

Bharat Biotech International Ltd

Ushering in a world of possibilities

In the biotechnology space, Bharat Biotech has emerged as one of the pioneers in R&D and manufacturing of vaccines. Its competence has made it go global, and today it has earned a huge name in the market.

Photo by: Suresh Vengappally



Jasleen Kaur Batra

Bharat Biotech International Ltd is a multi-dimensional biotechnology company that specialises in product-oriented research, development and manufacturing of vaccines and biotherapeutics. It was set up in 1996 and since then has grown by leaps and bounds. Dr Krishna M Ella and Suchitra K Ella, Founding Directors, established the company with the intention to develop next-generation vaccines and bio-therapeutic vaccines. It has a state-of-the-art manufacturing facility and is the largest of its kind in Asia-Pacific. Today Bharat Biotech takes pride having sold more than 1.6 billion of affordable vaccines to more than 100 countries. It was a moment of pride for Dr Ella and his team, when on June 6, 2011 Bharat Biotech announced that *ROTAVAC*, India's first indigenously developed Rotavirus vaccine would be made available for \$ 1 a dose, *ROTAVAC* expects India licensure during 2014

and WHO Prequalification in 2015 for supply to UN agencies. This is made possible only with the help of funding agencies who share the same vision

Bharat Biotech augmented the development of vaccines in the mid 1990s and launched its first product *Revac-B* with down research; this was the world's first cesium chloride-free recombinant Hepatitis-B vaccine, which hit the market in 1998. They further advanced their expertise and reputation in the market by developing *BIOGIT*, India's first indigenously manufactured probiotic yeast. The company has one of the leading brands in the product category with over 140 million doses dispensed till date with a strong pan-India presence. It was also the first company to develop and launch *INDIKINASE* in 2003. *INDIKINASE* is poised to offer substantial market expansion opportunities) and anti-rabies vaccine *INDIRAB*, which is indicated for both prophylactic (pre-bite) and therapeutic (post-bite) treatments.

Journey so far...

The company is the brain child of Dr Krishna Ella, a scientist by origin. He received the National Research Service Award from the National Institute of Health, Bethesda, Maryland and he became a part of the Research faculty at the Medical University of South Carolina, Charleston. He founded and established Bharat Biotech International Ltd in 1996 along with his wife Suchitra Ella. The company today is at the forefront of Indian biotechnology engaged in R&D, manufacturing and marketing of vaccines and bio therapeutics. The passion grew in them in the early 90s when they were in the US. The strong urge to come back to their nation was one of the key reasons behind establishing this company in India. "This particular industry at that time was not doing well; there were barely one or two bio technology companies in India with their own R&D and manufacturing unit." She continues, "We did have doubts of doing things in India, especially in the area of academics and the activity that we were planning to get into. But our experience and training in the realm of biology, research, teaching, marketing, financial administration gave us the boost to come here and set up our company. Both of us were risk takers and we wanted to plunge into this industry as entrepreneurs," reiterates Suchitra K Ella, Co-founder and Managing Director, Bharat Biotech International Ltd.

Mapping the road to success...

Establishing such a huge facility and achieving recognition did not come easily. They were one of the first few people to dream of establishing an R&D

and manufacturing unit. “The years 1996-98 were the most crucial years as there were funding, regulatory, marketing and human resource issues in India at that time. In India we faced problems while getting qualified manpower for the pharmaceutical industry, though there was a huge demand for skilled expertise in the biotech industry. There were companies where a number of products were being manufactured, but there was no platform on a commercial level in India where R&D was taking place,” avers Suchitra Ella. Besides, the industry at that point was not as transparent and smooth as one would want it to be, which further added to the challenges of establishing a company. The basic aim of Bharat Biotech was to establish a set of products, which were high on quality and commercially viable. Being a part of the healthcare segment and that too in vaccines required the highest level of norms and guidelines to be followed. In that era, India did not possess the kind of technology that Dr Ella was planning to work on. “Everything had to be imported from other countries, the technology, raw material, equipment and more. As a country we lacked internationally validated and acceptable quality and the level of equipment that we used. Also, the vaccine industry at that point in time was confined to mostly the government labs. On the whole as a country, the regulatory mechanism was also absent and there were no guidelines to follow. We would run from pillar to post to educate ourselves and get the necessary approvals,” says Suchitra Ella. She further highlights on the challenges,



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Suchitra K Ella

Co-founder and Managing Director, Bharat Biotech International Ltd

“At that time people were skeptical about high technology products, hence funding was a big issue. We showcased our projects to a number of banks and investors, but the system as a whole was extremely skeptical. Assuring that an Indian company would be able to deliver high quality product and standards in line with the foreign brands was a challenge then,” she informs.

