

F R O S T *&* S U L L I V A N
2007 & 2008 WINNER BEST PRACTICES AWARD



PILGRIM SOFTWARE:
STREAMLINING
COMPLIANCE AND QUALITY
MANAGEMENT
ACROSS THE ENTERPRISE

OBJECTIVE

This white paper discusses the inherent benefits associated with implementation of an enterprise-wide compliance and quality management (ECQM) system for Life Science companies. It also provides a brief summary of Pilgrim Software's best practices and value propositions within the enterprise compliance and quality management space.

About Pilgrim Software, Inc.

Pilgrim software, Inc. is a world-leading provider of Enterprise Compliance and Quality Management solutions for global organizations. Pilgrim helps organizations manage industry and regulatory compliance, reduce manufacturing costs, and improve customer satisfaction. For more information, visit Pilgrim Software's website at www.pilgrimsoftware.com.

Pilgrim Software is the recipient of the 2008 & 2007 North American Enterprise Compliance and Quality Management Company of the Year Award from Frost & Sullivan.



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**2007 & 2008 North American Enterprise Compliance & Quality
Management Company of the Year Award
Pilgrim Software**

EXECUTIVE SUMMARY

Pilgrim Software has been awarded the North American Enterprise Compliance & Quality Management Company of the Year Award from Frost & Sullivan for the second consecutive year. This prestigious award is presented to companies that have demonstrated unparalleled excellence within its industry in terms of business development, competitive strategy, and customer satisfaction. This award recognizes Pilgrim Software's continued leadership within the medical devices segment, and its expansion into new segments, such as other FDA-regulated and healthcare industries.

In 2007, Pilgrim Software was commended on its solutions that provide a comprehensive view of quality management at the organizational level and its proactive approach to quality management and compliance initiatives. The innovative solutions that Pilgrim Software offers are modular allowing clients to mix and match components to meet their specific needs. The ability for enterprises to facilitate seamless sharing of data and information, internally and externally, assured their success with a simplified quality and compliance management approach.

In 2008, Pilgrim Software demonstrated sustained their growth and momentum with expansion into new industries and continuing to drive value for their existing customers over the past year. The benchmark approach to on-demand solution-based Software as a Service (SaaS), a monthly subscription service that provides clients with updates, was designed to provide infinite scalability. SaaS responds to the challenges that enterprises face regarding the integration of disparate systems and flexibility. Pilgrim Software continues to provide solutions while reducing IT infrastructure costs which require constant updating.

Frost & Sullivan's North American Enterprise Compliance & Quality Management Company of the Year Award recognizes Pilgrim Software's outstanding management and consistent growth, especially over the past two years, as well as their high quality products and services, positive social and economic impacts on local and national communities. In 2007 and 2008, Pilgrim Software was recognized for the demonstration of outstanding achievements and superior performance in the areas of: leadership, technological innovation, customer service, and strategic product development.

2008 AWARD WHITE PAPER

The recipient of Frost & Sullivan's 2008 Company of the Year Award in the enterprise compliance and quality management (ECQM) segment, for the medical devices industries, is Pilgrim Software. The company has yet again demonstrated its continued leadership in the medical devices segment with a 60.0 percent market share, globally and sales growth of 30.0 percent during 2007. The company has sustained this momentum by venturing into new segments such as healthcare insurance, while continuing to drive value for its existing customers. Its on-demand solution-based software as a service (SaaS) application delivery model has ensured lower initial investment, reduced overhead, infinite scalability, increased accessibility, improved collaborative productivity, easier implementation, and improved security with optimal performance, leading its customers to a position of competitive advantage. While most peer group companies provide a tool kit approach to address quality issues, Pilgrim Software remains a benchmark for its superior solution offerings that are 'out-of-the-box' through a best practices approach, that provides a seamless integration platform to users across varied functions, resulting in enterprise-wide visibility of data.

The need to reduce information technology (IT) infrastructure cost is a key challenge for end-users, as applications, operating systems, storage, networks, and databases need to be constantly upgraded. Pilgrim Software's SaaS-based on-demand solution is delivered to its clients on a monthly subscription basis that includes software, validation packs, storage maintenance, and support services. The application hosting is done by Pilgrim Software, thereby helping customers eliminate investment in expensive infrastructure and related overhead cost associated with employing and training IT staff. The cost is predictable for clients ensuring minimum upfront investment from clients. This approach yielded a significant sales win for Pilgrim Software from a major diagnostic testing and information services provider during the year 2007.

The manufacturing outsourcing phenomenon has not only provided ample opportunities but also posed significant scalability challenges to medical device firms. Pilgrim Software's on-demand solution is designed in a way that it accepts users on an incremental basis, providing infinite scalability. Traditionally, the on-premise software license ownership has led to high capital expenditures. Pilgrim Software delivers its solution through the Internet, thereby completely eliminating the installation and setup cost, thus ensuring less capital expenditure for its customers.

The Food and Drug Administration (FDA) has registered the largest number of nonconformance in complaint handling procedures during 2007. Pilgrim Software through its electronic medical device reporting (eMDR) software solution has inspired customers to use its integrated software solutions with functionalities built into SmartComplaints for direct electronic reporting to the FDA. The company has gone one step ahead in ensuring that medical device companies get their eMDR's transferred and

approved by the FDA. Its effort to provide application support in the good laboratory practices (GLP) domain is commendable.

Integrating disparate systems and improving flexibility have been huge challenges for solution providers. Pilgrim Software has met such challenges by adopting the 'operational process management' approach in place of a 'business process management' approach. This lends flexibility across various functions that support quality. Pilgrim Software provides a pre-integrated solution that links the quality system with the IT infrastructure, thereby ensuring quicker implementation among end-users. The company has ensured that the integration between enterprise functions using a single platform can leverage the simplicity of the flexible platform to improve key performance indices. It has specific integration strategies like content management connectors, enterprise resource planning (ERP) connectors, and customer relationship management (CRM) connectors adopting an out-of-the-box approach. It also has robust plans in place to integrate computer-aided design (CAD)-based modeling tools such as Pro E and Solidworks into its quality solution. Its Smart Connector solution is a classic example of a pre-built software adapter that has helped clients to optimally leverage their investment on SAP and Oracle interfaces, furthering enterprise-wide quality operations for its customers.

