

Managing the Integrity of Innovative Products

A Holistic Approach to Mitigating Product Risks
and Expanding Globally with Confidence

Table of Contents

- 3 **Product Compliance: Why It's Not Enough Anymore**
The Drivers of Change
- 4 **Demand for Product Integrity Brings New Risks and Opportunities**
- 5 **Realize Product Integrity**
Key Elements of Traditional Product Safety and Stewardship
- 7 **Extend Traditional Product Safety and Stewardship Processes to Cover True Product Integrity**
Taking a Deeper Dive
Enabling Processes and Software
- 9 **How SAP Can Help**
Enabling Holistic, Integrated Processes for True Product Integrity
Realizing the Benefits
[Learn More](#)

Product Compliance: Why It's Not Enough Anymore

For years, ensuring compliance with complex global regulations was the prerequisite for doing business. But times are changing. Today, customers are looking for products with true **product integrity** – which means they are not just compliant but also safe, ecofriendly, and trustworthy. For your business, this means accepting responsibility for what you procure, design, sell, and ship in far-reaching ways. But how? What systems and processes must be in place to achieve product integrity?

For chemical companies that develop and manufacture products, a top priority has been ensuring compliance with regulations. Compliance has grown in complexity in recent years, thanks to ever-changing requirements and new regulations such as the Registration, Evaluation, Authorization, and Restriction of Chemicals, or REACH. And it will always be a top business concern for any chemical business, as it's a prerequisite to selling into markets around the world.

But compliance alone isn't enough anymore – at least not for chemical companies seeking to sell and expand globally. Today, regulators, corporate customers, retailers, nongovernmental organizations, and consumers also expect products to be safe and more ecofriendly. On a practical level, this means suppliers must be able to:

- Provide correct product information regarding ingredients, origins, ecofriendliness, safe use, and hazardousness
- Have products that meet quality specifications
- Ensure that products are not corrupt due to contamination, ill treatment (due to an interruption of a cooling chain, for example), or imitation (due to product counterfeiting, for example) along the value chain
- Have a rock-solid process in place to quickly return all products back to the manufacturer in the event of a product recall

This list points to an important reality for chemical companies today: product compliance is just one aspect of what customers are looking for when they evaluate products and suppliers. Today, they expect true **product integrity** – a term describing

a product that is compliant, safe, ecofriendly, and trustworthy. At the highest level, achieving product integrity requires that in addition to ensuring compliance, you also:

- Procure sustainable raw materials as you develop new products
- Collaborate with supply chain partners to address supply chain exposures and coordinate with suppliers for fast and accurate batch tracing in the event of recalls
- Design for the full lifecycle of a product – from development and use to recycling or safe disposal

So ensuring product integrity means accepting responsibility for far more than just compliance with rules and regulations. You also need to assume responsibility for what you procure, design, sell, and ship in radical ways compared to years ago.

THE DRIVERS OF CHANGE

What's causing this shift from a focus exclusively on compliance to a broader set of expectations around product integrity? Key drivers include:

- **Growing product safety awareness** – Increasingly, people are questioning the safety of products because of their ingredients. Science is just beginning to understand the impact of many chemicals on humans and the environment, so suspicious or less well-known substances are often not tolerated in products.
- **New industry initiatives** – Industries are creating their own consortia to drive changes in business behavior. Consider the effect of the Walmart supplier survey, which targeted halogen content in consumer products and led to a push for halogen-free products. This is an example of an industry-driven initiative to provide products free of certain chemicals.
- **The push by nongovernmental organizations (NGOs) and Wall Street** – NGOs are growing in strength. For example, GoodGuide uses a simple rating system to determine how sustainable different products are. This NGO now has a mobile app that allows buyers to scan their product and immediately access its GoodGuide rating, as well as view suggested alternatives that are greener.
- **Vast and increasing legislation** – Governments are being proactive about driving business behavior by passing massive legislation such as the Restriction of Hazardous Substances (RoHS) directive and REACH.

Demand for Product Integrity Brings New Risks and Opportunities

For chemical companies, meeting demand for true product integrity is both a challenge and an opportunity. It's a challenge because as stakeholder expectations and product compliance requirements increase, there's a greater risk of potential failure in one or more areas. At the same time, demand for true product integrity is an opportunity. Why? Because it gives you the chance to differentiate your products from the competition by meeting and exceeding customers' expectations – and doing so more quickly and efficiently.

