Sparta Systems

How Chemical Companies Increase Visibility across the Value Chain

WHITE PAPER

Overview

Most executives at chemical companies view quality management as a cost center for the organization despite its potential to generate revenue. Chemical manufacturers typically lack visibility into and control over quality processes throughout the organization, which leads to a profit challenge in today's market. While all manufacturers have standard operating procedures (SOPs) in place for quality operations, how do executives know if individuals across the company's various business units and geographic regions are following procedure?

The chemical industry is continuing to outsource operations to contract manufacturers and packagers and utilize global raw materials suppliers in the development of chemical products. For chemical companies, it is often difficult to determine the source of quality issues arising when third party contractors are employed and to maintain ownership and responsibility for the quality of the end product. It is estimated that 52% of product recalls can be traced back to supplier and contract vendor issues[1], making transparency into value chain partners' processes extremely important.

Global chemical manufacturers are turning to enterprise quality management systems (EQMS) to take control over quality operations and ensure everyone at every stage of the process, in every business unit and region—both internal resources and external third parties—are complying with SOPs, ISO standards, United States (US) Toxic Substances Control Act (TSCA) and European Union (EU) REACH, and other global compliance regulations to deliver safe and effective chemical products to the marketplace. EQMS provides manufacturers with immediate access to comprehensive information on quality operations. As a result, manufacturers can quickly identify and address deviations and complaints, uncover potential issues and implement global continuous quality improvements to cut up to 40% in quality management costs.[2]

In this paper, we examine the regulatory, operational and economic challenges facing chemical executives today as they work to deliver safer chemicals products in an increasingly regulated and competitive business environment; how a disconnected approach to quality management increases risks and costs for global chemical manufacturers; and, how an EQMS implemented as part of a company's overall business strategy delivers operational and cost benefits that transform quality management from a cost center to a revenue driver.

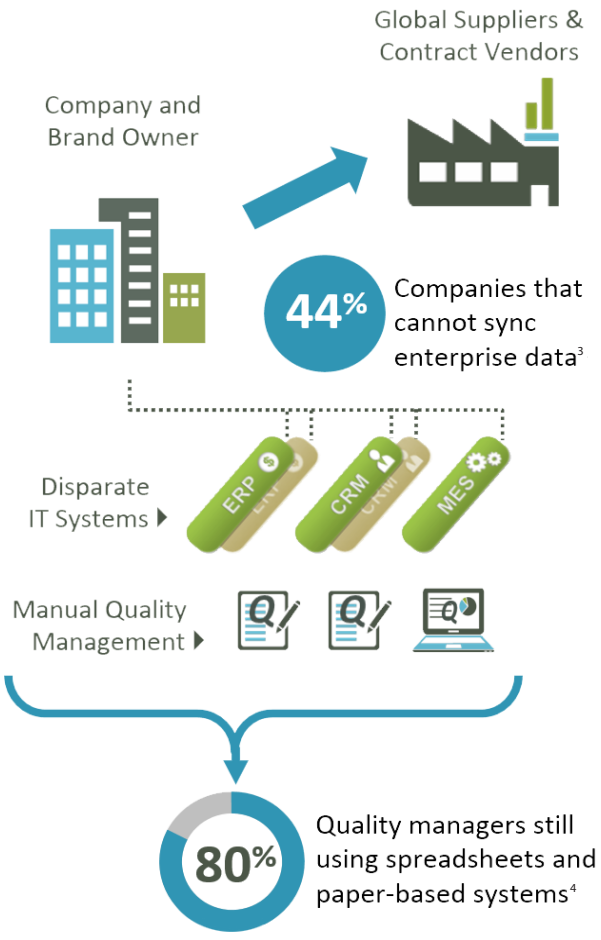
Challenges Facing Global Chemical Manufacturers

While industry and government regulations clearly spell out the steps chemical manufacturers must take in order to achieve and maintain compliance, companies are conducting business in an increasingly complex environment. Today a global chemical manufacturer's operations are rarely conducted within its four walls. Instead, most manufacturers rely on a wide variety of third parties scattered across the globe—and are responsible for ensuring each one is operating in full compliance with SOPs.

Quality Process Variability

While all chemical companies have SOPs in place around quality operations, how many have the capability to ensure all parties in the chemical development and manufacturing processes—both internal and external—are following these procedures?

Most chemical manufacturers today are relying on disjointed systems to manage quality operations. According to a global manufacturing study, 44% of companies still struggle to synchronize and integrate data across various management systems and internal groups.[3] Furthermore, quality process can vary widely from one site to another and manufacturers typically have little visibility into the activities of third party contractors.