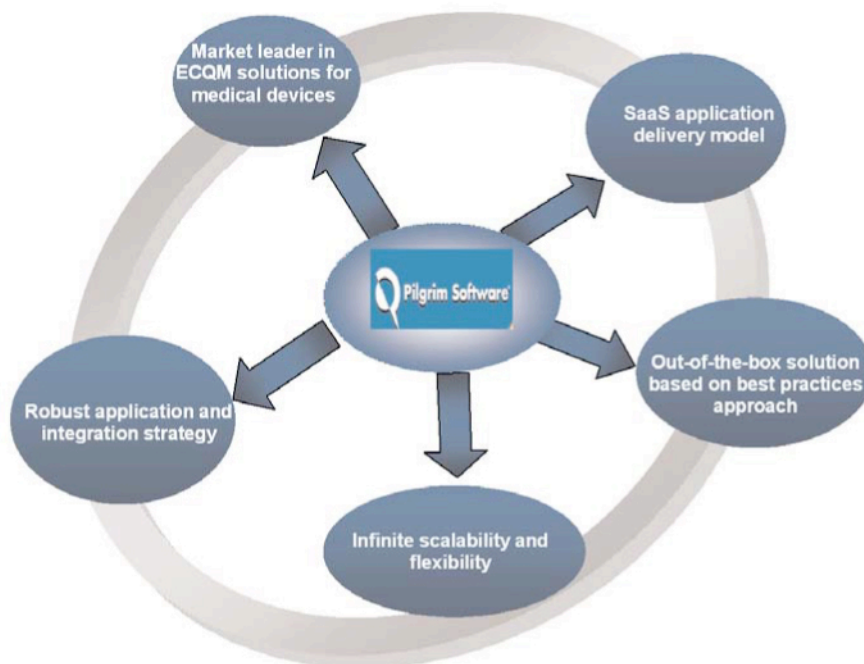
The existing vendors of enterprise systems such as product lifecycle management (PLM), manufacturing execution system (MES) and CRM, offer solutions that include a quality focus limited to their specific domain. For example, most of the PLM/MES providers offer mandatory content management and nonconformance-related services, but are yet to provide a complete view of quality across various functions. Pilgrim Software's ECQM platform has been extremely successful in providing a complete enterprise-level visibility of quality conformance parameters.

Pilgrim Software has been quick to provide enhancement to its existing document management system by adding a computer-aided design platform that links engineering to other functions in a seamless manner. Collaborative architecture solutions driven by the 'quality by design' approach at the system level and across the entire value chain have enhanced key performance metrics for end-users. Pilgrim Software has shown tremendous capability in developing a quality-oriented business intelligence tool called Smart Pulse, which is focused on improving the key performance indices of its customers. The company has also gone one step ahead of its competitors in developing an operational risk management solution along with a holistic enterprise product risk management perspective.

Medical devices companies not only try to reduce their production expenses and time to market, but also commit themselves to continuously improving the quality of their products. Currently there is a gap in the integration of legacy manufacturing systems and engineering systems. This has been addressed well by Pilgrim Software, which is proactively engaged in strategic partnerships with leading MES and ERP vendors to

support cross-functional enterprise systems across the value chain, thereby maximizing customer value.

While competitors have systems in place to detect and respond to deviations, Pilgrim Software provides an auditing solution called SmartAudit that enables its customers to prevent deviations and gain crucial competitive advantage. Pilgrim Software's solution enables the creation of smart templates and graphical workflow models that are customized and at the same time, highly adaptable to diverse customer-specific quality requirements. On a scalability front, the company is in the transformation phase from .NET 1.1 to .NET 3.0 and is expecting to migrate to 64 bit architecture with Oracle 11g database. Pilgrim Software's ability to collate its past experiences in deployment from diverse end-user industries into a best practices approach in the form of pre-configured solution is highly appreciated by users.



Source: Frost & Sullivan

Pilgrim Software's industry-specific solutions are backed by people with strong domain expertise. The company has sustained its dominant position as an enterprise compliance and quality management solution provider in the medical devices market, consistently improving its market share, globally. Operating in a space characterized by complexity, it is to Pilgrim Software's credit that it has simplified compliance and quality management, thus enabling customers to handle day-to-day challenges in an efficient manner. In recognition of its ongoing commitment to excel in technology and customer value, Pilgrim Software is awarded with the 2008 Frost & Sullivan Award for Company of

the Year in the North American Enterprise Compliance and Quality Management Software Solutions-Medical Devices Market, for the second consecutive year.

Enterprise Compliance and Quality Management Software Solutions - Medical Devices Market: 2008 Frost and Sullivan Company of the Year - Pilgrim Software.

2007 WHITE PAPER

Executive Overview

In a global industrial climate characterized by competitive pressures and tight profit margins, life sciences companies are forced to drive operational efficiency to increase their bottom-line revenues. They have discovered the need to leverage information technology (IT) in a significant way to optimize processes. While most life sciences companies have taken a siloed approach to quality by procuring solutions at a department level, it is imperative that these companies look at quality as an integral part of their global best practices. Global manufacturers must incorporate quality and corrective and preventive action (CAPA) workflows into their manufacturing architectures and integrate them with

enterprise quality and production systems. Achieving predictable product quality requires local deployment of tightly integrated manufacturing and quality management systems that can sense and respond to exceptional events as they occur.

As the record keeping requirements of the life sciences companies increase, they are increasingly moving away from paper-based records to electronic batch recording (EBR). As they aim to increase the likelihood of defect-free products, manufacturers are scouting for tools to integrate quality with the production process. Manufacturing Execution Systems (MES) can help companies improve manufacturing efficiency and product quality, while at the same time lowering manufacturing costs and developing products that meet the Food and Drug Administration (FDA) regulations. However, MES vendors in the past did not incorporate quality processes into their products. Production data was exported to the quality system separately, leading to cycle time delays. This has led to increased partnerships between MES vendors and compliance and quality management providers. While niche applications are provided by some specialized quality management providers, MES and Enterprise Resource Planning (ERP) vendors are also trying to offer an integrated solution by incorporating quality functionality within their suites.

Compliance and quality management solutions are in demand in the life sciences space as traceability and genealogy is required at the component level. While most peer group companies provide a siloed approach to quality, Pilgrim Software has created a niche for itself by offering solutions that provide a comprehensive view of quality at the organizational level. Banking on years of experience in designing and building quality management solutions, Pilgrim Software has always been quick to identify and solve nonconformances. It has differentiated itself by being one of the very few companies to operate with a single minded focus on the compliance and quality management space and has thus emerged as an epitome of best practices within this market.

