

## **Greater emphasis on Pharmacovigilance will increase need for software solutions**

20 June 2013 | News | By BioSpectrum Bureau

### **Greater emphasis on Pharmacovigilance will increase need for software solutions**



Recently TAKE Solutions launched a new version of their proprietary software PharmaReady 5.0. The software involves regulatory document workflow submission for small and medium enterprises. TAKE Solutions says it has the local advantage, since this involves generic companies, those that have a good market share in India. Currently there are over 45 customers for Pharmaready 5.0 in India. Mr. Ram Yeleswarapu, president and Chief Executive Officer envisions that this number will increase with Indian manufacturers increasing their investments in drug safety and risk management. He adds, "Today, there is a greater emphasis on pharmacovigilance and Pharmaready is uniquely poised to allow customers to incorporate that. Currently very few adverse events are being reported, we want to provide tools to streamline the process and contribute to that."

PharmaReady 5.0 recently included an option that allowed the entire process for submission of documents to the Saudi FDA in the NEEDS format. It has also built Arabic language prompt. This version has strengthened the hyperlinking and technology for documentation.

In addition to providing IT services, TAKE solutions also has a data oriented CRO for the US and EU market for Phase I, Phase II and Phase III trials. They cover clinical, regulatory and safety functional coverage areas in addition to strategy consulting, technology solutions, business services, analysis etc. The services also include SAS data sets, data management, encompassing all components involved upto an NDA approval. Mr. Ram says, "Our role begins when the data is collected by the company and handed over. We offer services that are involved in the journey from I&D to NDA."

TAKE Solutions offers services to deploy their partner's solutions, engage in co product development that is headquartered in Chennai and also offer cloud hosting environment for some of our customers. Oracle is one of their biggest portfolio partners when it comes to Life Sciences. Currently 70 percent of TAKE Solutions' revenues are from US/EU and the rest are from India.

When it comes to biologics, Mr. Ram is hopeful, "So far, most of our work has been with regards to formulations and APIs. I believe we can add a tremendous value to other players in biologics and vaccines as well, however, we need to plan for that specifically."

Software solutions for regulatory submissions are currently compliant with USFDA, EMA, and Canadian regulatory agencies. When asked if they would expand these services in India, he says, "A discipline is required in terms of filings, before we do anything. However, it is a configurable solution. We have focused on the India market, however we do not have any customized solutions for Indian companies yet."

In terms of future plans, TAKE Solutions is making efforts towards building Intellectual Property in terms of biology. They had also done case studies in supply chain management and hope to explore it further. In 2011 TAKE was recognized as a leader by IDC's MarketScape Worldwide Life Sciences R&D IT Outsourcing for 2011. It is headquartered in Chennai, India while its U.S. headquarters is located in Princeton, New Jersey. It has over 400 customers worldwide.