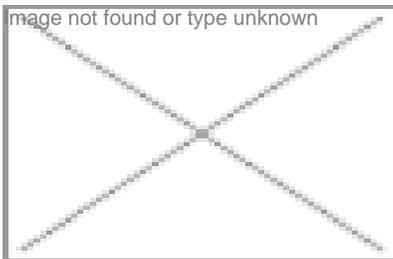


## From Plasma to Biotech

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Bharat Serums and Vaccines, a BioSpectrum Top 20 company, has the capability to take up a research project through all the phases of development independently with its own infrastructure and manpower.



Bharat Serums and Vaccines was started in 1971 with a vision to make India self sufficient in the life saving plasma products as there was hardly any indigenous manufacturing of blood products in the country. Today, it has established itself as one of the fastest growing pharmaceutical firms in India with a CAGR of more than 50 percent in the last three years. The sales turnover stood at Rs 72.37 crore (2002-03) as against Rs 46.41 crore in 2000-01 and Rs 57.34 crore in 2001-02.

"BSV is a very focused organization with a long-term strategy. Even though BSV is family owned, the directors besides monitoring the day-to-day operations are technically sound. It is poised for a big leap," said an employee of BSV.

Bharat Serums was primarily started to fill the demand-supply gap in blood fractions and blood products. And later it became a leading supplier. With the changing times, though there is very good demand for its products (the current market size for plasma products in India is estimated at Rs 250 crore with no company manufacturing them indigenously), BSV has decided to look at long-term objectives and other lucrative options by investing more on R&D activities and focusing on biotechnology and Novel Drug Delivery Systems (NDDS). It has developed its competency in the areas of NDDS and in development and purification of equine-based therapeutic products. With a strong work force of 520, BSV was able to file eight patents of which

five received approval. For future growth BSV is targeting the regulated markets for its products through "technology licensing".

### **Stumbling blocks**

BSV had faced obstacles in its growth path. One of the major hurdles is the regulatory framework of the country which has not kept pace with the rapid technological advances in the areas of pharmaceuticals and biotechnology. During the last decade or so, BSV has been able to develop innovative products, many of them for the first time in the world. However the time required to reach the market, which is critical, has been considerably increased by the regulatory procedures and clearances.

"The other challenges are very similar to any technology intensive industry. The continuous need to stay abreast with the technological advances, shorter product cycles and the constant need to provide products, which deliver better value to the customer at affordable costs require lots of investment in research and development," said Dr Vinod G Daftary, founder and chairman emeritus, Bharat Serums and Vaccines.

In spite of the challenges, BSV has some memorable events in its history of three decades. Dr Daftary, the man behind the success of BSV observed, "It is difficult to pinpoint one particular event as 'the' memorable event for BSV. The initiation of BSV, the grant of import substitution awards, the success of the R&D efforts in terms of the Indian and international patents for many drugs as well as launch of several innovative products, commissioning of our state of the art injectable facility at Ambarnath, have all been remarkable events in our history. Recently BSV has signed a distribution agreement with Baxter, USA, for marketing and distribution of our drug Propofol covering over 40 countries. It is probably the first Indian company to supply finished formulation of an injectable drug to a MNC pharma company for the global markets."

During 1982-96, BSV evolved the competency to develop novel drug deliveries, which it has now been able to leverage to bring out novel formulations and drugs as well as create intellectual property. Dr Daftary observed, "This has been one of the most fruitful periods for BSV."

### **R&D initiatives**

BSV has always recognized the importance of R&D and hence has extensively focused on building in-house R&D capabilities to develop drugs, using emerging tools of biotechnology. It has made substantial investments in R&D infrastructure including high quality laboratory facilities, experienced research scientists and personnel. Investments made in R&D have been at par with international R&D spending at approximate seven percent of its turnover. Its R&D facility has been granted recognition by the Department of Scientific and Industrial Research.

The company has developed core competency in developing NDDS (especially injectables) in the areas of anesthesia, anti-fungal and oncology. The technologies developed are patentable and would not infringe upon the existing technologies. BSV has been cleared by PCT on three of its patents and another seven applications are at various stages of filing and registration.