Introduction

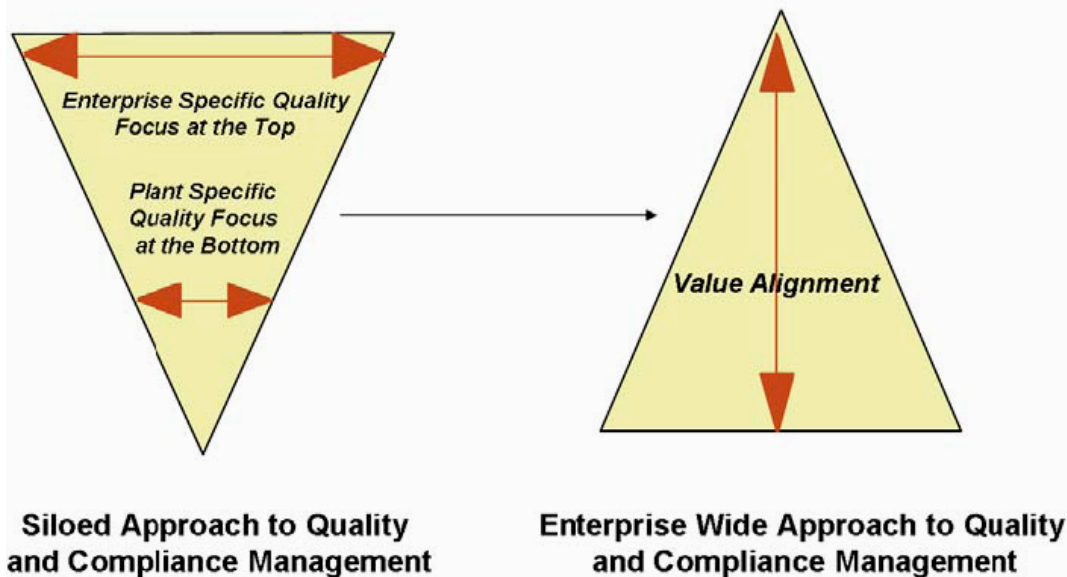
In highly regulated industries like life sciences, quality is of paramount importance. Negative brand recognition due to product recalls can be damaging to a company's reputation. Manufacturers realize that product or service non-compliance can affect business performance. Hence, they must make investments that go beyond passive compliance. Companies must embrace active compliance management and take a proactive approach toward quality. With the advent of contract manufacturing and outsourcing of manufacturing to low-cost locations across the world, life sciences industries have to exploit a global footprint. Hence, manufacturers must incorporate quality workflows into their manufacturing architectures and integrate them with enterprise and production systems.

Given the circumstances, there is a need for the life sciences end users to identify the challenges in this quest for operational excellence which ultimately leads to enterprise-wide excellence. Frost & Sullivan has identified a key challenge framework that needs to be addressed by global life sciences companies. Three challenges with related value trends are critical. (Value trend is the underlying motivation behind all key actions to achieve operational excellence.) The challenges are competition, compliance, and collaboration, with the underlying driver being the pursuit of operational excellence by driving out wasteful costs and adopting industry best practices. In the past, most end users have taken either a departmental or a regional approach toward quality. Hence the value propositions from existing quality management solutions are not felt across the organization. The objective of this whitepaper is to reiterate the importance of value alignment which is to get all people to work together to attain the goal. In this case, the goal is facilitated by the presence of an enterprise wide compliance and quality management system.

Chart 1.1 reflects the paradigm shift that is expected of life sciences end users to develop a better framework for managing risks across the organization.

Chart 1.1: Paradigm Shift to Develop a Better Framework for Managing Risks

Paradigm Inversion



There has been a paradigm shift in terms of who drives value within an enterprise. People used to think that the executives at the top were solely responsible for driving value or understanding or maintaining quality and compliance. However at the shop floor, people were looking at only the transaction level and did not have an enterprise wide view of risk. Hence, there has been a disconnect between corporate objectives and actions on the shop floor. Now, most people understand that there needs to be seamless collaboration across the enterprise if a company needs to take an enterprise wide view of quality. For value alignment to work in the real world, and achieve critical business benefits, there is need for effective integration. Integration helps to drive out inefficiencies in the systems. Value Alignment signifies that the enterprise, both within the four walls and outside of it, is now working together towards a common goal. The goal could be different for different businesses, profit, availability, or production. The key reality is that everyone has a role, and the overall goal cannot be achieved without value alignment, not just within the enterprise but also across the entire supply chain. The risk, in spite of sub contracting of manufacturing, lies with the manufacturer. Hence, the role

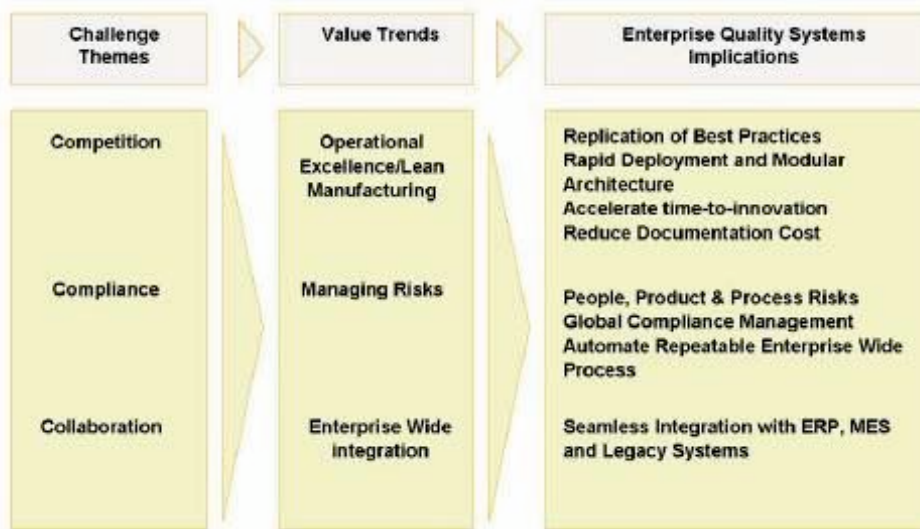
of the compliance and quality management system in achieving this integration is paramount for life sciences companies.

CHALLENGES IN THE LIFE SCIENCES INDUSTRIES

Chart 1.2 illustrates the key customer challenges and value trends.

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Chart 1.2: Key Customer Challenges and Value Trends



Competition

A surge in competition has been witnessed in recent times due to globalization and the need to deliver shareholder value, continuously innovate and manage cost pressures. This growing competition has increased the drive toward lean manufacturing, efficient enterprises, and optimization. Quality practices are integral to the success of any company. The success of a product hinges on the time to innovate while at the same time adhering to compliance and quality parameters. An explanation of the value trend for the challenge theme of competition is given below.

