BioSpectrum the business of Bio & Health Sciences

"We work with companies which give us unique propositions to build capabilities"

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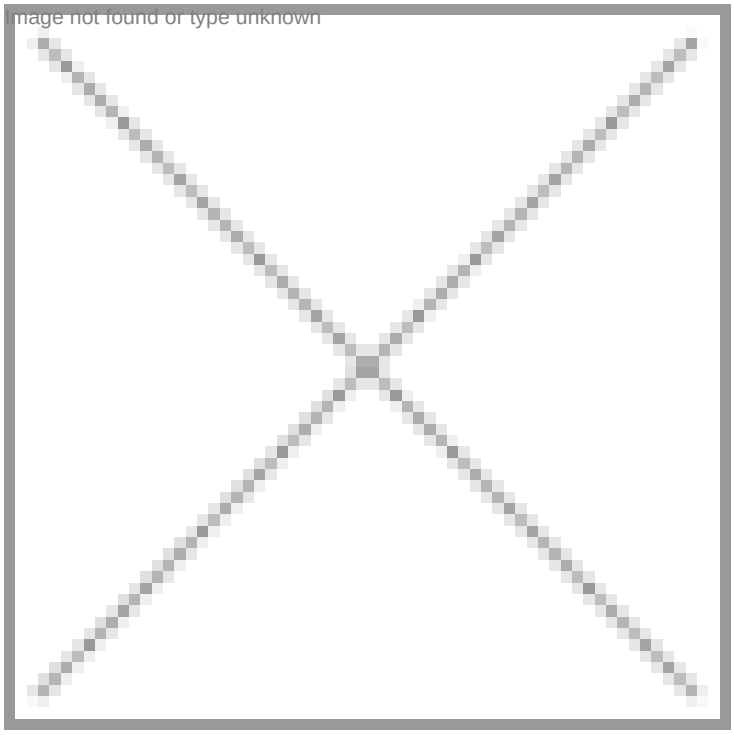

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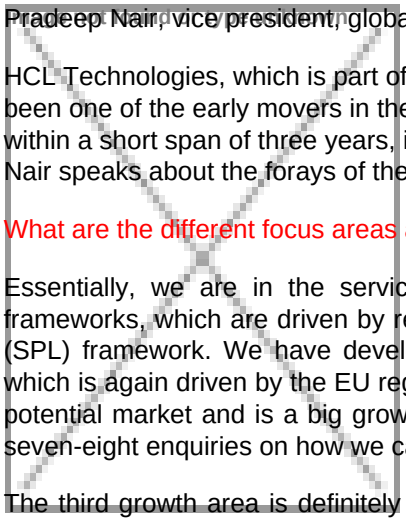

Pradeep Nair, vice president, global life sciences practice, HCL

HCL Technologies, which is part of $3-billion HCL Enterprise, is one of India's leading global IT service companies. It has been one of the early movers in the life sciences and healthcare areas. The life sciences practice started in July 2003 and within a short span of three years, it has emerged as the fastest growing vertical at HCL. In an exclusive interview, Pradep Nair speaks about the forays of the company in this niche space.

What are the different focus areas at HCL Life Sciences?

Essentially, we are in the services space and whatever we develop is for the customer. We are focusing on some frameworks, which are driven by regulatory compliance. We are the first company to develop the Structure Product Labeling (SPL) framework. We have developed a framework on Removal of Hazardous Substances for Medical Devices (ROHS), which is again driven by the EU regulatory bodies. Second, we are in the area of clinical data management, which has a huge potential market and is a big growth area for us. We have a number of customers and as of today, we are sitting on about seven-eight enquiries on how we can help and support in clinical trials and data management.

The third growth area is definitely our device business-working on Class I, Class II and Class III devices and designing the

products, while the fourth is the manufacturing of the devices itself.

These focus areas are in addition to our traditional business of application support and management which has also seen continuous growth. We have expanded our offerings from pure IT to the sales and marketing division of our customers, supporting some of the applications there. In addition, we also offer support for their manufacturing and execution systems.

Could you elaborate on the regulatory frameworks developed by HCL?

Earlier any data or any information that was submitt ed to the FDA was either paper-based or could be in a Word or PDF format. Since it was becoming difficult for the FDA to analyze the entire data, from last November they wanted everything to be submitted in an XML format, which is an extended markup language and helps slice and dice the data as and when required. So now for any preexisting drug, the data needs to be converted to XML and for any new product that the drug companies are launching, the data has to be submitted to the FDA on XML format. HCL has developed a tool-Structure Product Labeling (SPL) which helps in this conversion. When we launched this product, we were surprised to find that 70 percent of the queries came from the Indian drug companies. In future, we see a lot of potential in this segment.

