



SAP S/4HANA for Pharmaceuticals

A next-generation ERP system for the pharmaceutical industry offering real-time data, end-to-end traceability, and regulatory compliance (21 CFR Part 11, GxP).

<https://www.sap.com/industries/life-sciences.html>

Overview

SAP S/4HANA for Pharmaceuticals is an industry-specific version of SAP's flagship Enterprise Resource Planning (ERP) system, built on the in-memory SAP HANA database. It is designed to serve as the digital core for pharmaceutical, biotech, and life sciences companies, providing a single source of truth to manage complex, highly regulated operations. The solution integrates all critical business processes—from R&D and raw material procurement to manufacturing, quality control, finance, and distribution—ensuring data consistency and end-to-end traceability.

Key Benefits and Value Proposition

The primary value of SAP S/4HANA for Pharmaceuticals lies in its ability to enforce and document regulatory compliance while driving operational efficiency. It enables real-time data processing and analytics, allowing businesses to make quicker, better-informed decisions. By streamlining processes and providing full visibility, it helps reduce operational costs, minimize production downtime, and accelerate time-to-market for new therapies.

Main Features and Capabilities

Quality Management & Compliance: Built-in Quality Management (QM) processes, electronic batch records (eBR), detailed audit trails, and support for GxP, GMP, GLP, GCP, and FDA 21 CFR Part 11 requirements.

Batch Management & Traceability: Comprehensive batch genealogy, serialization, RFID integration, and advanced track & trace functionality (often via SAP Advanced Track and Trace for Pharmaceuticals - ATTP) for end-to-end product visibility from raw material to finished goods.

Supply Chain Management (SCM): Enhances demand planning, inventory management, logistics optimization, and advanced available-to-promise (ATP) by leveraging real-time data.

Production Planning for Process Industries: Tools for production scheduling, capacity planning, resource optimization, and handling process manufacturing (recipes/formulas) including active ingredient potency calculations.

Financial Management: Real-time financial analytics, reporting, cost control, profitability analysis, and revenue recognition.

R&D and IP Management: Functionality for formula management, sampling, controlling, and managing patents, intellectual property (IP), and royalty payments.

Target Users and Use Cases

The software is primarily targeted at **Large Enterprises** and **Mid-Market** pharmaceutical, biotech, and life sciences companies with complex, global operations. It is used by major global pharmaceutical companies (e.g., Pfizer, Merck, Novartis). Key use cases include: achieving continuous regulatory compliance, optimizing global supply chain and logistics, managing complex process manufacturing, and enabling rapid batch recalls/investigations through granular traceability.

Key Features

- FDA 21 CFR Part 11 & GxP Compliance
- End-to-End Batch Traceability & Genealogy
- Real-Time Analytics and Reporting
- Integrated Quality Management (QM)
- Process Manufacturing & Production Planning
- Global Supply Chain Management (SCM)
- Serialization and Track & Trace
- Financial and Cost Management

Pricing

Model: enterprise

Enterprise subscription model. Pricing is not publicly disclosed and is customized based on company size, number of users, specific modules implemented, and deployment type (cloud vs. on-premise). Requires direct consultation with SAP or an authorized partner.

Target Company Size: medium, enterprise

Integrations

SAP Business Technology Platform (BTP), SAP Advanced Track and Trace for Pharmaceuticals (ATTP), SAP Extended Warehouse Management (EWM), SAP Integrated Business Planning (IBP), Laboratory Information Management Systems (LIMS), Manufacturing Execution Systems (MES)

Compliance & Certifications

FDA 21 CFR Part 11, GxP, GMP, GLP, GCP, SOX

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