Operational Excellence/Lean Manufacturing

Competition has intensified across life sciences industries. Hindrances to the workflow, as well as technical or human error resulting in unplanned downtime, have a negative

influence on the bottom lines of companies' balance sheets. Operational excellence has thus become a key mantra for life sciences companies. This excellence in operations can be achieved through elimination of waste and accelerating the time-to-innovation, hence contributing to the efficient functioning of the organization. The present day compliance and quality management solutions are expected to drive operational excellence by providing an enterprise view of all quality-related processes. Providing this complete view would enable rapid and early detection of non-conformances by life sciences companies. Increasing pressure on margins compels manufacturers to restructure their operations and 'to do more with less'. There is a growing pressure on the production, quality assurance, and quality control departments to reduce operational costs. There is a need for implementing lean and flexible concepts within the pharmaceutical industry to reduce wastage and bring drugs to market faster.

Extensive Use of Paper-based Records and Legacy Systems

Paper-based history records consume a lot of resources and are highly susceptible to errors. Since most records available today are paper based, manufacturers are unable to deal with quality in a proactive manner. They are faced with a situation in which they are either under a regulatory watch or have been served a product recall notice. Since most of the quality control aspect is disconnected from the actual manufacturing process, companies are found reacting to discrepancies rather than addressing preventive measures. Substantial resources seem to be wasted in pinpointing the source of the problem rather than identifying the source earlier. By the time manufacturers identify the reason for the non-compliance, the products are already out in the market.

Compounding the problem is the fact that most of the legacy software systems are unable to deal with large and complex manufacturing environments that involve higher throughput and quality records. Although there are independent standalone solutions that address specific quality functions within the manufacturing setup, quality is one function that needs to be looked at from an enterprise level. Most of these siloed solutions lack the functionality to work in complex environments and do not seamlessly integrate with other solutions like ERP or MES. The need is to reduce the high cost of compliance caused by paper-based systems and disparate legacy systems that create manual and labor-intensive processes. Thus, life sciences companies can gain crucial competitive advantage if they are provided with solutions that take a comprehensive view of quality across the enterprise.

Compliance

The total cost of compliance with internal audit systems and quality systems that manage external regulations comes to about one-fourth of the total operating budget of a typical medium-sized pharmaceutical company. From the above statement, it is imperative that companies balance compliance costs with the incremental business risk that they deliver. By understanding the nature of the compliance-related risk, companies must be in a position to assess significant operational improvement opportunities. Life

sciences companies must be geared toward integrated risk management. Even though risk should be evaluated at the departmental level, unless they are collated and their implications on the entire business realized, enterprises will always find themselves in a situation where their investments on compliance constantly fall short of their objectives.

Managing Risks

Varied Perception of Risks

The definition of risk changes as we move from the shop floor to the enterprise level. At the section supervisor level, the interest is in managing operations within set point limits on a day-to-day basis. From a plant manager's perspective, the importance of maintaining asset utilization levels and managing cost-to-produce (CTP) is key. However, from an asset director's level, overseeing the operations of several production assets, the ability to translate business plans across the enterprise and deliver expected results is critical. Clearly, as the event horizon broadens, the risk definition changes, as does the value at risk to the corporate enterprise. At the operations or maintenance manager's level, the needs are more tactical and operational. However, at a plant manager's level, information from several departments needs to be collected and a cohesive risk management strategy needs to be adopted. A plant manager has to evaluate the criticality of risk and then select a suitable combination of solutions that meet his needs.

An integrated risk management approach within the life sciences companies should look at quality and regulatory controls at the enterprise level. While reviewing compliance cost, one key aspect that an enterprise needs to take into account is the total cost of ownership (TCO). While initially a quality management system includes implementation, training and validation, ongoing cost includes the cost of keeping the compliance management system and the personnel in sync with the constantly evolving standard operating procedures (SOP). A fine balance between people and system is necessary for an effective compliance and quality management across the enterprise. Companies must balance risk and cost tradeoff and, at the same time, satisfy market imperatives. A concerted effort to view compliance more as a business opportunity rather than a challenge to meet regulations differentiates leading innovative life sciences companies.

Balancing Risk with Innovation

As in most other industries bound by stringent regulations, life sciences companies find it challenging to balance risk and compliance management with innovation. The risk of nonconformance or non-compliance is further exacerbated by hefty fines, plant closures, and extensive negative coverage for the product and company involved. Apart from the need to consistently deliver defect-free products at a competitive price, stringent regulations require them to meticulously document detailed traceability records and follow strict procedures to demonstrate compliance. Life sciences companies must be in a position to track every component or ingredient and finished product that goes through the entire manufacturing process throughout their lifecycle. Since the cost of non

compliance is extremely high, life sciences companies have realized that they need to improve quality and manufacturing efficiency in order to stay profitable. Traditionally, research and development (R&D) and protection were the key drivers for the life sciences companies; however, with increased globalization, stringent regulations and change in competitive scenario, savings on cost have become an important criterion for profitability. It is of utmost importance for life sciences companies to ensure that their product goes to the market with minimal risk. Hence, life sciences end users are increasingly looking at improvements in manufacturing efficiency and quality as key objectives in their thrust toward maximum profitability. Some of the key regulations and corporate governance policies that life sciences companies have to adhere to are given below.

Key Regulations and Corporate Governance Policies

The FDA's mission as a public health protector is to ensure that human and veterinary drugs are safe and effective and there is a reasonable assurance of the safety and effectiveness of devices intended for human use. FDA's Good Manufacturing Practices (GMP) guidelines are intended to ensure that life sciences products are produced satisfactorily enough to support its mandate. This involves evaluating the product's fitness for use and other regulatory controls. GMPs are defined as regulations that describe the methods, equipment, facilities, and controls required for producing. These regulations are found in the Congressional Federal Register (CFR) 21 in the following parts:

- ∞ Human pharmaceutical products and veterinary products (21 CFR 210-211)
- ∞ Biologically derived products (21 CFR 600 and 21 CFR 620)
- ∞ Medical devices (21 CFR 820)
- ∞ Processed food (21 CFR 100)²

Brief introductions to some of the key regulations to be adhered to by the life sciences companies are given below.

21CFR Part 11

Part 11 provides criteria under which the FDA will consider electronic records to be equivalent to paper records, and electronic signatures equivalent to traditional and written signatures. Part 11 applies to any paper records required by statute or agency regulations and supersedes any existing paper record requirements by providing that electronic records may be used in lieu of paper records. Electronic signatures which meet the requirements of the rule will be considered to be equivalent to full handwritten signatures, initials, and other general signings required by agency regulations.

21 CFR Part 820

21 CFR Part 820, also known as the Quality System Regulation (QSR), outlines cGMP regulations that govern the methods, facilities, and controls used to design, manufacture, package, label, store, install, and service all finished devices intended for human use.