To minimize the risks and exploit the opportunities, you need to establish integrated business processes spanning many areas of your organization – processes that extend and embed safety, sustainability, and compliance into everything you do, as well as manage change with ease. Once established, these new processes will also help you better ensure true product integrity so that all your products reflect your commitment to safety, sustainability, and compliance.

THE HIGH COST OF LOW PRODUCT INTEGRITY

What happens when businesses fail to ensure high levels of product safety, sustainability, and compliance? They will find it increasingly difficult to grow their business with confidence. For example, working with multiple regulatory environments and globalized supply chains increases the risk that products will be noncompliant, or that adverse events will result from the use of products that are hazardous due to quality issues or inappropriate handling.

These processes will impact how your organization plans and operates – including how you:

- **Introduce new products into existing markets** – To be successful, your products must be compliant and appreciated by customers for their quality, safety, and ecofriendliness.
- **Introduce existing products into new markets** – These processes will impact not only the introduction of products into additional countries and regions but also their use in new application areas in other industries and customer groups where other compliance requirements and regulation frameworks might apply. In addition, achieving compliance for new products can be easier than staying compliant over time, which may involve meeting additional requirements and applying new regulatory frameworks.
- **Globalize your supply chain** – To fulfill demand globally, you need to source and produce in global supply networks. This means obtaining raw materials from all over the world at the best rates, as well as collaborating with manufacturing contractors and logistics services providers. But this not only increases the risk of noncompliance (for instance, what if you fail to comply with chemical restrictions in different countries or don't meet compliance requirements specific to certain business partners). It can also impact the safety of your products due to higher instances of counterfeiting and greater complexity involved in resolving quality issues.



Product integrity is the hallmark of truly marketable products in today's complex marketplace.

Realize Product Integrity

How can you achieve true product integrity? By extending your traditional product safety and stewardship processes with integrated systems that cover the full range of safety, sustainability, and compliance processes for products. We refer to the use of integrated systems and processes that help ensure that products are safe, compliant, and trustworthy as **operationalizing product integrity**.

KEY ELEMENTS OF TRADITIONAL PRODUCT SAFETY AND STEWARDSHIP

Traditional product safety and stewardship requires that you have the systems and processes to successfully answer three basic questions:

- The first question – What is in my product? – is impacted by chemical-specific regulations such as REACH and RoHS.
- The second question – How do I label, handle, and transport my product? – is impacted by global and local regulations concerning globally harmonized systems, the U.S. Occupational Safety and Health Administration, dangerous goods, and classification, labeling, and packaging.
- The third question – How do I handle my product's end of life? – is impacted by regulations such as the Waste Electrical and Electronic Equipment or the End-of-Life Vehicle directives.

As illustrated in Figure 1, the SAP® ERP application consists of components that help companies answer these questions by supporting traditional product safety and stewardship processes, as summarized in the following sections. The core software includes the SAP ERP; SAP Environment, Health, and Safety Management (SAP EHS Management); and SAP Recycling Administration applications. SAP EHS Management is based on the specification database for the maintenance of various substance-related information. Together, SAP solutions support companies in creating an efficient platform to help ensure product integrity.

Figure 1: Core Product Safety and Stewardship Processes Supported by SAP® ERP



The product safety and stewardship foundation illustrated in Figure 1 can generally be deployed outside of an enterprise resource planning (ERP) application, but embedding it into an ERP application provides significant benefits from native business process integration.

Chemical Compliance Management and Substance Volume Tracking

Chemical management legislation (such as REACH) requires manufacturers to assess compliance on imported and produced chemicals and ingredients for possible registration, notification, and declaration obligations. This means manufacturers have to register with authorities the maximum quantities of substances exceeding certain thresholds that they plan to purchase, import, produce, sell, or export within a certain period.

Substance-volume tracking software can help facilitate compliance by automatically recording the quantities of substances that need to be tracked. For example, SAP provides software that compares recorded quantities with the limit values and issues warning messages before a limit value is exceeded, helping to ensure business continuity. If a limit value is exceeded, the software can block the respective business process, preventing noncompliance. This kind of functionality is particularly important for compliance with REACH legislation. REACH requires that manufacturers and importers register the substances that they import or manufacture in volumes of more than one ton per year and assess corresponding risks based upon application-related exposure scenarios during the lifecycle of the substances. REACH compliance management supports the supply chain communication process related to the exchange of use information and the organization of the REACH registration process for the substances. This functionality is provided by SAP EHS Management.

