

SAP Solution Brief
SAP for Life Sciences



ENABLING GROWTH AND TRANSFORMATION IN PHARMACEUTICAL AND BIOTECH R & D

The Efficient, Effective, Compliant Way to Manage Innovation

The SAP® for Life Sciences solution portfolio transforms your R & D processes to help you innovate with greater efficiency and effectiveness. Integration facilitates collaboration among functional areas and improves visibility across the entire product portfolio, while powerful analytics provide real-time business insight for decision-making support. You can monitor resources, prioritize projects, optimize the clinical trial supply chain, and maximize the overall value of your product portfolio. The end result is innovation made easier, faster, and more effective.

Whether you're a niche-market start-up developing a single compound or a well-established global company with dozens of projects in the pipeline, the pressure to innovate in the life sciences industry is unrelenting. Across the industry, development costs are rising and competition is driving prices down. For some companies, looming patent expirations threaten long-standing revenue streams. For others, increased competition shortens the time of product exclusivity. Everyone is in a race to get highly complex treatments and drugs to market as quickly as possible while maintaining strict compliance with governmental regulations and industry standards.

Designed for companies of all sizes, the SAP for Life Sciences solution portfolio aligns R & D with your overall business strategy, connecting functional areas within the enterprise and enabling more efficient business processes. Powerful analytics and increased data visibility enable business insight and decision support, while improved transparency and robust document management capabilities enable full compliance with regulations such as the U.S. Sarbanes-Oxley Act, the Code of Good Manufacturing Practices (cGMP), and 21 CFR Part 11. Sophisticated collaboration tools help you interact with internal colleagues and external development partners. And the solutions are powered by the SAP NetWeaver® platform, the scalable, flexible platform that works with SAP® and non-SAP systems to provide a solid, open foundation for future growth.

Optimize Your Investment Decisions

Healthy, growing life sciences companies must keep their development pipelines filled with promising new products. Executives need visibility across active projects and the ability to quickly evaluate the corporate portfolio to dedicate the right resources to the right projects at the right time. With a tailored dashboard that provides a consistent flow of real-time data and analytics, SAP for Life Sciences delivers powerful portfolio and program management capabilities that help you achieve the following:

- Gain real-time visibility to make informed decisions faster
- Prioritize projects to maximize ROI
- Run simulations and quickly analyze issues of time, cost, value, and risk across the entire project portfolio
- Make quicker, more informed go/no-go development decisions and better in-licensing/out-licensing choices

With SAP for Life Sciences, you can focus on the quality of your portfolio discussions rather than the quality of your data. SAP for Life Sciences is built on an open, scalable platform that benefits large and small organizations alike. The end result: higher productivity, lower costs, maximized portfolio value, and competitive advantage.

Keep Projects on Track, Suitably Staffed, and Properly Funded

Life sciences companies must constantly strive to distribute finite resources across any number of high-potential development projects while balancing the unceasing drive to be first to market, capture market share, and capitalize on patent exclusivity. To that end, SAP for Life Sciences helps you meet the following challenges:

- Understand capacity constraints and commit resources accordingly
- Make better decisions about projects thanks to global real-time visibility into forecasts, costs, resources, and time lines

- Avoid bottlenecks through greater ability to create plans and modify schedules across multiple projects
- Increase efficiency through streamlined approval processes and Web-based time-entry tools

Whether your firm works on a few projects or many programs, SAP for Life Sciences helps you optimize resources by providing quick and easy access to accurate, timely, and harmonized data. The solutions scale to your needs, helping you meet domestic and global project management demands as your organization grows.

Manage Documents and Regulatory Submissions with Greater Efficiency

In the light of regulations like 21 CFR Part 11, efficient document management is critically important for the life sciences industry. You need a document management solution that adheres to emerging standards and can easily manage the tasks required for large dossier submissions. SAP for Life Sciences gives you the following capabilities:

- Easily collaborate with business partners during the development stage
- Use electronic signature functionality to increase document approval efficiency in full compliance with 21 CFR Part 11
- Quickly compile required documentation and submit dossiers to regulatory authorities in paper or electronic Common Technical Document form
- Reduce the need for end-user training with an intuitive user interface

Ultimately, SAP for Life Sciences improves productivity for all tasks related to document management and helps you share knowledge throughout your organization. The solutions help speed up the submission process, supporting current regulatory requirements while giving you the flexibility you need to adapt as regulations change.