Further, there was no Venture Capital (VC) funding at that time. And in India most of the institutions did not support the project as it needed a gestation period of at least 3-4 years. As coming out with a new molecule takes considerable research and more than 5-7 years of time. So even the VCs shied away from spending in biotechnology, which posed as a challenge for us, that we overcame gradually. “The investments came majorly from our pockets, Angel investors; an investor company in US saw the potential in our venture and supported us. We also received term funding from IDBI, but only after a year of starting the company. They came in 1997 in term loan and equity. The Technology Development Board of India, which comes under the Ministry

of Science and Technology, ensured that there was a commercial product from this technology. The advantage of having them on board was comforting and the interest rate was much lower as they were trying to promote technology and technology driven products,” informs Suchitra Ella.

She continues, “Once we launched our first vaccine we were delighted since a lot of credibility came to us with that. Though we did not have deep pockets we somehow managed to sustain the products. It takes at least a ten year curve to come out of sustainable entity and to make it a larger enterprise. R&D is the backbone of such a company and we need to be involved in R&D right from the beginning. A lot of intellectual contribution to the company and the product has to be made and we did that and overcome all the speed breakers in our journey.”

When BBIL started manufacturing hepatitis B vaccine, the cost of preparative ultracentrifuge was prohibitively high. The necessity drove the company to develop an alternative technology relying on salt fractionation, patented as *HIMAX* technology, which

Photo by: Suresh Vengappally



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► L-R: R&D Lab; Quality control department; Dr Krishna M Ella in the R&D Lab



► L-R: Quality Control department; a QC analyst working on Axsym equipment; packaging line

was as effective as ultracentrifuge in separation of VLPs. The relatively lower capital investment and cost effective manufacturing process gave the company the edge to market its vaccine at very low prices that revolutionised the vaccine industry in India.

Current scenario

Ella further continues on the company's focus on biotechnology. "We could make generic products but we knew that it would not take us very far. There are very few players in the industry - including the MNCs. Innovation and Intellectual Property Rights (IPR) will be the way forward for all the companies in the biotech industry," feels Ella.

But the scenario has changed now. The government as well as VCs have entered the industry. "It is only during the last 15 years that India has evolved in the biotechnology industry in terms of manufacturing. The state has improved today and has helped us grow," feels Suchitra Ella.

BBIL has gone ahead of time to keep updated with the disease pattern that one can see not just in India but even in other countries as people migrate to different nation on a regular basis. "Today, the diseases are becoming global, thanks to the frequent travelling of people across countries. One needs to be prepared for tackling such global diseases. This preparedness comes only from our own R&D capabilities. We could come out with H1N1 vaccines in six month after we got the strains. The strains come from the US, and they are the raw material for our vaccines. There are a few diseases that can be

noticed in nations like Latin America, Africa, South Asian countries; we have infectious diseases, which we have not even seen, eg, Rotavirus is a cause of major concern as it kills more than 200 thousand children in India every year," says Suchitra Ella.

Affordability is another factor that BBIL concentrates on; it has introduced new technology as well as manufacturing techniques that would help them reduce cost to make it more affordable. "The market size and the potential in our country is huge. But we also know the burden of the population. It is a situation where we need to develop cost-effective technology. Vaccines are preventive medicine and not curative and so it has to be affordable. The technology used to create the Hepatitis-B vaccine in 1998 was sold at about ₹ 1,500-2,000 per dose. Vaccines are extremely expensive and the Indian population cannot afford high cost technology even if it is available. India and the developing world needs low cost highly effective world class quality. In spite of introducing high technology we have managed to reduce the cost by an approximate amount of 40 per cent and are trying to reduce it further," avers Suchitra Ella.

Manufacturing process

Biotechnology always starts from an academic background. Biotech entrepreneurs are people who pin up from great medical institution and come out and start their own R&D companies, which is later acquired by a biotech company. A few issues are faced while dealing with vaccines. Importing

strains is one of them. Continuous electricity, clean and pure water, high level of cleanliness, air purifiers to keep the small particles away and such more are things that have to be given a lot of attention as they can influence the outcome of a research. "In India, most of the areas have electricity cuts. But we need to have a back up of 30 seconds for electricity as the processes are live and stopping the process is not possible. These are all biologically controlled products and it needs to be taken care of in a continuous process. We run 24x7 and have three shifts to ensure that the process is ongoing. There are a number of such minute details that a vaccine manufacturing company has to keep in mind, which makes the entire process further complex," informs Suchitra Ella.

"When we take our product to an international level a few companies expect the trials to be repeated, especially phase III, as each country has their own set of regulations. It takes us at least about 18-24 months to register one product in other countries. A number of countries follow the WHO guidelines, which are stringent. It is only after we cross all these levels of quality check that the vaccine is allowed to be imported to different countries," says Suchitra Ella. Over the years, Bharat Biotech has maintained high quality and reliability. Today, it is a global player and have fared well. It is currently working on a number of products, which are likely to change the shape of India and the healthcare system; looks like we are in good and safe hands. **MPh**

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