Hazardous Substance Management

Operational safety and hazardous materials legislation require manufacturers to adequately classify and manage hazardous materials. Manufacturers need to track receipt, location, and volume of hazardous materials and ensure inventory is stored in the right (safe) location, which becomes challenging when the number of materials increases. For example, software for hazardous substance management helps manufacturers ensure operational safety and legal compliance by centralizing safety data management and supporting operational controls. This functionality is provided by SAP EHS Management.

SDS Creation and Distribution

Operational safety and hazardous materials regulations require manufacturers that sell and ship products containing hazardous substances to provide safety procedures for handling and working with those products. Increasingly, companies also provide safety information for chemical and biological products as a responsible best practice. To do this, most companies use software for product safety that helps to ensure operational safety and legal compliance by:

- Supporting the entire process of collection and determination of the required information
- Automating the creation and shipping of the required documents such as (extended) safety data sheets (SDSs)

This functionality is provided by SAP EHS Management, the SAP EHS Regulatory Content packages, and the SAP EHS Regulatory Documentation OnDemand service.

Labeling

Operational safety and hazardous materials regulations require manufacturers to adequately label their products. When change occurs – for instance, when the volume of labels needed increases or operational data like serial numbers and destination-dependent data must be added to labels – manual labeling processes can break down and jeopardize business continuity. That's why companies increasingly deploy software for global labeling management that helps them enforce legal compliance by centralizing development and publication of labeling data and templates, and enabling local and remote printing. This functionality is provided by SAP EHS Management and SAP EHS Regulatory Content.

Dangerous Goods Management

Operational safety and hazardous materials transportation regulations require manufacturers to ensure hazmat-classified products are packaged and transported accordingly. Especially for high-volume operations with worldwide distribution, it's essential to automate both dangerous goods classification and checks along the value chain. For example, software supporting dangerous goods control from SAP helps manufacturers protect revenue and ensure operational safety and legal compliance based on shipment destination and transportation mode. This functionality is provided by SAP EHS Management and SAP EHS Regulatory Content.

Recycling Administration and Reporting

Manufacturers, specifically brand owners, have seen an increase in legislation worldwide mandating what is termed extended producer responsibility for end of life of packaging, batteries, and even electronic products. To manage compliance, manufacturers are deploying software that supports recycling administration and reporting to avoid over- and underpaying recycling fees. This functionality is provided by SAP Recycling Administration.

Extend Traditional Product Safety and Stewardship Processes to Cover True Product Integrity

As explained previously, streamlining and operationalizing traditional compliance processes isn't sufficient to enable true product integrity. You need **extended** product safety and stewardship – enabled by complementary systems and processes – to help you answer more complex product-related questions. For example:

- Regarding the procurement of sustainable raw materials to develop new products, you'll need answers to questions such as these: What is the impact of each substance in your formulations? Are you using green substances? What are critical thresholds of hazardous materials? And are your product designs within these thresholds?
- As you collaborate with supply chain partners to address supply chain exposures and coordinate with suppliers for fast, accurate batch tracing in the event of recalls, you'll need to be able to respond to queries such as this: Did your suppliers of raw materials register what they sold you?
- As you design for the full lifecycle of a product – from development and use to recycling or safe disposal – you'll need answers to questions such as these: What do your customers do with your materials? Do you check and document before you ship materials?

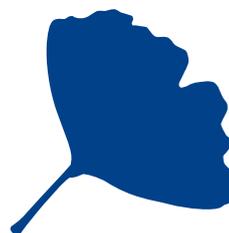
TAKING A DEEPER DIVE

But what does extended product safety and stewardship look like? Consider the need for high product safety – a key aspect of product integrity. Safety involves more than just controlling the risks that result from hazardous ingredients through appropriate warnings, packaging, and handling (all of which are covered by traditional product safety and stewardship processes and

enabling software). It also involves having products that meet a wide set of quality specifications – and being able to deploy a recall if something goes wrong.