Lack of global visibility into quality operations

While chemical executives are committed to ensure the quality of company branded products, most do not have the technology in place to gain an enterprise-wide view of quality operations. In many cases, different departments, business units and sites use individual systems and processes for monitoring product quality, identifying and tracking deviations and incidents, applying corrective and preventive actions (CAPAs), handling complaints and managing change.

Without a way to see the "big picture," chemical executives cannot confirm that operations are being conducted in accordance with SOPs, placing both the company—and themselves—at risk for noncompliance with regulations, and jeopardizing the quality of products entering the marketplace.

Reactive versus proactive quality management

Those global chemical manufacturers that lack enterprise quality management systems often find that processes for uncovering and addressing quality issues at the site level are reactive versus proactive. Rather than having access to detailed, accurate and timely quality data and reports that enable the prediction of potential problems, manufacturers are forced to put out fires as they happen. This poses the risk for minor problems escalating into major setbacks that go undiscovered by the company.

According to Dr. W. Edwards Deming, best known for being the leader of the quality evolution in industrial management, quality does not come from inspection but from doing it right the first time. He developed the "1-10-100 Rule" to explain how costly errors are when they are not addressed early in the process. For example, when a facility receives supplier's materials and an issue is identified, the cost to address the situation is one times (1x) the cost of the material since it has not affected other materials. The suspect material can be quarantined and returned to the supplier. When a problem is identified after production, it costs the company ten times (10x) the standard cost of the material to address the situation.

However, the cost skyrockets when finished goods enter the supply chain and an issue is identified—usually as a result of a customer complaint—and product needs to be recalled. This can cost a company 100x to 1000x the cost of pre-production material. So it is in the best interest of a chemical company to proactively manage the supplier network and identify problems early to reduce the impact on costs, operational resources, brand reputation, market share and public safety.

Implementing change in a silo

Another drawback of not having a global view into quality operations is that change must take place in a silo. When a site uncovers a problem and implements a procedure to fix it, it is difficult for the company to determine whether that same issue could happen elsewhere. As a result, chemical manufacturers become locked in a cycle of identifying an issue at site level, resolving it and then waiting to see where that problem might happen next. Implementing change in this manner is both inefficient and costly.

The dangers of disparate processes

Without a system in place to manage processes across business units, organizations end up operating in silos with little visibility into changes at a particular site or anywhere within the enterprise. This could lead to quality and safety issues and jeopardize timely product launches.

For example, one chemical manufacturer was managing global product registrations for each active ingredient and finished product using spreadsheets and paper-based records. The approach limited the ability to track new registrations, requirements and testing results and documentation needed for each country. In the event of a management of change (MOC) to a product, often times that information was not shared with the regulatory affairs team and submissions would not be updated. As a result, product launches and distribution would be delayed since registrations were not consistent with the final product. The consequence of these registration delays was quarantined inventory consuming valuable warehouse space, business plans falling short of expectations, and the competition capturing market share.

Evolving Regulatory Environment

ISO 9001[5]

Oversight of today's chemical marketplace is complex and challenging based on meeting requirements at the country, state or local level. ISO standards are a leading requirement for most industries today. The International Organization for Standardization (ISO) in an independent organization made up of 163 member countries who have established more than 19,500 standards and specification to ensure quality, safety and efficiency. The benefit for a business is that standards help reduce costs by minimizing waste and errors and increasing productivity and enables organizations to enter new markets and to facilitate fair global trade.

Most industries, including chemical, strive to ensure compliance with ISO 9001 requirements, which is focused on quality management systems and how an organization can meet the needs of customers while maintaining regulatory requirements related to a product.

ISO 9001 Quality Management… The standard that pays for itself

According to 2011 Client Satisfaction Survey[6] done by The British Assessment Bureau (BAB), 44% of respondents said that they won business as a result of becoming ISO 9001 certified. The top three reasons companies implemented the standard:

- **Client requirement (57%)**
- **Win more business (31%)**
- **Improving internal processes (24%)**

In regards to the quality system itself, companies need a system that includes capabilities for process performance and product quality monitoring, corrective and preventive action (CAPA), change management and management review. This includes appropriate processes, resources and responsibilities to provide assurance of the quality of product and services. The effectiveness of the ISO system also depends on senior management's commitment to monitor, control and improve quality. Without executive support of the success of ISO 9001 throughout the organization, companies will only obtain a certificate for display without the operational and cost efficiencies achieved from implementing an integrated quality management system.