Optimize the Clinical Trial Supply Chain

To ensure efficient clinical trials, you must optimize your clinical supply chains. SAP for Life Sciences lets you forecast, plan for, and manufacture the right quantity of supplies and have them labeled, packaged, and delivered on time to the correct site.

You can accomplish the following:

- Reduce clinical supply-chain cycle time
- Streamline the label review and approval process
- Quickly adapt and respond to changes in the clinical plan
- Work efficiently with manufacturing partners and investigator sites
- Generate timely reports that provide vital insight into critical clinical supply issues

21 CFR Part 11, cGMP, and European Union regulations have a significant impact on order-supply processes. With SAP for Life Sciences, you can order supplies via a simple Web interface or via an interactive voice response system, and design and print embedded labels and bar codes. Substance and regulatory databases ensure that labels are accurate and comply with regulations. A multilingual phrase library facilitates the management of country-specific inserts and labels. You can trace lots from raw materials to finished goods, monitor shelf life, and establish controls to ensure that kits are shipped only after Institutional Review Board approval, all without compromising study blindness. Together, these capabilities help streamline the clinical trial supply chain by expediting cycle times, giving you real-time visibility into related processes, and providing better inventory control.

Manage Clinical Trials with Greater Efficiency

At a time when clinical trials are run in a global context with an array of partners operating on a variety of platforms, life sciences companies must improve efficiency and effectiveness. By increasing transparency, enhancing collaboration, reducing administra-

tive overhead, and improving productivity, SAP for Life Sciences helps ensure consistent, high-quality results – whether you run your own clinical trials in-house or outsource them to clinical research organizations (CROs). You'll have the following capabilities:

- Increase visibility into your clinical studies
- Manage investigator grants and track expenses and payments across multiple currencies
- Increase productivity with tools for managing relationships with investigators, key opinion leaders, and contacts
- Monitor studies and collaborate with CROs

You can track progress and recognize potential bottlenecks to keep clinical trials on track, ensuring a smoother experience for all parties involved.

Accelerate Drug Formulation

For many companies, efficient drug formulation is impeded by persistent master-data redundancies, difficulties in tracking changing recipe parameters during pilot runs, and a lack of access to critical information such as material specifications, stability studies, and project plans. SAP for Life Sciences helps you overcome these challenges by allowing you to accomplish the following:

- Automate master-data management tasks to eliminate redundancies
- Track changing recipe parameters in an orderly manner
- Increase visibility of critical data by integrating with project management and experimental planning solutions
- Quickly evaluate experimental results and improve recipes
- Run and monitor multiple experiments on multiple recipes simultaneously

By improving access to information, SAP for Life Sciences also helps you to enhance interactions with vendors and suppliers when you're defining raw materials and product properties. And when it comes time to move from the pilot phase to scale-up manufacturing, the solution provides structured specifications – adhering to ISA S88 industry standards – that provide the basis for new product introductions from clinical to commercial manufacturing. The resulting increase in drug formulation efficiency accelerates new products through manufacturing and into the market.

Innovation Made Faster, Easier, and More Efficient

Companies of all sizes are using SAP for Life Sciences to transform R & D, thereby gaining new efficiencies that help maintain competitive advantage. SAP for Life Sciences delivers the following strategic benefits:

- **Greater R & D process efficiency.** By linking disparate functional areas and facilitating collaboration among internal groups and external partners, SAP for Life Sciences drives vast new efficiencies.
- **Improved business insight, analytics, and decision support.** Using real-time information, SAP for Life Sciences supports decision making at critical junctures. Managers can control costs across projects and make informed portfolio decisions, weighing available resources against defined corporate priorities and maximizing ROI.

- **Reduced risk of noncompliance.** Clinical trial supply management capabilities help you track materials, while sophisticated document management allows you to interact with regulatory authorities and submit required dossiers in a timely manner. Finances become transparent to meet the demands of Sarbanes-Oxley. You can achieve full regulatory compliance while reducing related costs – relieving concerns of shareholders and freeing your company to focus on its business goals.

Find Out More

To learn how SAP for Life Sciences can help you transform your R & D processes for long-term competitive advantage, SAP would like to provide you with a comprehensive, personalized value assessment. Please contact your SAP representative or visit us on the Web at www.sap.com/lifesciences.

Powered by SAP NetWeaver

SAP for Life Sciences is powered by the SAP NetWeaver platform – the open integration and application platform that provides the best way to integrate all systems running SAP or non-SAP software. SAP NetWeaver unifies integration technologies into a single platform and is preintegrated with business applications, enabling change and reducing the need for custom integration.