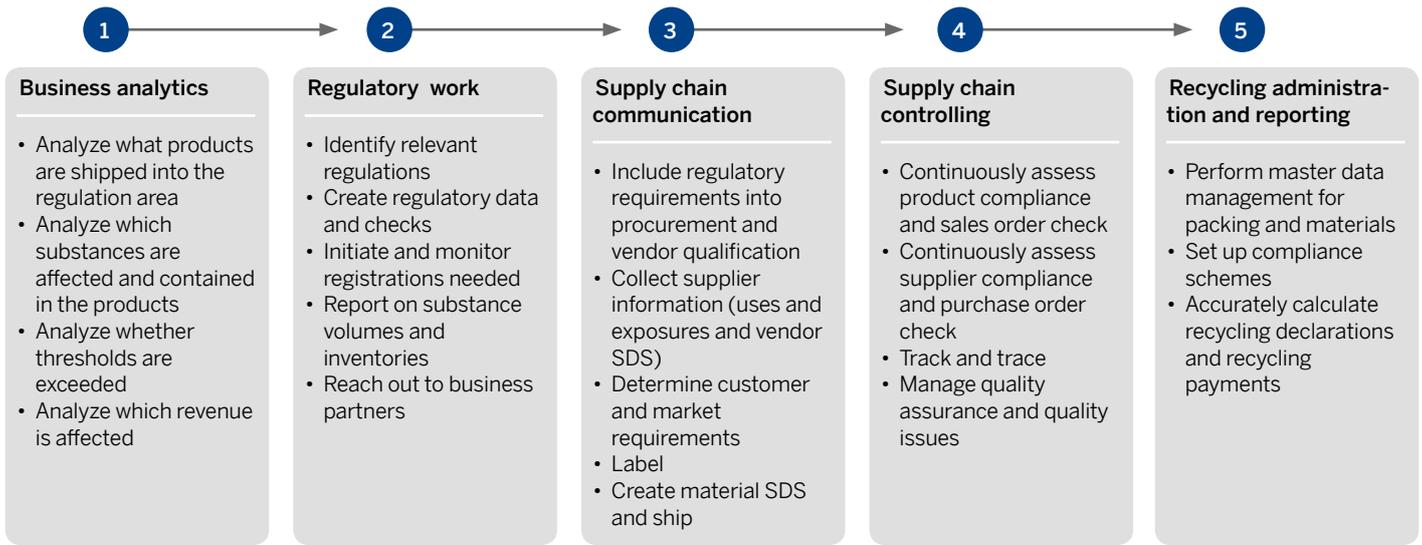
To take our example further, let's imagine that there's a chemical company that has operationalized processes to enable the multifaceted aspects of product safety. This company produces power cleaners with a mixture of hazardous and nonhazardous solvents. Customers who purchase these cleaners at do-it-yourself stores have noticed a leak in the packaging and started to complain. The chemical company, which has a quality issue management system in place, notes the issue and starts an investigation.

The investigation report discovers that all complaints refer back to the same batch number. To find out where the issue started, a genealogy of the batch is investigated using a global batch traceability system. The system eventually determines that the caps on the bottles aren't properly secured, causing the bottles to leak. Because the bottles contain hazardous solvents, the company wants to make sure this packaging issue hasn't impacted any other batches. If any other batches were impacted, the company will have to initiate a product recall, which – thanks to item serialization and product traceability – can be done easily. Without the integration of product traceability and item serialization software into quality management software, the chemical company would have had great difficulty pinpointing the exact location of the corrupted products.



To minimize the risks and exploit the opportunities, you need to establish **integrated business processes** spanning many areas of your organization – processes that extend and embed safety, sustainability, and compliance into everything you do.

Figure 2: Key Steps in an Extended Product Safety and Stewardship Process

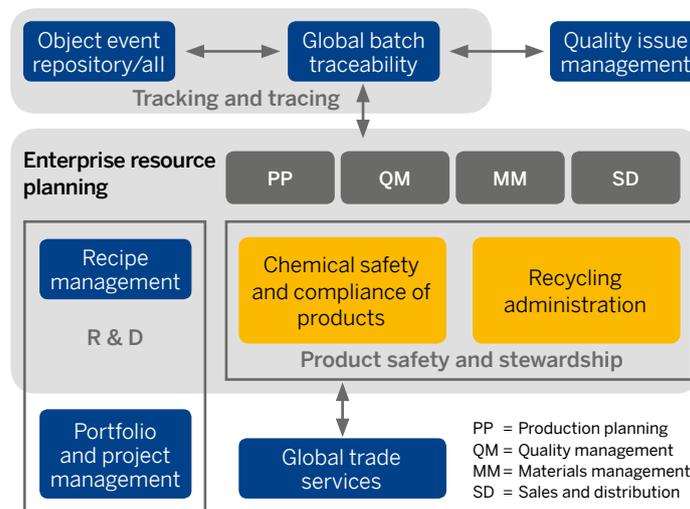


What made this scenario possible is **extended** product safety and stewardship enabled by the right software that supports compliance, safety, and sustainability in an integrated way. Figure 2 illustrates what this looks like from a functional perspective.