Toxic Substances Control Act in the US

Chemical ingredients and products are receiving more attention and scrutiny from legislators and environmental regulators alike. These regulations affect the sale, import and export of chemicals and the products that contain these chemicals to ensure public and environmental safety.

In 1976 the United States passed the Toxic Substances Control Act (TSCA) to provide the Environmental Protection Agency (EPA) the power to review and regulate any chemicals being distributed in the US. Today more than 84,000 chemicals[7] are regulated by the TSCA.

Pre-manufacturer notification and new product registrations must be submitted to the EPA Central Data Exchange, which is the agency's electronic reporting site. Products imported into the US must be accompanied by certification stating that the chemical complies with TSCA requirements or be denied entry into the US. There are even individual state programs to regulate chemicals used in consumer products, such as the "Green Chemistry Initiative" and the "Department of Toxic Substances Control" (DTSC). Managing submissions and testing requirements for complex regulatory requirements is a daunting task.

REACH in the EU[8]

In 2007, the European Union enacted the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) which requires any chemical exceeding one ton be registered and data submitted on the chemical's identity, production process, usage instructions, safety guidance, and effects on human health and the environment to the European Chemicals Agency (ECHA). For quantities above 10 tons additional testing information on environmental hazards, toxicity pollution assessments and other long-term hazard analysis must also be submitted. As a result, there are over 14,000 registered substances in Europe with more than 3,100 pending registrations, and another 13,000 chemicals that have been produced or imported that meet the volume requirements.

Under the REACH evaluation process, ECHA reviews the testing proposals and compliance verification of the active ingredient or products registered and a risk assessment is performed. Any substances considered "high concern" cannot enter the EU market unless authorized in the registration of the active ingredient or the mixture of the indicated product. Any chemical over the one ton requirement needs to be registered under REACH between November 2010 through May 2018, with timing based on the volume and toxicity levels of the substance.

Costs to implement REACH

The EU Commission has estimated the total REACH implementation costs to be incurred by industry could cost up to $7.0 billion. However, other studies have indicated that the total direct and indirect costs associated with REACH implementation could reach as much as **$32 billion.**[9]

Conclusively, chemical manufacturers are increasingly global and dispersed, conducting operations across multiple business units and sites and relying on third parties to supply raw materials and packaging, perform toll conversion or complete manufacturing of liquid or dry chemicals. Often times, chemical companies are managing these processes in spreadsheets or paper-based records which prevents visibility into trends or issues before the issue escalates. But at the end of the day, it is a manufacturer's senior leadership that owns quality management and will be held accountable for any quality issues that arise—whether they are caused by those employed by the company or an external contractor.

Benefits of a Globally Integrated Enterprise Quality Management Solution

Operational and economic advantages

With regulators requiring chemical manufacturers to have in place comprehensive quality management systems that enable executives to ensure the quality of products produced, and the cost and risk implications of taking a piecemeal approach to quality management, leading global manufacturers are turning to enterprise quality management systems (EQMS) to gain visibility into and to take operational control.

Global view of quality operations across the enterprise

When an EQMS is integrated with a manufacturer's key business processes, it enables chemical employees—from the shop floor to the top floor—to manage, track and report on the company's quality management processes across the entire enterprise. The system must include functionality for incident management, corrective and preventative actions (CAPAs), hazard analysis, audit management, complaint handling and management of change, so that it is directly aligned with the requirements of regulations.

Having all quality management processes flow through a single system provides chemical executives a comprehensive view of their quality operations that they can leverage to make accurate, timely and impactful changes during all phases of product development and manufacture, and across all business units. And the use of cloud technology enables companies to achieve that same type of visibility and transparency with third party contractors and suppliers.

Enforce compliance with standard processes

With all quality personnel leveraging the same platform for activities and reporting, chemical executives can put into place enforceable processes to ensure compliance with standard operating procedures (SOPs). An EQMS should be configurable so that all individuals involved in product quality—both internal and external—are not only following the right processes but also executing tasks in the correct order. This boosts the effectiveness of quality operations, improves efficiency and reduces the risk for costly and potentially dangerous errors.

Reduce risk and avoid loss through proactive and comprehensive change

Having enterprise wide visibility into quality operations and a single system through which quality activities are processed and recorded provides chemical executives with the information and insights needed to make proactive changes. Rather than waiting for a quality related failure, executives can identify leading indicators and intervene before a minor issue becomes a critical and costly impediment in the product development or manufacturing process. The regulatory affairs team also has visibility into changes with a product's formula, testing or specification that will enable them to update product registrations globally to prevent product launch delays.

