

COMPLIANT MANUFACTURING OPERATIONS IN LIFE SCIENCES COMPANIES

COMPLIANT OPERATIONS TO LEAD THE COMPETITION

With compliant manufacturing operations, you can deliver quality products to customers consistently and meet good manufacturing practices regulations at the lowest cost possible – all key to leading the competition. How can you achieve such objectives? With software and services from SAP and our partners.



Global competition, more-demanding patients, new regulations, and high development costs are driving life sciences companies to deliver higher-quality products at ever-lower costs. Executives worldwide must find new ways to deliver quality products to customers consistently and meet good manufacturing practices (GMP) regulations at the lowest cost possible.

For many life sciences organizations, a key impediment to compliant manufacturing operations remains the disconnect between enterprise and plant systems. This results in unsynchronized business processes and inadequate use of resources, which in turn increases the risk of noncompliance, inadequate quality of finished products (with potentially life-threatening implications), and lower performance from people and processes.

Simply connecting systems will not fully overcome these challenges. World-class life sciences companies are going further, integrating and aligning core processes to achieve transparency between the plant floor and the enterprise across even the most widely distributed manufacturing operations. This approach enables you to monitor, measure, analyze, and control performance deviations in real time – across processes, plants, and personnel. This, in turn, ensures consistent levels of quality and compliance and higher overall equipment effectiveness, while driving down bottom-line costs and cycle times.

Yet even with these gains, there remains more work to do to run compliant manufacturing operations in a competitive – and increasingly regulated – marketplace. Quality and genealogy need to be documented, tracked, audited, and reported for compliance with stringent regulations. Life sciences companies need to find ways to reduce both the costs of compliance and the risk of noncompliance while continuing to increase operational efficiency.

How can you achieve these goals? With integrated software and world-class services from SAP and our partners.

Deliver High-Quality Products Consistently to Customers

For many life sciences companies there still exists a huge gap between the enterprise and the plants. That disconnect prevents visibility into operations and creates inefficiencies that make it all but impossible to adjust plans quickly in response to changes in customer orders and production mix. Additionally, information latency can cause poorly coordinated manufacturing activities, supplier and delivery delays, quality and compliance exceptions, and ultimately a decrease in customer satisfaction.

Integrated software from SAP can help you bridge this gap by connecting your enterprise and plants – whether in one location or around the world. Such connections create the visibility required to

run compliant manufacturing operations. You are better positioned to coordinate globally while executing locally, plan effectively, and execute efficiently on the plan. You can plan production in alignment with business objectives, manage manufacturing and supply constraints, and maintain inventory levels in keeping with service levels. Moreover, with software from SAP you can monitor and analyze the factors affecting lead times and respond more quickly to changes in customer orders so as to meet customer delivery commitments for high-quality products consistently.

Ensure Compliance with GMP

For a life sciences company, compliance with GMP and validation of that compliance is critical to the development and delivery of quality products and responsible, sustainable corporate profitability. Whether at the product level or the process level, regulatory noncompliance can affect your company through fines, penalties, negative publicity, loss of customers, or the prohibition against selling your products in the market.

Manufacturing controls play an essential role in meeting those compliance requirements. Integrating such controls within your operations can help you reduce safety risks even as they help you improve product quality.

Software from SAP can help you comply with, document, and validate requirements for GMP and manage these by exception. For example, workflow tools within SAP® applications can help you drive inspection processes and enable corrective action, including quarantining specific components, if necessary, and

issuing quality alerts through supplier Web portals. The software can even provide tracing and reporting functionality to help you analyze root causes for compliance failures.

SAP partners can extend support for manufacturing controls even further. By connecting third-party applications with your SAP software, for example, you can track hazardous substances, exposures, packaging, dangerous goods classifications, and waste codes. This can help reduce the number of defective or noncompliant products as well as reduce the costs associated with such noncompliance.

Reduce Costs of Manufacturing Operations

At the plant level, on a day-to-day basis, it is critical to manage production and materials optimally, according to plan. Inefficiencies on the top floor, though, can lead to operational inefficiencies on the shop floor. A poor-quality plan, for example, can lead to infeasible production schedules, wasteful activities, and excessive inventories – all of which contribute to higher operating and inventory costs.

SAP provides integrated software and services that can help you optimize production planning and scheduling across your globally distributed manufacturing operations. You can use this software to integrate and standardize production operations as well as manage plant-floor activities in real time and at levels that support your Six Sigma strategy. With complete support for Six Sigma initiatives, just-in-time (JIT) processes, and other continuous-

improvement efforts, you can optimize day-to-day operations, eliminate waste, reduce operating costs, and lower inventories to ensure sustained operational performance.

