

## **It's wise to have synergy between pharma and biotech companies to avoid cannibalization**

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Any promising industry sector is bound to have both existing and new companies rushing in to establish their presence in the area. Whether it is diversification or greenfield entry, a focused approach is always key to lead the way to success. Today, the trend seems to be that a lot of pharmaceutical companies diversifying into the biotech sector. However, it is not going to be wise decision for many to lose the focus on their existing strength, says **Dr Krishna M Ella, Chairman and Managing Director of the Hyderabad-based Bharat Biotech International Limited (BBIL)**. Dr Krishna, also member of National Task Force - industrial biotechnology, Indo-USA Vaccine Action Programme, National Health Mission and AP Task Force on Drugs and Pharmaceuticals, in an exclusive interview with **Joe C Mathew** of Pharmabiz.com talks about the current trends in biotechnology industry in the country. **Excerpts:**

### **How do you rate the performance of Indian biotech companies when compared to the advances in medical biotechnology R&D; world over? Are we much behind them or do we have the capabilities to match the latest developments in the field ?**

Indian biotechnology is more into Biogenerics. As far as the technology is concerned we are behind by almost 15 years. The biotechnology in India is still in the infant stage, similar to high school level, yet to be graduated.

Development has still to take place in various fields like protein folding, protein stabilizing, downstream processing, new expression system and clinical research. In another five years Indian companies will definitely be in an advanced position, provided they focus on development of new molecules in therapeutic and vaccines.

### **What are the promising sectors in biotechnology that Indian entrepreneurs should concentrate on? Do you feel that Indian biotech sector has been witnessing a healthy growth ?**

Most of the companies in India today, are only concentrating on R&D; or manufacturing which is not a good sign for the biotech sector. The biotech entrepreneurs in India should also focus on other service agents critical for the success of biotechnology like vectors, expression host, documentation, servicing of equipments & systems. There is a definite lacunae which needs to be addressed along with the traditional biotech industry issues like manufacturing, clinical documentation and GMP. Yes, the Indian biotech sector has been witnessing a healthy growth; at the same time there are more death rates in this industry.

### **What are the chances of established pharmaceutical companies diversifying into biotech sector? Will biotech industry find new entrants like you establishing themselves faster than others ?**

The trend seems to be that more and more pharma companies are diversifying into the biotech sector. It would be prudent to have a synergy between the pharma and biotech companies to avoid cannibalization and killing of effective products. The pharma industry should not lose focus at the market place. Biotech industry is more individual based and hence the emergence of new players cannot be ruled out. To create a knowledge base for any biotech industry takes a minimum of 5 years. This time frame is difficult to bypass.

### **Indian biotech companies are often said to be single product entities. Do you feel genuine R&D; efforts are being carried out by Indian companies to grow big? How successful is the industry-institution tie-ups in medical biotechnology sector ?**

Many biotech companies would like to have multi-product range. Unfortunately, each protein is different which in turn requires various skill and technologies to suit them individually. Lot of time and effort is required to develop such skills. The infrastructure requirement for each protein expression is also different. Various companies are associated with Institutions. Bharat Biotech, along with an academic/research institution is developing a new biotech molecule against "Staph" infection. This will be the first of its kind in the world. BBIL has got an International patent for this.

The industry-institution tie-ups will be successful only if the goal is to achieve the broader milestones set in the interest of the society at large. Giving due credence to confidentiality and exclusivity and by co- developing the technology, if the institution feels that they are developing the company; then the purpose is diluted. However, if they are aware that in the long run the country/mankind is benefited and if we are able to achieve this model, it can be called a success.

### **How do you rate the performance of various government departments like DBT in promoting biotech industry? Do you feel the need for clear-cut norms from DCGI when it comes to inspections and approvals of recombinant technology based products ?**

Various government departments only facilitate the process. It is for the entrepreneur to effectively utilise these opportunities. Very often the entrepreneur has no specific goal or clarity of vision and blames the government. The government at the same time has a larger responsibility of addressing the industry issues and facilitate the

growth, with the objective of serving society. One should think positively and not negatively, as there is opportunity for everyone. I feel that it is time for a single window system like CBER in US FDA. This model can be implemented in India for better industrial growth.

**How do you place Bharat Biotech among other Indian companies? What is the current market share for your Hepatitis B vaccine? Do you have any programme to utilize the excess capacity in a useful way? What are the other products that are to be launched soon ?**

Established in 1996, the company is best known for Revac-B, a recombinant Hepatitis B vaccine, which has been sold over 32 million doses till date. The company has set up one of the biggest vaccine manufacturing facilities in this part of the world and is involved in continuous research in developing next-generation vaccines and biopharmaceuticals. It has several awards to its credit, which includes the National Award for Best Biotechnology Company by All India Biotech Association, National Award for R&D; efforts in Industry by the Department of Scientific and Industrial Research (DSIR) and the FAPCCI award for 'Best Technological Development in R&D; by an Industrial Scientific Organisation.'

Our fight is against Infectious Diseases and not other Companies. Our competition is at a global level. We are happy to inform that we are the only company from India to develop a new therapeutic molecule that obtained World patent for Lysostaphin. We have also filed patents for new downstream processing and for Streptokinase. This speaks for our R&D; strength. Besides, we do have other plans on structural biology, which is in various stages of development. We have a capacity to produce 100 million doses of Hepatitis B vaccine, the second largest biological facility for Hep B in the World. This speaks volumes of our infrastructure strength. Our Hep B vaccine has been well received in the International market and we hope to start export marketing soon, though we do not have any exclusive marketing tie ups. We are currently considering various proposals for utilizing our excess capacities. Bill Gates Foundation is one such organisation currently utilising our capacity. The products in the pipeline are Typhoid vaccine, Streptokinase, EGF and Human Insulin.

**Have you been successful in marketing Himax technology effectively ?**

HIMAX technology is the proprietary technology of Bharat Biotech. We are presently not keen on marketing it. However, if companies are interested we are open to negotiating a working arrangement.

**Any private placement or major expansion plans ?**

We have expanded our facility matching International standards with an investment of about US\$10 million. We do not have any plans to go for private placement at present.