These requirements are meant to ensure that medical devices are safe and effective. Medical device manufacturers undergo FDA inspections to ensure QSR compliance.

21 CFR Part 1270-1271

21 CFR Part 1270-1271, also known as Current Good Tissue Practice (CGTP) for Human Cell, Tissue, and Cellular and Tissue-based Product (HCT/P) Establishments; Inspection and Enforcement: governs the methods used in, and the facilities and controls used for, the manufacturing of HCT/Ps; recordkeeping; and the establishment of quality programs. These requirements are intended to improve protection of the public health while keeping regulatory burden to a minimum, which in turn may encourage significant innovation.

21 CFR Part 210-211

21 CFR Part 210-211, also known as CGMP in Manufacturing, Processing, Packing or Holding of Drugs (210); CGMP for Finished Pharmaceuticals (211): require that all drugs are compliant with the latest GMPs. The regulations ensure that drug products meet regulatory requirements as to safety, strength, quality and purity.

21 CFR Part 606

21 CFR Part 606, also known as Current Good Manufacturing Practice for Blood and Blood Components, outlines requirements for blood labeling, laboratories, reporting and recordkeeping. It is meant to ensure that blood and blood components for human use are safe, pure, and effective.

Sarbanes Oxley Act (Sox)

In 2003, the U.S. Congress passed the Sarbanes-Oxley Act (Sox), the accounting reform and investor protection legislation aimed at making corporate America more accountable. At the surface level the rule seems to impact the role of the Chief Executive Officer (CEO) and Chief Financial Officer (CFO) more than any one else, especially by asking them to certify financial results. However, at a more functional level, compliance means establishing a set of policies and checkpoints to ensure the independence of board members and audit committees. The most important implication from the point of view of operational real-time data is the implication of the act that "timely and accurate disclosure of the material events" is now incumbent on top management. Widely held consensus is that companies will now have to disclose events that affect business fairly quickly. For example, if a glitch in a pharmaceutical production unit was noted and medicines had already reached the end customer, corporations would now have to report this fairly quickly, perhaps simultaneously with efforts to recall the lot. The Securities and Exchange Commission (SEC) the Sox's enforcer—could now potentially call for records of production to ascertain if the company had knowingly withheld data from the shareholder, especially data that impacted the future profitability.

Collaboration

Quality control has historically been treated as a function that is separate in its own right with no connection with the enterprise and production systems. However, with a plethora of regulations on the shop floor and the need to comply with Sox throughout the enterprise, manufacturers are realizing that quality cannot be regarded as a separate function and that it has to be tightly integrated with all systems throughout the breadth of the enterprise. Manufacturers still visualize compliance systems as isolated IT investments. In the event of a recall, life sciences manufacturers face challenges due to the existence of disconnected quality siloes that delay the identification of the source of the defect. Most quality management solutions are point solutions with limited visibility. As the authorities place immense importance on compliance, there is an increasing need for an end-to-end compliance and quality management solution that would provide a top-down, risk-based approach toward product quality.

For maximum benefit and accurate visibility into all compliance and quality issues within the organization, it is important that compliance and quality management systems are tightly integrated with the ERP and the MES. This tight integration implies seamless connectivity between systems that control product quality at the shop floor level with document management and workflow-based systems that automate quality processes at the enterprise level. Quality management covers a lot of aspects of an enterprise that includes functions spanning operations, R&D, manufacturing, and supply chain.

With increased globalization, authorities are focusing on manufacturing compliance that goes beyond specific functions and geographies. Global manufacturers need visibility into quality aspects across all individual functions for early and quick detection and redress of nonconformance events across the enterprise. The key focus for compliance and quality management providers going forward is to provide a system that will proactively manage processes and best practices to ensure consistency and compliance across all locations. Since companies have global facilities, products from one part of the world are being exported to other regions. This necessitates that life sciences companies conform to global regulations. There cannot be inconsistencies within a company on compliance management across global locations.

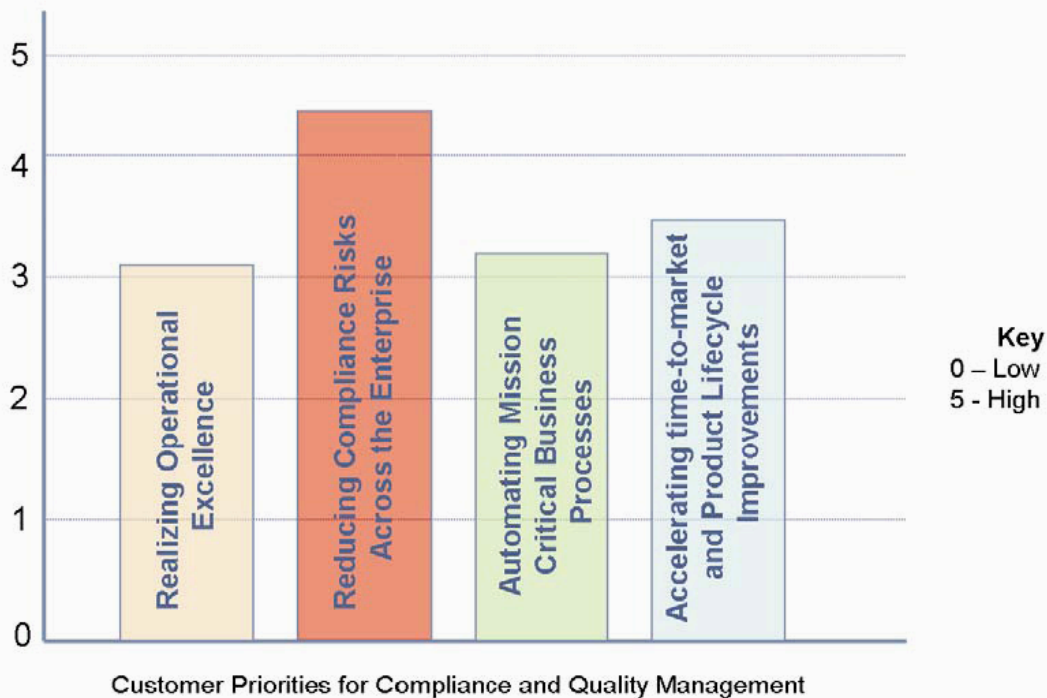
Enterprise Wide Integration

While ERP and MES systems have aspects of quality integrated into their suite, a standalone compliance and quality management solution should be built on a modular architecture that provides process documentation, event workflows, exceptional event detection, and real-time visibility. While ERP vendors provide compliance and quality functionality that has visibility into logistics and supply chain, MES vendors provide quality functionalities that have visibility into non-conformances on the shop floor. There are other functions such as engineering and R&D that are not covered by such IT systems. In such cases where nonconformances have to be escalated to a CAPA platform, it is imperative to have an enterprise wide quality system which will detect and

report non-conformances across multiple departments. This enables life sciences end users to not only reduce quality failures but also proactively manage quality throughout their global operations to gain competitive advantage in terms of quality, time to market, and costs. The end objective is improved business performance and compliance. By integrating all functions across an enterprise under one quality platform, better quality products can be made available to the market faster and substantial cost savings can be realized for the enterprise.