ENABLING PROCESSES AND SOFTWARE

The blue boxes in Figure 3 show what additional functionality is required to extend traditional compliance processes to support true product integrity in an integrated way.

Figure 3: Key Capabilities Needed to Operationalize Product Integrity



How SAP Can Help

SAP offers a comprehensive, integrated set of software that helps you operationalize product integrity. In addition to our traditional core product safety and stewardship solutions, you would deploy:

- **SAP object event repository** – which provides highly scalable, object-level event processing throughout the supply chain. It enables discovery, tracking, reporting, and other supporting business processes such as product tracking and authentication.
- **SAP Global Batch Traceability application** – which provides a corporate-level view of a cross-system product genealogy. This enables fast insight into how batches were used, precision product recall or withdrawal, and timely reporting of product issues.
- **SAP Quality Issue Management application** – a modern and flexible tool for handling issues and activities of all kinds and in all industries. It enables easy tracking, analysis, and monitoring of issues and related activities across systems and applications. Furthermore, it supports integrated scenarios by triggering issues from other applications, linking issues with processes in connected applications, and even initiating follow-up actions in connected systems during the course of an issue resolution. In addition to enabling standard quality issue resolution, the software supports improvement requests and activity management for continuous improvement programs.
- **SAP Product Lifecycle Management application** – which supports recipe management, development of sustainable, compliant products, and products to be sold in target markets. It also helps find alternative materials to meet legal requirements or improve your company's reputation (for instance, by using recycled materials).
- **SAP Global Trade Services application** – which supports sanctioned-party lists and prevents shipping of products to countries where materials used are banned.

