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MOVERS & SHAKERS

Nikki Willett

Vice President of Product Marketing & Regulatory Affairs at Pilgrim Software

"We Accelerate Growth"

Frost & Sullivan Senior Industry Analyst Muthuraman (Ram) Ramasamy recently had the opportunity to meet with Nikki Willett, vice president of Product Marketing & Regulatory Affairs at Pilgrim Software. As a Frost & Sullivan Thought Leader partner, Pilgrim Software is a world-leading provider of enterprise risk, compliance and quality management solutions for global organizations. Nikki is responsible for managing all aspects of Pilgrim's worldwide product, industry and strategic marketing initiatives. She is a seasoned professional with an extensive background in marketing, technology and regulatory industries. With more than 25 years in software, Nikki has focused on advancing technology through the constant evaluation of business trends to help organizations progress and succeed through the use of automation. Frost & Sullivan takes a few minutes to catch up with Nikki and Pilgrim's continued best-practice approach to the market.

Muthuraman Ramasamy: From Pilgrim's perspective, how have end-user attitudes changed toward quality and risk compliance?

Nikki Willett: From our perspective, especially when looking at the life sciences, there has been a paradigm shift in the approach to quality over the past couple of years. When we first became a provider within the life sciences industry in the late 90s, the focus was all about product quality within manufacturing. This has changed to a level where people are now looking at quality throughout the product value chain, starting with design and R&D, all the way through unit distribution and logistics.

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Risk has shown the most noticeable change in the past couple of years. Whether it is business and strategic risk, compliance and regulatory risk, operational risks, financial risks and so forth, risk management isn't new to the life sciences industry. However, compliance has been foremost in an organization's collective consciousness over the last few years due to the significant media exposure that has resulted from very large product recalls and continued enforcement from the FDA.

Part of the reason for this enhanced focus is a result of defensive actions being taken by companies because they have issues with the FDA, either about a warning letter or an upcoming inspection, or issues with regulatory actions. These reasons have led to a key transition in the compliance area, whereby companies are now taking a proactive stance by ensuring that everything within the company, throughout all processes and the product value chain, are in compliance, and any risks associated with the regulatory issues are minimized. This proactive approach first took root during the ENRON debacle, which underscored the financial risks companies face.

In recent times, companies have placed more focus on risk across the enterprise, resulting in the creation of the role of chief risk officers—a completely new position—along with the development of risk committees, which are steering committees comprised of different areas associated with risk, such as strategic, financial, operational or legal risk. These committees bring on board all of the appropriate stakeholders into a forum to understand and obtain clearer visibility into the company's risk potential.

Enhanced focus on risk has impacted how companies view quality. Everything concerning quality is now being examined from a risk approach. People are focusing more on planning assessments and understanding risk throughout the lifecycle. So more risks initiatives are forcing serious internal and external audits and examining the results through detailed CAPA (Corrective and Preventive Action). These risk

strategies and approach has driven a new focus on change management as well. Changes to products, process, equipment, IT or other general business operations have a high risk of adversely impacting the company unless managed correctly. Change management used to be more about engineering changes or dock changes. But now it is about risk at the enterprise level.

MR: When we look at the changing business models, with more focus on risks, how do you see the perception of new-age companies coming into play? I believe one of the customers of Pilgrim has been Dendreon, which focuses on customized medicines. So, is that a paradigm shift that we are observing as a trend in healthcare and diagnostics as well? From that perspective, compliance is going to play a more important role. How do you see the changing dynamics in the healthcare industry impacting your solutions?

NW: From our perspective, it does not have much impact with the exception of increased focus on the compliance risk that goes along with the market transitioning into personalized medication. This is not a continuous process anymore, but rather short production cycles.

From the beginning, it is variability that has been directly impacting an organization's design of manufacturing and production process. In terms of longer production cycles, there is a cost involved when scrap or waste is associated with the production cycle for traditional devices or brand-name blockbuster pharmaceuticals. It is in the best interest to avoid those costs even if it does not necessarily have the highest impact on profitability.

When you have shorter production cycles because you are dealing with customized and personalized medicines, there is going to be a lot more emphasis on quality by design (QbD). A company will really focus on quality from the beginning of the design cycle and have a solid understanding of the potential risks as it moves through the production cycle. The impact here is not necessarily a direct impact in terms of changes in our solution, but rather an integral need to improve the overall process, especially in the integration with other critical systems to ensure they have the correct data.

Here, critical systems refer to product lifecycle management (PLM) systems, ERP systems, shop floor MES or monitoring systems, and so forth. The entire network of supply chain systems becomes critical to the process to be able to share data and have insight into compliance, quality and risk throughout the entire department.

Our risk, compliance and quality solutions are focused on business, from general business, to finance, to the operational side of things. Another issue that is going to be of key importance is environmental concerns. Companies now have to be more sensitive to environmental issues, like carbon emissions, and push to be greener from several different mechanisms. There is a competitive advantage to this consideration, but there is also the cost factor.

It would be interesting to see how this would impact overall risk, compliance and quality as environmental issues would likely arise more frequently at the beginning part of the process versus the traditional way of functioning. This puts even more emphasis on risk, compliance and quality throughout EH&S and the manufacturing process.

We also have to look at how companies are dealing with the evolving workforce, both from the aspect of baby boomers that are retiring and new people coming aboard. The workforce reduction in the market place has had an impact on the current economy. Companies are still being forced to follow the traditional motto of "do more with less," and that includes the IT organizations as well. So I think that automation companies felt the need to add more people resources. But this was not a decision which they could make due to economic concepts, and hence, it had an impact on more people looking at solutions like ours.