Consider this: Using decision-support tools that enable you to simulate and compare alternative manufacturing scenarios, you can more easily match production rates to optimal production targets. You can map production activities to customer orders more effectively, taking material, capacity, and labor constraints into consideration when prioritizing your activities. Life sciences software from SAP partners can extend these benefits still further. You can lower your operating costs, for example, with integrated software that supports your weigh and dispense activities. Furthermore, you can manage inventory levels, capacity constraints, and resource allocation to minimize queues. SAP software can also help connect the plant floor to the enterprise at the lowest cost of ownership. This enables effective management of production execution by generating feasible and executable schedules that take into account bottleneck information based on real-time visibility.

Software and Services for Compliant Manufacturing Operations

Integrated software and services from SAP and our partners can provide you with the functionality you need to manage compliance across the entire plan-to-produce scenario. These include your key business processes for enterprise planning and control, plant-level operations, manufacturing intelligence

and collaboration, manufacturing execution, product quality, safety and environmental compliance, and Six Sigma. Several applications comprise this integrated solution.

The **SAP ERP** application helps you streamline your compliant manufacturing process – from planning and scheduling through sequencing and execution to monitoring and analysis – and improve efficiency along your entire value chain.

The **SAP Supply Chain Management (SAP SCM)** application enables collaboration, planning, execution, and coordination of the entire supply chain network.

The **SAP Lean Planning and Operations (SAP LPO)** application extends the value of SAP manufacturing solutions by providing lean planning and scheduling functionality for plant execution.

The **SAP Manufacturing Integration and Intelligence (SAP MII)** application provides the direct connection between business operations and shop-floor systems. It ensures that all data that affects manufacturing is visible in real time – including information about orders, materials, equipment status, costs, and product quality. The application also delivers manufacturing visualization tools, analytics tools, and reports that empower decision making and support your continuous-improvement initiatives.

The **SAP Manufacturing Execution application by Visiprise** provides a powerful means for managing production and ensuring compliance across medical device manufacturing operations. Integrated with your SAP ERP software,

the application facilitates the flow of information between the production floor and the rest of the enterprise.

The **PAS-ECMI application from Werum Software and Systems** integrates with SAP ERP and SAP MII to help pharmaceutical companies meet regulatory requirements and increase operational performance. The modular software package supports best-practice business processes for biopharmaceutical manufacturing operations – for example, weighing and dispensing – as well as monitoring and tracking of all critical business procedures out of the box.

Working together, these integrated applications can help you align manufacturing operations and resources between the core enterprise and plants and achieve high compliance from end to end with:

- Complete visibility across manufacturing operations in a multiplant environment
- Streamlined operations from the plant floor to the enterprise
- Integrated quality and safety controls
- Compliance with GMP

Underlying these integrated applications is the SAP NetWeaver® technology platform. SAP NetWeaver unifies technology components into a single platform, providing the best way to integrate all systems running SAP or non-SAP software.

In addition, the SAP Services organization can help assess your manufacturing processes and present a clear road map toward excellence in compliant manufacturing operations. Using best business practices developed during more than



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105,000 business engagements in 120 countries, SAP Services can help you keep your manufacturing operations running at peak compliance levels in support of your business goals.

An End-to-End Solution for Operational Excellence

With integrated software from SAP, you can:

- Consistently deliver high-quality products
- Ensure compliance with GMP
- Reduce costs of manufacturing operations

For More Information

To learn more about how integrated software from SAP can help your organization, call your SAP representative today or visit us on the Web at www.sap.com/solutions/executiveview/operations/run-efficient-manufacturing.

Summary

With compliant manufacturing operations, life sciences companies can deliver quality products to customers consistently and meet good manufacturing practices (GMP) regulations at the lowest cost possible. Software and services from SAP and our partners can help you bridge the gap between your core enterprise and plant-floor systems at the lowest total cost of ownership.

Challenges

- Inconsistent levels of quality and compliance
- Lack of visibility across manufacturing operations
- Operational inefficiencies across the plant floor and the enterprise

Supported Business Processes and Software Functions

- **Enterprise planning and control** – Establish an achievable master plan aligned with customer requirements and business objectives and constraints, and control manufacturing activities across all plants
- **Plant-level operations** – Plan and manage manufacturing lines, schedules, and resources on a daily basis
- **Manufacturing execution** – Execute production according to schedule while considering exceptions and deviations in real time
- **Manufacturing intelligence and collaboration** – Gain insight into manufacturing activities and performance while ensuring collaboration across your plants and those of contract manufacturers
- **Product quality, safety, and environmental compliance** – Ensure that your products and processes comply with GMP
- **Lean and Six Sigma** – Manage manufacturing activities at Six Sigma levels and benefit from complete support for lean initiatives

Business Benefits

- Consistently deliver high-quality products
- Ensure compliance with GMP
- Reduce costs of manufacturing operations

For More Information

Call your SAP representative or visit us online at

www.sap.com/solutions/executiveview/operations/run-efficient-manufacturing.

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