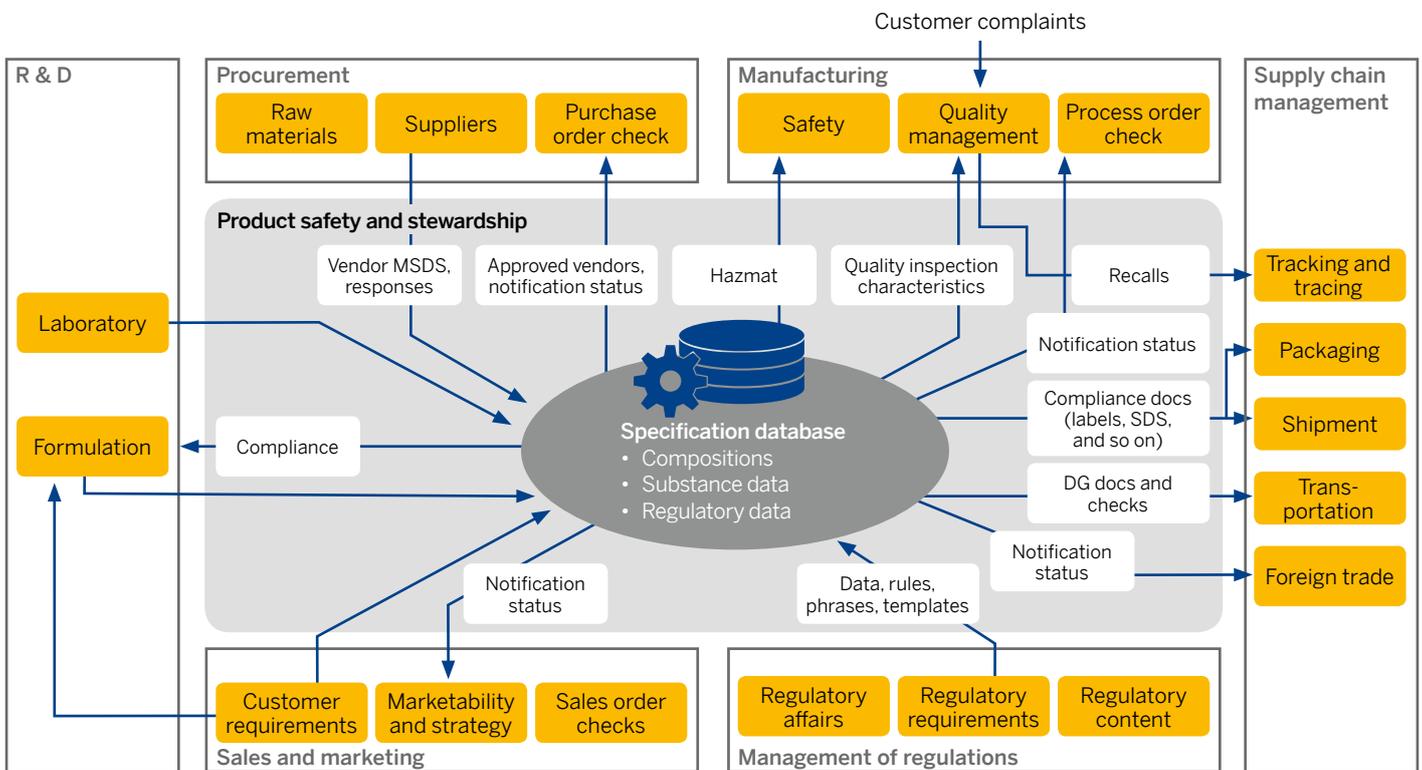


How can you [achieve true product integrity](#)? By extending your traditional product safety and stewardship processes with integrated systems that cover the full range of safety, sustainability, and compliance processes for products.

ENABLING HOLISTIC, INTEGRATED PROCESSES FOR TRUE PRODUCT INTEGRITY

As shown in Figure 4, these complementary SAP products integrate with SAP software supporting traditional product safety and stewardship. Together, they support a comprehensive, holistic approach to product integrity.

Figure 4: A Holistic Approach to Achieving Product Integrity



MSDS = Material safety data sheets
DG = Dangerous goods

The blue box represents traditional (or core) product safety and stewardship functions. All software leverages a central specification database (visualized as the dark gray oval) where chemical information is maintained. In light of environmental friendliness and safety of products, it becomes more and more important to have a chemical view of a product beside the logistical view of a material. The chemical view means that a

material is described in terms of its chemical composition (which substances are in it), and for these ingredients chemical, physical, toxicological, and regulatory information has to be maintained as well. There might even be business-partner-specific information like uses of products with related exposures to substances and registrations.

This specification database is fed by the organization's R & D department, which determines chemical, physical, and toxicological data in laboratories and hands over chemical compositions determined during recipe development. The specification database is also fed regulatory substance information created by regulatory affairs experts or received from information service providers.

Compliance checks for manufacturing, purchase orders, and sales orders are executed against this information and handed over to quality inspection planning for the creation of quality inspection criteria and their values that have to be confirmed in quality inspections. The information can also be used to:

- Define approved suppliers and raw materials
- Check imports and exports against chemical regulations
- Create and ship compliance documents automatically
- Identify chemical risks in production
- Define safety measures
- Evaluate and conduct legally compliant handling
- Determine the storage and transportation of substances and products that will become "dangerous goods" once handled outside the plant

The final steps to operationalizing product integrity are managing customer complaints and setting up a tracking and recall program (for example, in cases where products shipped are found to be of poor quality, or if there are safety or compliance issues). Tracking also prevents products from being corrupted or counterfeited along the value chain.

REALIZING THE BENEFITS

An SAP performance benchmarking survey shows that when customers operationalize product integrity using integrated applications and processes, they realize:

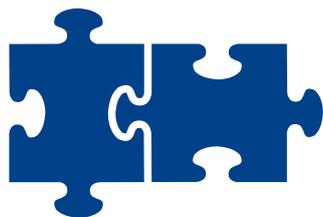
- 38% lower product lifecycle management cost when new development projects are managed by a documented process from concept to product launch
- 31% higher operating margin where executives across the company meet regularly to review product portfolio performance and competitive positioning
- 75% less audit cycle time for top-quartile organizations included in the survey, as compared to average performers
- 25% lower environment, health, and safety (EHS) audit cost with standardized EHS-related processes across all business units
- 63% less EHS costs for top-quartile companies as compared to average performers
- 79% fewer citations for top-quartile companies as compared to average performers
- Billions of dollars of revenue protected
- Millions of dollars in compliance costs saved

Once established, these extended processes will help ensure true **product integrity** so that all products reflect your commitment to safety, sustainability, and compliance.

LEARN MORE

To learn more about SAP and our solution portfolio for product innovation and integrity, contact your SAP representative or visit us online at

https://rapid.sap.com/se/#vm?indids=i_chemical&lobids=all.



SAP offers a comprehensive, integrated set of software that helps you operationalize product integrity.

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