

Solution Brief

SAP Solutions for Governance,
Risk, and Compliance

SAP® solutions for governance, risk, and compliance help you institutionalize compliance throughout the enterprise. Across operational, financial, global trade, and environmental compliance activities, you can reduce costs and risks while boosting productivity and increasing your competitive advantage.

GOVERNANCE, RISK, AND COMPLIANCE FOR LIFE SCIENCES COMPANIES

INSTITUTIONALIZE COMPLIANCE TO REDUCE COSTS AND INCREASE PRODUCTIVITY

As a life sciences company, issues of governance, risk, and compliance (GRC) touch on nearly everything you do. But many organizations approach GRC in an ad hoc manner – implementing point solutions, one after another, in response to regulatory demands as they arise. This approach is inefficient and costly. It also leads to the proliferation of silos and a lack of transparency concerning compliance issues.

A more effective approach is to institutionalize GRC throughout the global enterprise. This is where SAP® solutions for governance, risk, and compliance can help.

Turning GRC into a Competitive Differentiator

SAP solutions for GRC support a holistic, enterprise-wide approach to compliance and risk management. While point solutions focus on document management and retrieval, SAP solutions for GRC break down silos to establish a 360-degree view of compliance and audit trail transparency. No matter what new regulations tomorrow brings, you'll start from a position of enterprise-wide data visibility, process flexibility, and role-based access to enterprise resources. Powerful decision support based on real-time key performance indicators empowers personnel to manage compliance and risk efficiently and securely at the lowest cost. The solutions also automate many compliance and risk management processes, allowing you to manage by exception.

SAP solutions for GRC rest on a solid foundation of enterprise technologies and applications that include the SAP ERP application and the SAP NetWeaver® technology platform. These applications support industry-specific best practices that help you streamline compliance processes. SAP NetWeaver provides a foundation for enterprise service-oriented architecture (enterprise SOA). This enables you to rapidly develop highly flexible enterprise services that leverage your information and process foundation to meet specific requirements as they emerge.

Equally important is the SAP GRC Repository application, which documents and stores all governance, risk, and compliance information centrally. Its location-specific output (required language and data, for example) gives you a pool of information from which to analyze risk and make informed decisions. The software also promotes reuse by enabling enterprise-wide access to existing controls to meet the demands of new regulations.

What you get is a single platform that helps you manage financial, operational, environmental, and global trade compliance and risk more effectively than previously possible. By institutionalizing compliance throughout the enterprise, SAP solutions for GRC allow you to minimize your risk while enabling innovation. This turns compliance from an obligation into a competitive advantage.

Financial Compliance

To comply with the Sarbanes-Oxley Act of 2002, Basel II, and other regulations, life science companies need appropriate segregation of duties (SOD) and strict access controls to safeguard against fraud and enable sound corporate oversight. The SAP GRC Access Control application helps by constantly monitoring, testing, and enforcing access and authorization controls. Not only does this assist corporate compliance stakeholders in collaboratively enforcing SOD policies, it helps you identify and remove access and authorization risk from IT systems, which heightens your compliance with financial reporting, data privacy, and current Good Manufacturing Practice (cGMP) mandates. With the software, you can identify and remediate potential risks, such as conflicting authorizations within a single user's access profile; pinpoint actual risks, such as business functions that violate SOD mandates; and embed preventive controls in business processes to help you reduce the time, risk, and cost associated with compliance.

The SAP GRC Process Control application centralizes control management by integrating directly with control documentation in SAP GRC Repository. The application monitors financial-related controls and performs autovalidation at predefined periods. An easy-to-use dashboard employs a global heat map interface that helps you pinpoint control violation risks. Detailed root cause analysis helps you rectify problems and continuously improve processes for more effective corrective and preventive actions. The software creates remediation cases for each control

exception, immediately alerting control owners and managers to take action. In the end, you're able to establish controls that promote desired employee behavior, optimize business processes, and ensure cost-effective compliance.

