

Mitigating Risk in the Life Sciences Industries: Challenges and Solutions in Today's Competitive World

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Frost & Sullivan has engaged in a new research initiative titled, “**The Vision of the Future of Manufacturing and Production,**” or Visi-MAP. This innovative research uses Frost & Sullivan's proprietary 3-C framework (the challenge themes of Competition, Compliance and Collaboration) and the business imperatives that will reshape manufacturing and production in the next decade.

Frost & Sullivan believes the 3-C framework very clearly articulates the challenges faced by manufacturing organizations on a global level. This article will address the challenge theme of compliance and the business imperatives that are driving the risk mitigation trends within the life sciences industry.

As part of the Visi-MAP and Best Practices research, a Frost & Sullivan analyst team conducted industry market participant and client interviews, rigorous analysis, and extensive secondary research into the best practices among software providers for the life sciences industry. This work was done in an effort to find out what specific companies are doing now to address those potential issues through their forward-thinking products and services they are bringing to their customers.

CHALLENGE OF COMPLIANCE IN TODAY'S LIFE SCIENCES INDUSTRY

The compliance challenge can span a wide array of issues, from government regulations, to safety issues, to customer specification and quality demands, to data records of production processes, to environmental regulations, and so on.

Many manufacturing industries operate within an environment of stringent regulatory and legal mandates. The hygienic vulnerability of certain manufacturing industries, such as pharmaceuticals manufacturing, requires that these types of manufacturers incorporate effective, standardized methods by which they can mitigate their risk in terms of meeting product handling and safety governance, compliance and quality management standards.

Industry benchmark companies in a wide variety of segments have realized that compliance is not a burden to be tolerated; it is a necessity of doing business that, if managed properly, can actually add value to the enterprise. Serious compliance violations can result in fines, lengthy or even permanent plant shutdowns, and significant negative publicity for manufacturers. As such, companies have begun to approach compliance as a process of business operations that must be designed, implemented and managed effectively. Best-in-class enterprise risk, compliance and quality management (ERCQM) solutions can help companies streamline processes and systems to produce sustainable across-the-board practices, including everything from equipment and system performance to customer service levels, to optimal financial performance and operational effectiveness.

FROST & SULLIVAN'S TAKE: BEST-IN-CLASS SOFTWARE SOLUTIONS IN ENTERPRISE RISK, COMPLIANCE AND QUALITY MANAGEMENT

In today's global environment, connecting geographically-dispersed assets and enabling collaboration across a remote workforce poses substantial challenges to many companies, particularly those in highly regulated industries such as life sciences. There are a number of business imperatives that are driving change within the industry, including the need to speed the time-to-market product lifecycle, manage an increasingly mobile workforce, and improve operational

consistency in terms of standardized quality metrics and complaint-handling procedures. Meeting these imperatives requires a high degree of collaboration and enterprise-wide visibility between different independent divisions within their organizations in order to mitigate the impact of current economic uncertainty coupled with emerging regulatory standards. The question becomes, how do companies meet these business imperatives while concurrently establishing, implementing and maintaining a cost-effective risk management solution that can be tightly integrated into their existing business operations?

Pilgrim Software, through its flagship SmartSolve® solution, offers an end-to-end enterprise risk, compliance and quality management (ERCQM) platform that streamlines the entire compliance management cycle. Pilgrim's holistic ERCQM solutions, as provided through the pre-integrated and best practices pre-configured SmartSolve® platform, provide compliance risk management on an enterprise-wide scale by allowing automated regulatory recordkeeping, safety and compliance monitoring, risk audit reporting and enterprise-wide standardized workflows.

The platform, built on service-oriented architecture (SOA), allows end-users to easily tailor and extend their forms and work-flow application processes. Through these distinct functionalities and flexible application design tools, this holistic solution allows end-users to capture and monitor data from diverse sources, translate that data into actionable knowledge, and implement standardized processes to prevent ERCQM process errors and sustain complaint-handling best practices.

In order to bring about improvement to the time-to-market product cycle, companies must find ways to allow their dispersed workforce to communicate and collaborate in real-time. For data visibility and smooth collaboration, Pilgrim's Document Management module enables users to create, share and manage vital documents. This enterprise-wide visibility into employees' collaborative work and ideas allows for quicker decision-making, which results in a shortened time-to-market cycle. In addition, this type of collaboration facilitates the ability of management and colleagues to work with one another across broad geographical distances.

In addition to broad workplace collaboration, quality metrics must be standardized across all operations in order to have a sustainable and successful risk mitigation process in place. Companies must not only share data between diverse locations, but collate it into a single comprehensible version of truth that can be analyzed and synthesized into actionable knowledge. The Nonconformance and CAPA Management module offered by Pilgrim enhances the risk and quality management process by allowing end-users to capture event data from any location, assess and respond to the potential problem, and track all resulting actions taken. This provides management with the visibility and real-time knowledge necessary to make immediate decisions that will resolve the situation and ensure operations continue without compromise of quality.

In a similar manner, customers using Pilgrim's Complaints Management solution are able to take advantage of its Web-based system that can streamline the complaint-handling lifecycle. Complaints Management helps customers by standardizing the response processes involved across an organization, speeding complaint processing from complaint capture to resolution. Real-time visibility of the process enables immediate management of incidents, while the data captured can provide valuable analysis for reports and trends overviews, especially in helping organizations provide electronic reports to regulatory agencies.

Some other key modules that can be used in the SmartSolve platform include Audit Management, which helps customers assess their risk mitigation processes and enables the proliferation of best practices on an enterprise-wide basis. Training Management helps manage employee quality and compliance training and certification. SupplierQuality helps organizations monitor and manage their suppliers' compliance and quality information, something that is particularly important with the growing complexities and risk of today's global supply chains.

Lastly, Pilgrim provides key capabilities in transforming actionable data into visible intelligence to help companies with not only decision-support on immediate business issues and trends, but also providing a model to help with predictive analysis, moving a company from reactive to a risk-based proactive organization.

Being a best-in-class solution provider means not only providing companies with products that will meet their requirements, but offering them at an affordable price point, as well. Pilgrim Software's solutions are cost-effective in that they offer customers tremendous cost savings. SmartSolve's Web-based open architecture standard enables it to be easily integrated into a customer's existing system, saving them on installation and implementation costs.

Pilgrim also offers its solutions through a Software-as-a-Service (SaaS) or Cloud delivery model. This offers customers flexible IT pricing, while saving them costs in IT-related expenditures and hardware maintenance costs.

There are a number of different ERCQM solution providers available to the industrial consumer these days. However, following industry market participant and client interviews, rigorous analysis, and extensive secondary research into the best practices among solution providers in this market, Frost & Sullivan has recently recognized Pilgrim Software with its 2010 Best-in-Class Award for Customer Value Enhancement in recognition of its suite of best-in-class ERCQM software solutions.

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