MR: How does Pilgrim's solution help your customers overcome the challenge that you have just mentioned?

One of the key advantages for our customers is that we are an end-to-end solution provider and offer a platform for enterprise risk, compliance and quality.

NW: The key to this for Pilgrim is a combination of factors. One of the key advantages for our customers is that we are an end-to-end solution provider and offer a platform for enterprise risk, compliance and quality. Our solutions can be implemented even on a very small scale in small companies with niche functional needs and a small set of users. Our solutions are able to grow with an organization and can be trusted for large global deployments. We have the capability to address the needs of the market place as the dynamics change. We can work with very large companies and help them with continuous improvement for operational effectiveness. We look at the paradigm shift toward a lot of emerging growth, especially in the medical device and the biotech area. Our solutions provide for both areas with a single platform. We offer diversity in functionality. The solutions are out of the box and are based upon best practices, which are pre-integrated to reduce an end-user's workload. We have out-of-the-box integration with other mission-critical systems; therefore, we can be a lot more agile, which reflects positively on companies using our solutions. They can add functionality and also be able to add on other tailor-made compliance-centric applications. Therefore, we can help them to be set, not only for today, but for the future as well.

MR: From Pilgrim's perspective, what are your unique differentiating factors that have enabled you to experience consistent market growth and revenue growth, and customer loyalty as well?

Our continuing differentiators in the market place are being able to provide a complete platform with all of the functionality, out of the box with best practices, and the tools to be able to completely tailor and configure the solution.

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Within IT, the holistic view of "do more with less" is actually having a tremendous impact. We have seen a lot of consolidation and harmonization of systems because of disparate systems. The cost associated with multiple integrations for disparate systems throughout the enterprise is coming back to IT. Therefore, IT is actually looking at and favoring "best-in-class" technology platforms and certain functional areas like enterprise risk, compliance and quality management. IT is also looking at the minimum amount of integration needed within the organizational systems rather than looking at the best-of-breed point solutions.

MR: When you implement solutions for small and medium enterprises, what kind of challenges do you meet and how are you best able to meet the requirements?

NW: We do have a lot of medium-sized businesses as customers, and we are seeing a growth in the small-sized business market as well. Small- and medium-sized companies do not have the resources to effectively execute all the solutions they may need, but they have to be compliant and even more agile than larger organizations in order to deal with issues such as the quality and regulatory requirements, whether in IT or in their own business segments. We assure our customers about the thoroughness of our product testing, and the compliance of our solutions such as the out-of-the-box functionality. We encourage our customers to start at a simpler level before venturing out to deeper and broader aspects of our functionality, which can be tailored to their needs. This has been a very successful approach with many of our customers.

MR: In terms of driving for market penetration and working for the Software-as-a Service model (SaaS), what would be Pilgrim's go-to-market strategy?

NW: You can see where the market is going by taking a look at the larger technology providers. The technology landscape has now become all about cloud computing. Now, ASP—hosting—SAAS is nothing new. We truly believe that cloud computing is being fuelled by the economy, and again, it goes back to the expectations that IT leadership within organizations deliver more for less. So from that perspective, there is going to be a lot more adoption of SaaS or cloud computing. We also believe that the technology of hosted solutions has matured. We are continuously able to keep up with the technology and able to offer something that is going to be palatable for the life sciences market, where there is tremendous sensitivity to security and privacy of information. We are continuing to focus and drive that technology and to work in tandem with each of our customers to satisfy their requirements.

MR: Can you add or elaborate on the security enhancement feature so that people can know what Pilgrim, as a company, is doing to ensure data security and IP-related issues?

NW: The key thing for us is that we are using a SAS-70 certified hosting facility. Our application has been certified to SAS-70 as well. Both our application and hosting go through an annual third-party audit. We have also built-in infrastructure with malware intrusion detection.

MR: When we look at your key markets, which are pharmaceuticals, medical devices and biotech, and your recent winning of funding from a private investment association, North America appears to be your primary focus. Should we expect to see your organization branching out into other geographic regions? If so, what would be the nature of the business model that you are going to execute?

NW: Pilgrim currently is focused on North America as well as Western Europe. The majority of our direct sales are in North America. We have been working within the European region for the past eight or nine years and also have channel partners for the other regions, such as India as well as Asia Pacific, and those avenues will continue to grow. Our focus is to continue expanding in all of these different regions as well as to continue expanding our vertical target for life sciences.

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MR: When we talk about the product strategy, you have an end-to-end solution, and it's all going well for Pilgrim in terms of new developments such as SaaS. What are the future road maps on the product strategy that we can expect to hear from Pilgrim?

NW: There are two kinds of customer requirements. While one group targets the whole application, the other group is only interested in procuring the tools for building the applications of their choice. The market has definitely matured for enterprise risk, compliance and quality management solutions. Customers are looking for a combination of products. They want to leverage all of the out-of-the-box features and best practices which have been tested and proven successful. They also want tailoring and design tools to be able to easily configure the system tools without involving IT or the vendor. So, that has been our focus in the last few years and is still going to be our focus for the future. We want to make sure that we have a strong out-of-the-box best-practice solution, along with strong capabilities to enable tailoring as well.

MR: What would you say is the long-term vision of your company and present-day execution strategies to achieve that?

NW: This goes back to our recent private equity investment that happened in February. It is a very exciting time and presents exciting opportunities for Pilgrim. We are going to continue to focus on growth with investment. Not only are we looking at organic growth, but now we have the flexibility and capability to pursue growth, which would help us expand regionally. So, that is where a lot of our attention is going to be geared as well.

MR: As always, a pleasure speaking with you, Nikki, and we look forward to Pilgrim's continued success in the market. Thank you!

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