Operational Compliance

Numerous regulations in the life sciences industry require meticulous management of business processes. Among them are current Good Clinical, Laboratory and Manufacturing Practices (cGxP) and the FDA's 21 CFR Part 11, which sets down requirements for establishing audit trails for electronic documents. To combat counterfeiting, companies must introduce electronic pedigree controls. The SAP GRC Access Control application ensures SOD compliance for cGMP between different areas of operation, for example, production and quality management. Powered by SAP NetWeaver, SAP solutions for GRC ease compliance with Part 11 requirements for documentation and auditability, while providing a common technical foundation that integrates with SAP Business Suite applications and related Part 11 functionality.

Global Trade Compliance

By embedding automated import and export compliance into your core logistics processes, the SAP GRC Global Trade Services application helps you meet the challenges posed by international, national, and regional trade regulations. The software automatically screens trading partners against officially sanctioned party lists, checks for embargo restrictions, and manages export and import licenses. It also provides information that lets you take



advantage of preferential trade agreements, such as the North American Free Trade Agreement (NAFTA) and those of the European Union. Ultimately, SAP GRC Global Trade Services ensures easy, cost-effective compliance with all trade regulations, while reducing cycle times, expediting customs clearance, and mitigating financial risks for global transactions.

Environmental Compliance

SAP and its partners provide a range of applications to help you proactively manage compliance related to environmental, occupational safety, and product safety regulations. Some of these include:

- **The SAP Environment, Health & Safety (SAP EH&S) application** – which helps manage product and chemical safety specifications, hazardous substance inventories, and dangerous goods, with functionality for safer handling, better tracking, and improved document management. The software helps you perform risk assessment, exposure logging, incident management, exposure profiling, and safety management for specific work areas and supports location-specific labeling.
- **The SAP Environmental Compliance application** – which helps you track, analyze, and record emission data and report to regulatory authorities. The application, which was developed jointly by SAP and TechniData AG, includes functionality for automatic emissions calculation, automatic notification of high emissions levels, and emissions credit determination and documentation for emissions trading markets.

- **TechniData CfP** – which collects, organizes, and analyzes data about products, factories, suppliers, countries, and customers. The application, developed by TechniData based on SAP NetWeaver, supports product content and substance list documentation, compliance checking, and automated communication with customers and suppliers.

Together, these EH&S applications form a solid foundation for ensuring a healthy work force, a clean environment, and ongoing product safety – while driving down the cost of compliance.

Comply and Thrive

By providing a foundation that promotes data transparency, process flexibility, and controls to enforce role-based access, SAP solutions for GRC help you institutionalize compliance throughout the enterprise. You'll be able to:

- **Reduce overall compliance costs** – with a holistic, enterprise-wide approach and industry-specific applications that help you comply with specific regulations at a lower cost
- **Minimize risk** – with processes that integrate compliance into the way you do business
- **Boost productivity** – with automated compliance that enables you to focus on core competencies
- **Increase competitive advantage** – with the ability to fulfill specific regulations faster and more effectively than your competition

Summary

SAP® solutions for governance, risk, and compliance (GRC) help you institutionalize compliance throughout the enterprise. With a holistic approach to GRC, you'll be able to drive down costs and reduce the occurrence of errors. This turns compliance from a regulatory obligation into a competitive advantage.

Challenges

- Highly regulated industry constantly subjected to new requirements
- Compliance landscape made up of disconnected point solutions that are difficult and expensive to maintain
- Low data visibility and limited audit transparency that make compliance costly and time-consuming

Supported Business Processes and Software Functions

- **Financial and operational compliance** – To establish segregation of duties and access and process controls
- **Global trade compliance** – To perform sanctioned party list screening and manage import and export licenses
- **Environmental compliance** – To support emissions management, product compliance, and environment, health, and safety management

Business Benefits

- **Reduce overall compliance costs** – Comply with individual regulations at a lower cost
- **Minimize risk** – Integrate compliance into the way you do business
- **Boost productivity** – Focus on core competencies by automating your compliance processes
- **Increase competitive advantage** – Fulfill specific regulations faster and more effectively than your competition

For More Information

Call your SAP representative today or visit us at www.sap.com/lifesciences.

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