Chart 1.3 shows the customer priorities for compliance and quality management systems.

Chart 1.3: Customer Priorities for Compliance and Quality Management Systems



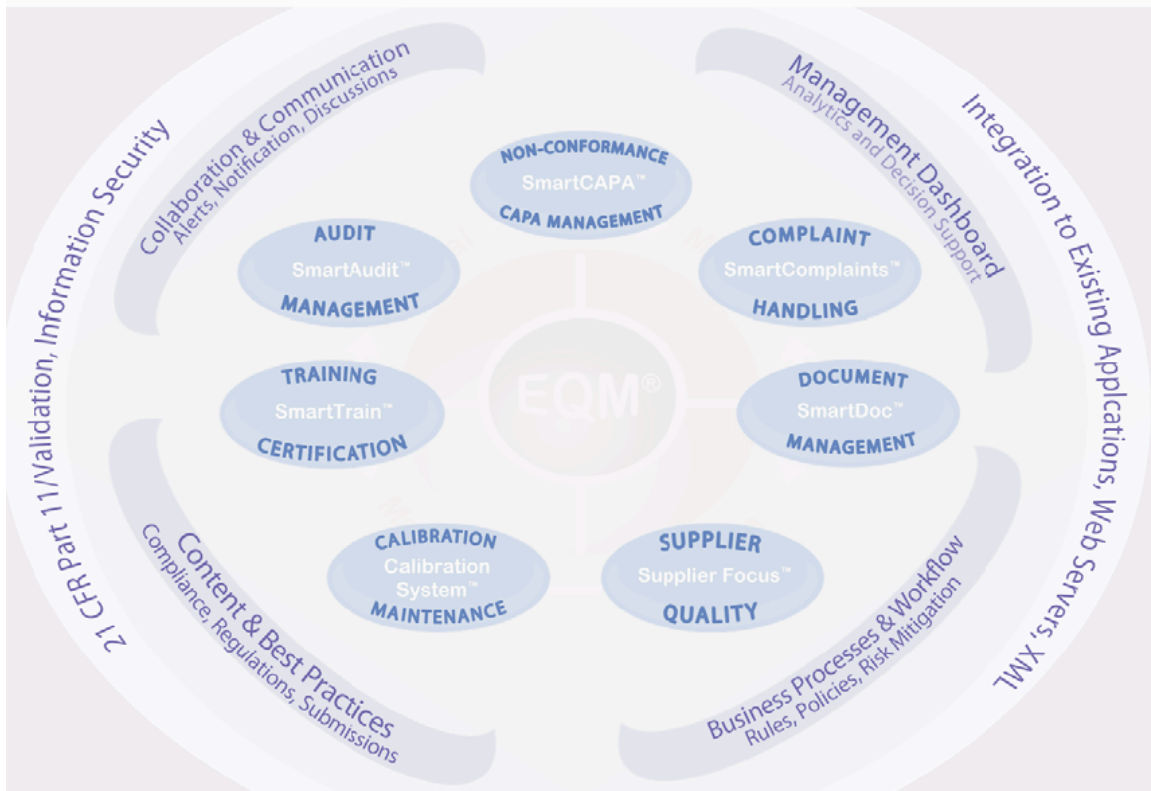
When a few select life sciences companies were asked to rank their priorities for compliance and quality management on a scale of 5, the need to reduce compliance risk across the enterprise ranked as the highest priority.

PILGRIM SOFTWARE'S VALUE PROPOSITIONS

Pilgrim Software provides an innovative approach by moving beyond compliance and quality to operations excellence. Its SmartSolve solution provides a single unified view of all quality-related activities by integrating with multiple systems to manage and deploy compliant processes across the world. Primarily operating in an industry that is purely compliance driven, it is to Pilgrim Software's credit that it has taken a more proactive approach to quality management and compliance initiatives. While most end users perceive quality management as a minimum necessity, Pilgrim Software has gone a step further by helping its customers to translate their compliance initiatives into positive increases in bottom-line and strategic competitive market advantages. The company offers an array of seven 'out-of-the-box' solutions that solve life sciences compliance and quality problems. The SmartSolve solution comprises SmartAudit, SmartCAPA, SmartComplaints, SmartDoc, SmartTrain, Calibration System, Supplier Focus, and Validation Packs. Pilgrim Software ensures that it has all aspects (products, process, and people) of an enterprise covered from a quality standpoint. This also facilitates seamless sharing of data and information both internally within work groups as well as externally with suppliers.

Chart 1.4 shows the seven 'out-of-the-box' modules as part of the SmartSolve solution from Pilgrim Software.

Chart 1.4: Seven 'Out-of-the-box' Modules as part of SmartSolve Solution



Replication of Best Practices

Pilgrim Software provides a completely pre-configured 'out-of-the-box' solution. Its solutions enable the creation of smart templates and workflows that are customized and, at the same time, highly adaptable to diverse customer-specific quality requirements. Comprised of 1,000 built-in modifiable forms for various supported processes, 100 diverse configurable workflows and 60 'out-of-the box' reports, Pilgrim Software's Web-based application suite is unmatched in its inherent flexibility. Pilgrim Software has the ability to collate its past experiences in deployment from diverse end-user industries into a best practices approach in the form of a pre-configured solution. Thus, the company propels its customers on a path of constant improvement as they can take these best practices and apply them within their own business area. Implementing a seamlessly

integrated CAPA, audit, training, supplier and compliant management, and calibration and validation system ensures compliance and reduces implementation costs.

Rapid Deployment and Modular Architecture

Life sciences customers are increasingly looking at quick deployment of solutions to gain crucial competitive advantage. Pilgrim Software's modular architecture enables them to choose components based on their immediate requirements and mix and match those components to satisfy their specific needs. The sheer scalability of the SmartSolve solution allows for modules to be added at any time in any number of sites during or after the duration of a particular deployment, subject to customers' requirements. End users need not spend time analyzing their needs and identifying their business practices, as they have the flexibility to choose their desired workflow with solutions offered by the company. Each workflow is coupled with a validation pack that allows customers to execute it immediately, thus leading to a rapid and smooth roll-out. Standards can also be introduced at the global level and enforced at all individual locations. This ensures rapid deployment and ease of use and provides end users with excellent return on investment (ROI).