### **Fruits of R&D work**

BSV has developed considerable market strengths in the domestic markets through its portfolio of niche primary line, life saving injectables at its production facilities at Thane and Ambarnath. It has an animal farm at Khoni, which is equipped with facilities for immunization of horses, harvesting of plasma, plasma separation and on site testing facilities. It has in its portfolio over 25 brands, most of them having the potential of being marketed in the global arena. Exports would continue to propel its growth in the coming years. Its product profile includes plasma derivatives, monoclonals, equine antitoxins and serums, cardiovascular, antifungal, anesthetics and hormones. BSV has also appointed distributors in over 30 countries for its various products to enable continuous availability of its products in these countries.

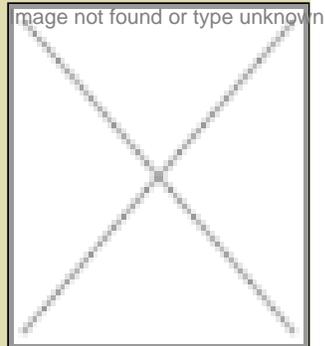
### **Brighter prospects**

BSV has a formidable product pipeline in various stages of development. Since it has quite a few potential blockbuster products in its portfolio, it is now looking for alliances with partners with proven strengths in the marketing and distribution of similar products. The preparations to meet the challenges of the TRIPS by 2005 will support BSV to become a key player in biotech industry in near future.

***Narayan Kulkarni***

## "Confidentiality laws have to be strengthened"

Dr Vinod G Daftary realized the need for domestic manufacturing of plasma products and founded Bharat Serums in 1971. In today's changed scenario, he shared his views with BioSpectrum on how BSV is gearing to face the challenges and the recent trends in the biopharma sector.



### **What are your preparations to meet the challenges of the implementation of TRIPS in 2005?**

Our preparation for the TRIPS goes back to 1996 when a conscious exercise was undertaken by BSV to identify its key strengths, which could be leveraged upon to compete not only in the Indian market, but also on a global scale. The result of the competency analysis led to the formation of three R&D divisions—biotechnology, equine products and Novel Drug Delivery Systems (NDDS).

BSV has always focused on high value niche segments of life saving injectable drugs. This focus continues to be the thread binding all development activities. We believe that significant technological entry barriers are the basic ingredients for long-term success of a product.

While the equine products have no patent issues, the difficulties associated with animal management, expertise in handling animal serum and developing plasma purification techniques pose considerable entry barriers to potential competitors. BSV has also been able to extend its expertise in handling and purification of animal serums to handling of cell cultures and purification and has now a formidable pipeline of promising biotech products.

BSV has been engaged in biotechnology development in recombinant proteins as well as monoclonal antibodies. We have adopted a slightly different strategy in biotech than most of the Indian companies by not focusing only on biogenics.

The NDDS developed by BSV have brought forth potential blockbusters, which would have global appeal and offer tremendous advantage over the existing therapy in terms of better efficacy and safety profile at affordable costs. This has also resulted in valuable intellectual property and a robust patent portfolio.

### **As the industry is gearing to meet the global challenges, do you feel the necessity of a code of conduct for the biotech industry?**

A code of conduct for the biotech industry should be welcome. The implementation of TRIPS itself has awakened the industry for the need of some kind of code of conduct. Biotech is a resource intensive industry with comparatively long gestation period. Investments will be made in this sector only if commercial exploitation of intellectual property is possible and if the investors are assured of the returns. Being knowledge based, the confidentiality laws in the country have to be strengthened. Companies have to invest substantially to create their own intellectual capital over an extended period of time. Respect of other's intellectual property and knowledge, scientific manpower and maintenance of data security and confidentiality should be the cornerstones of the code of conduct.

### **Do you face any competition from other Indian biopharma companies?**

BSV's pipeline consists of high value drugs some of which could be for the first time in the world. We would also seek patent exclusivity for such products. For other identified products, there are very few players on the global scene. Since BSV is following a radically different approach for its biotech foray, we do not foresee significant competition from most Indian companies.

### **Which biotech areas will become the focus of biopharma companies in the near future?**

In the therapeutic field, substitution of naturally occurring compounds with recombinant proteins would continue to be the focus for most of the companies. One of the other areas, which is attracting a lot of attraction and will continue to do so for quite some time to come is the area of monoclonal antibodies, especially in oncology.