need highly efficient R & D processes, as well as innovative ways to ensure regulatory compliance, speed time to value, and optimize the use of financial and physical assets. mySAP ERP delivers exceptional enterprise resource planning capabilities that enable companies to manage these and other complexities while maintaining high levels of product safety and quality. For these reasons, nearly 1,500 pharmaceutical, diagnostics, medical devices, and biotechnology companies worldwide rely on the comprehensive capabilities offered by mySAP ERP to survive and thrive in today's challenging business and regulatory environment.

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