Then there is a concept called Removal of Hazardous Substances (ROHS), based on which a big legislation is coming up in the Europe. According to this, for any device in the market, all European companies have to go through the ROHS by 2009. Each and every design of the device has to be looked into for any hazardous metals like lead or arsenic or any other components that are damaging to the environment. Such a component has to be taken out and replaced by some hardware or software that can take care of the functionality. This area is a huge opportunity for us. We have developed a framework on ROHS and are working with a couple of device companies currently. This legislation will also result in a lot of customers trying to reinvent their products and we are seeing that companies are moving from Class I to Class III devices.

Can you explain about your biomedical devices foray?

From the device perspective, we are seen as a cradle to grave concept company. We come up with a concept, and then we design it, develop it and manufacture it as well.

The customer comes with a concept and asks us, for example, to develop a drug delivery system which can be implanted in the body. It is a total iteration process where three consultant engineers from each field do a lot of research, come up with a concept and get back to the customer, present a model which is then fine-tuned. Once the concept is okayed, we do the software design, and we embark on the embedded high level design. Then we do the detailed design and the hardware design of the product. Today, the customer has asked us to even manufacture it.

At present, due to the ISO 13485, MQMS standards, the biomedical devices can be tested and implanted in the body for more than eight years of life. We have developed a device, which can be implanted in the spine for pain conditions, where the drug can be infused at the patient's behest. Here we have taken the best practices from avionics and automobiles and planted it into the medical devices practice.

What is your offering in the clinical data management arena?

Though there are a lot of clinical trial/clinical data management solutions available along with the home-grown applications, they are not able to provide end-to-end solutions to the customers. This is why we have started moving into the data management arena and have developed some tools which have a lot of inbuilt flexibility. Data management during the phase I, II, III, IV, and the pharmacokinetic trials entails a lot of market analysis.

Clinical data management is a huge opportunity today and it comes along with supporting the application of a pharma company. For example, for any drug that comes out, one develops a protocol on it and tries to develop software around it. Once the drug compound is out in the market for trials, the process of data analysis itself is a huge opportunity. We have recently tied up with a large drug company to support the whole process of clinical data management.

Moreover, this year we will also focus on the healthcare side where we have not done much till now, as hospital solution providers. We will focus on hospital management system and application based infrastructure.

Will HCL venture into the drug discovery segment as well?

In drug discovery there are two parts-target identification and target validation. Right now our focus is on target validation. We have developed algorithms which help to predict the gene protein structure. So we are trying to offer our consumers a complete basket of products which helps them validate the targets. The end result will be reduction in the time and expense to market to get the drugs, which is the biggest challenge.

What are the growth plans for this vertical?

We are the only practice that is growing 100 percent and we will again grow 100 percent next year and from then onwards we will start to grow at a 60-70 percent basis.

To support that, we need infrastructure in terms of people. So we are hiring dedicated delivery managers just for life sciences, who will work with all other technologies within HCL. We have also created a business solutions group having a team of 15 domain consultants. These people have over 15 years experience in the industry and are physicians, hospital administrators, compliance people who have worked with drug companies.

We are also ramping up the sales force in the US and Europe and most importantly we are making our frameworks more robust from the product or framework perspective.

What is the core business strategy at HCL?

Our business strategy is pretty simple. We want to work with certain focused customers. We want to pick our customers, which is a very bold statement to make. But that does not mean that we will work for only the Fortune 1000 companies. We will also work with small start-ups who are creating certain niche products or getting into the new areas. For example, we are working for a very small start-up company based out of Boston, which is developing solutions in the pharmacogenomics space, which we think is the next trend in the area. So we work with companies which give us unique propositions to build capabilities.

We keep ahead of competition in the application support space by offering regulatory frameworks and in to the devices segment.

Does the HCL Life Sciences vertical have a presence in the Asia Pacific region as well? How different is the life sciences industry in these regions?

HCL has operations in the US, Europe and the Asian region. We are using our Singapore office to enter the Asian region. We have acquired a customer in Singapore-SingHealth. Our Malaysian office is working with a device company offering SAP application support work. These countries have much more regulated processes than India.

Rolly Dureha