Accelerating Time-to-Innovation

Pilgrim Software's SmartCAPA module provides the required framework to respond faster to exceptional events by reducing unplanned variability. Day-to-day manufacturing activities take place under a very demanding atmosphere. Usually, such situations give rise to unforeseen disruptions, which most often than not leave a major impact on the organization. There are standard workflows that are built into Pilgrim Software's CAPA processes. It is a closed loop process whereby the customer is able to identify the source and type of non-conformance, understand the severity and nature of the problem, take appropriate corrective and preventive actions, and finally measure the impact of the CAPA on the problem to check the necessity for further investigation. Depending on the severity of the problem, the solution's inherent flexibility ensures that customers can choose workflows that are either simple or complex instead of following standard processes repeatedly. There are predefined workflows based upon the type, source, and product line. The workflow engine itself will direct a CAPA through the right path by identifying the right people involved and automatically notify them to quickly address the issue. Hence, the ability to prevent the occurrence of any abnormal situation in itself would be a source of competitive differentiation for the company. This differentiation is facilitated through reduced life cycle-related costs, increased throughput, and faster time to market, leading to greater and improved overall organizational performance.

Reduced Documentation Costs

As life sciences manufacturers strive for paperless manufacturing and try to integrate several disparate document management systems, Pilgrim Software provides an

integrated document management system called SmartDoc that acts as a central repository that collates, manages, and archives key documents that include SOPs and best practices. Implementation of such an enterprise wide document management system improves knowledge management and enables companies to comply easily with FDA regulations. SmartDoc thus acts as a central repository of data that helps companies benchmark against key performance indicators (KPI) and discover new business opportunities.

People, Product, and Process Risks

Pilgrim Software has been able to identify the importance of the 'people' aspect of organizations. SmartSolve is designed in such a way so as to ensure that corporate policies are clearly understood and implemented at the lower levels as well. SmartTrain is a testimony to this fact as it ensures that operators are trained not only on the on-the-job functionalities but also on company policies so that they are compliant with the FDA instructions. While most training systems focus on compliance, SmartTrain tracks changing training requirements to ensure workforce efficiency and productivity. It integrates seamlessly with document management solutions to check proper training enforcement.

One of the key aspects of Pilgrim's training module is gap analysis. It ensures that operators are certified beyond their job functions to reduce the chances of employee noncertification during an FDA inspection. As employee training has to point toward certain SOPs, it is imperative that training goes beyond the classroom training or self-assessment training. Pilgrim Software has a system in place whereby it tracks any change in corporate policies or work instructions and immediately notifies on any release of new documents so that employees can train themselves. Depending upon the complexity of the document that is released, the training module determines the specific mode of training that is required and ensures that the employee gets trained appropriately. Apart from the people aspect, the process and product aspects of the business are also taken care of as SmartCAPA looks to solve non-conformances at the equipment as well as the enterprise level.

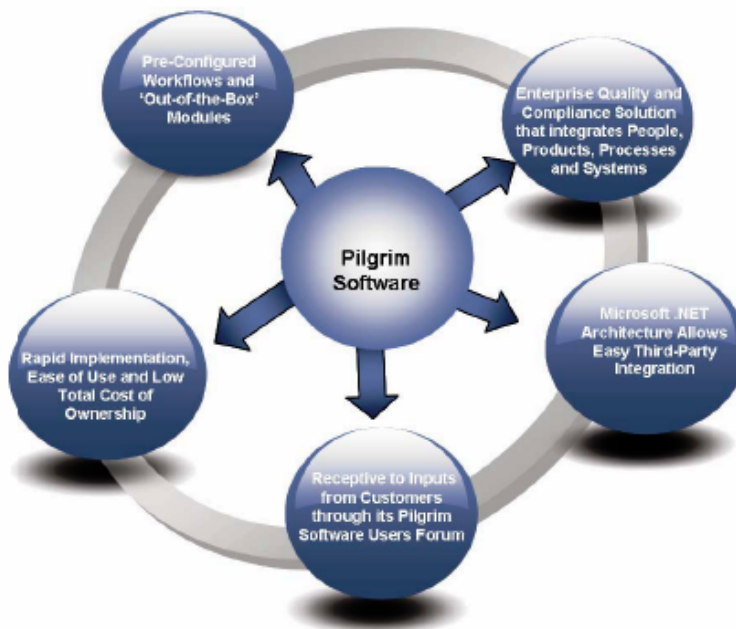
Global Compliance Management

Pilgrim Software is the preferred vendor for end users who have a global deployment vision and can readily utilize the built-in best practices approach. The company has successfully addressed the need that has arisen as a result of globalization by providing a truly Multilanguage application that not only covers display but also data entry functions. Pilgrim has introduced a port to Unicode that has enabled it to use different languages within a single database. This provides a key advantage for global companies as their operators across the globe are able to easily detect and address CAPA as the instructions are easily understandable. Pilgrim Software strives to provide visibility at the

top level and forces standardization across the entire corporation. This ensures that all the manufacturing plants across the globe are in compliance with global regulations.

Chart 1.5 provides a summary of Pilgrim Software's key success factors within the compliance and quality management space.