The data derived from an EQMS also enables chemical executives to implement comprehensive change across operations rather than just at the site level. When a manufacturer identifies a quality issue locally and determines its root cause it can then use its EQMS to determine which other sites have the same conditions and apply preventative actions to stop the same problem from occurring, or at least intervene in a timely manner to lessen its impact. For example, hazard analysis within the facility is imperative to ensure product and employee safety.

According to one global chemical manufacturer, using its EQMS in this way enabled it to significantly improve its bottom line by reducing the number of quality events impacting its operations. For instance, a company's operations team found out that a piece of manufacturing equipment was grinding fine metal particles into its chemical pigment and determined it was because the screen attachment was outside specifications resulting in it detaching during production. They immediately identified all other sites using this equipment, sent findings to their equipment vendor, and had new replacement parts sent to each location, and applied CAPAs to address the problem before it adulterated the finished product at these sites.

One global chemical manufacturer using a quality management system found that it is finally possible for the first time to initiate CAPA processes that are a central component for process and product improvement. The possibility of deriving key performance indicators (KPIs) contributes to transparency and to improving the overall process.

Manage change globally for consistency across operations
Having an enterprise wide quality system that is fully integrated with business operations provides chemical executives with the visibility necessary to ensure all parties in the chemical development and manufacturing processes are operating consistently for efficiency, effectiveness and safety. When a change is necessary on the site level, executives can evaluate its impact and determine whether the same change must be implemented at other sites to maintain consistent product quality and ensure organization-wide compliance with SOPs. The employment of systematic changes generates greater efficiency and lower costs compared with applying a piecemeal approach.

Complete IT integration for better visibility

Having enterprise systems—such as ERP and MES—in place is great for managing finance or manufacturing transactions, but the complexity of managing workflow processes are not that easy. Whether it is a complaint, investigation, audit, CAPA or MOC, there are a series of steps that need to be set up that other IT systems cannot handle. An EQMS is a proven solution to document SOP and other workflows and store data into one central repository. It also integrates with existing enterprise systems to share master data, send alerts or assign tasks to project team members for follow up, and quarantine suspect material from entering the supply chain.

Quality management self-assessment

For global chemical manufacturers, quality operations can be transformed from a cost center to a revenue generator through the use of an EQMS. The enterprise-wide visibility and control provided through such a system enables executives to make accurate, timely and impactful decisions to quickly uncover and address issues, thereby improving operational efficiency, reducing risk, driving down costs and getting products to market sooner.

To determine what benefits your organization can derive from implementing an EQMS, use the following questions to conduct an assessment of your current quality management processes:

1. Do you manage quality processes in the same manner across all phases of your product development and manufacturing process?

Variations in quality management processes not only place you at risk for non-compliance with industry and government regulations, but can also add time, labor and cost to your operations. Chemical manufacturers have reported that deviations in quality processes can increase costs up to 30 percent.

2. Do you manage quality processes in the same manner across all of your business units, and across all countries and geographic regions?

Chemical manufacturers are required to operate according to their established standard operating procedures (SOPs). Can you use your current quality management system to ensure all personnel across your global enterprise are following procedures and performing tasks in compliance with your SOPs? If not, you are placing yourself at risk for potential regulatory action and jeopardizing the quality of your products.
3. Do you manage quality processes in the same manner both internally and externally?

Although many global chemical manufacturers today outsource various aspects of chemical development and manufacturing processes and rely on third party suppliers of raw materials, it is the chemical company itself and its executives who are ultimately responsible for the quality of the final products. Determine whether your current quality management system is configured to ensure all parties —both internal and external—are following the required procedures to generate products that meet your quality standards.

Sources

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To learn more about this topic and how Sparta Systems can help, visit www.spartasystems.com

Sparta Systems, an industry pioneer and leading provider of enterprise quality management software (EQMS) solutions, enables businesses to safely and efficiently deliver their products to market. Its TrackWise® EQMS, a trusted standard among highly regulated industries, is used by quality, manufacturing and regulatory affairs professionals to manage compliance, reduce risk and improve safety across the global enterprise. Headquartered in New Jersey and with locations across Europe and Asia, Sparta Systems maintains an extensive install base in the pharmaceutical and biotechnology, medical device, electronics manufacturing and consumer products markets.

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