Chart 1.5: Summary of Pilgrim Software's Best Practices



Automate Repeatable Enterprise Wide Processes

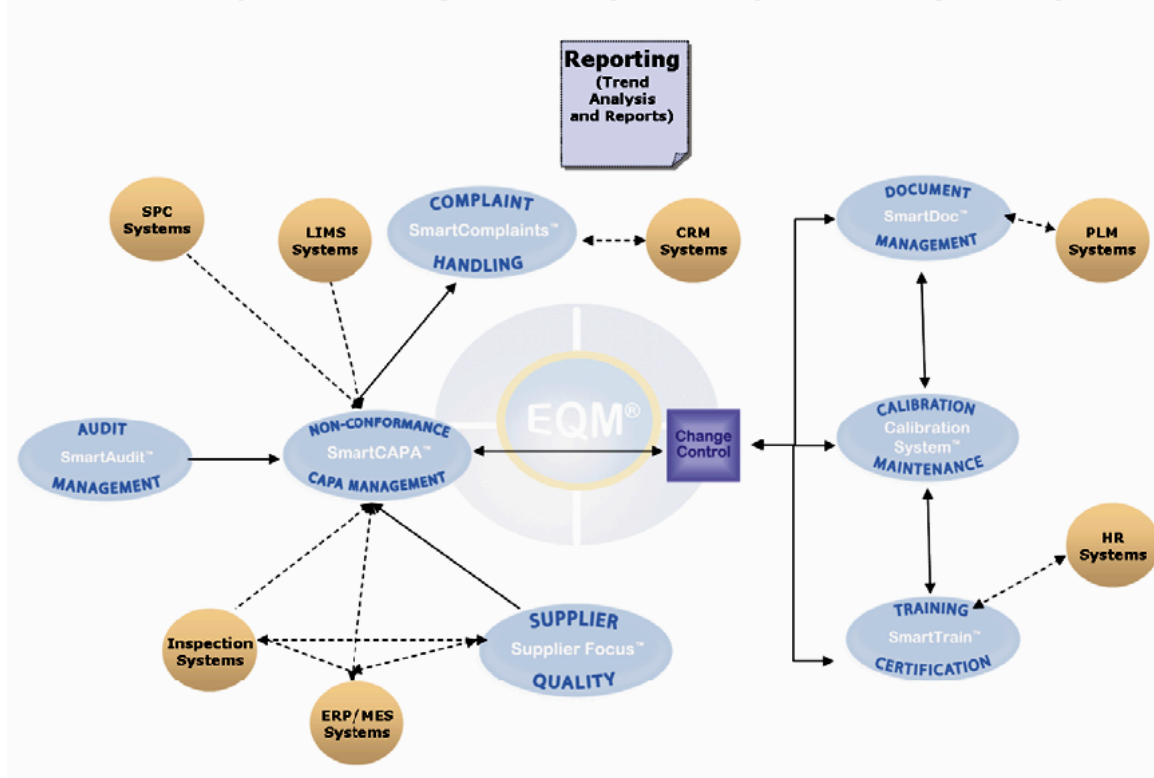
End users can take full advantage of the CAPA building blocks as they can use them to create a best practices workflow template. With more than 100 pre-configured notifications, the system determines the business processes involved and automatically generates notifications accordingly. Life sciences companies can immediately implement and personalize the workflows that are validated and readily available for use. The key value proposition for Pilgrim Software is the seamless integration that it provides across its modules. In case a CAPA throws up a non-conformance in training, the CAPA module immediately notifies the training module and appropriate steps are taken to automatically schedule additional training for the employee. Subsequent to the training, an employee review is done to close the loop. Pilgrim Software's solution has enabled companies to respond faster to deviations with greater efficiency by providing a centralized system that detects errors upstream and alerts the users with emails or messages. This enables customers to have early visibility and reduce rework.

Seamless Integration with ERP, MES, and Legacy Systems

Non-conformances can result from process, people or equipment deviations. With Pilgrim Software’s solution, life sciences companies can obtain a detailed view of trends into the non-conformance activity beyond the shop floor. As the company provides seamless integration with solutions across the enterprise, its customers can obtain information on all collected CAPAs from its database through business intelligence tools to obtain a complete view of all quality-related activities at an enterprise level. The .NET foundation enables SmartCAPA to easily integrate with existing systems, providing a strong framework for enterprise improvement efforts. Typically, in large companies, due to the extensive use of ‘best-of-breed’ solutions, it is imperative that compliance and quality management solutions have tighter integration with them. With its provision for seamless integration between modules as well as with legacy systems, SmartSolve is a highly integrated and complete compliance and quality solution that reduces the total cost of ownership. This integrated solution offers customers the superior ability to collect and analyze KPIs and translate them into actionable information enabling rapid action.

Chart 1.6 shows Pilgrim Software’s enterprise wide integrated compliance and quality management system.

Chart 1.6: Enterprise Wide Integrated Quality and Compliance Management System



CONCLUSION

For a life sciences company, the most critical business objectives are to control costs and to maximize the probability of product success. Life sciences companies are driven by the need for information integration. The key challenge is to implement a solution that covers all functions within an enterprise, address regulatory compliance needs as well as manage quality by playing a central role. Traditionally, quality applications have either been too broad, operating at the enterprise level, or too narrow, focused on operational silos such as production or incoming inspection. The collaboration that is required to facilitate new product development, to reduce variability in manufacturing, to minimize risk and to balance customer demand with supply, necessitates the need for an integrated platform to manage all exceptions. Pilgrim Software delivers the industry's best and most complete compliance and quality management solution that connects and automates the complete flow of quality related information across the enterprise. As a result, Pilgrim Software's customers are realizing the benefits of a fully integrated platform for top-down regulatory compliance, including minimized business risks, optimized costs, and reduced time to launch. This has enabled them to provide the highest quality and the safest products at the lowest cost to meet customer demand.

AWARD DESCRIPTION

The Frost & Sullivan Award for Company of the Year is presented each year to the company that has demonstrated unparalleled excellence within its industry. The Award is based on numerous factors including the company's business development, competitive strategy, customer satisfaction, and leadership within a particular Frost & Sullivan Industry Research Group (IRG). This company is perceived to exhibit outstanding management and consistent growth. The company must offer high quality products and/or services and have positive social and economic impact on local and national communities. The company's customer service offerings and performance are expected to be of very high caliber. The company should have proven expertise in taking advantage of market changes by capturing and solidifying market presence, or through execution of innovative strategies within the existing competitive landscape.

RESEARCH METHODOLOGY

In order to select the Award recipient, analysts quantify several market factors for each market participant according to predetermined criteria, paying close attention to their combined operations efforts. This process includes interviews with all the market participants, customers, and suppliers, along with extensive secondary and technology research. The companies' efforts are then analyzed based on the number of new customers, new segments, and commitment to business expansion coupled with market growth. Industry participants are then ranked based on the predetermined measurement criteria. The Award recipient is the company that received the number one industry rank.

MEASUREMENT CRITERIA

In addition to the methodology described below, there are specific criteria used to determine final competitor rankings in this industry. The recipient of this Award has excelled based on one or more of the following criteria:

- Market share and revenue growth rate in the industry
- New market penetration (geographic, product)
- Marketing, promotion, and visibility of the company through various media
- Evidence of success through strategy innovation
- Technological innovation and leadership
- Increased name recognition
- Improvement in customer satisfaction and loyalty levels

ABOUT BEST PRACTICES

Frost & Sullivan Best Practices Awards recognize companies in a variety of regional and global markets for demonstrating outstanding achievement and superior performance in areas such as leadership, technological innovation, customer service, and strategic product development. Industry analysts compare market participants and measure performance through in-depth interviews, analysis, and extensive secondary research in order to identify best practices in the industry.

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