

## The Trend Setter

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*As the first Indian company to launch an r-DNA vaccine in 1997, Shantha heralded a new beginning for biotechnology in India.*

Shantha Biotechnics

Business: Research, development, manufacture and marketing of biotechnology-based human health care products

CEO: KI Varaprasad Reddy

Biotech Revenue: Rs 115 crore

Start-up Year: 1993

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Shantha is the pioneer in India for modern biotech products for human healthcare. Its r-DNA Hepatitis B vaccine, Shanvac-B and Shantetra (combination of DPT and hep B) are pre-qualified by WHO, Geneva for supplying to UN agencies. Shanvac-B is the first Indian hepatitis B vaccine to be pre-qualified by WHO. Shantha caters to major international markets including Asia-Pacific, Africa, CIS and Latin America in addition to supra nations like UNICEF and PAHO. Shantha aims to expand its current vaccines portfolio by launching combination vaccines and new generation vaccines produced indigenously at its WHO cGMP plant near Hyderabad. Shanvac-B is exported to more than 50 countries. Other novel products developed by Shantha include Shanferon (r-DNA Human Interferon Alpha 2b) and Shanpoietin (recombinant human Erythropoietin). Shantha Biotechnics and Merieux Alliance announced a strategic alliance to create a global R&D hub for prophylactic vaccine research in India. In association with Shantha Biotechnics, the European company, which has a strong presence in preventive medicine, aims to develop a global strategy for managing the infectious diseases segment.

Shantha is conducting exploratory research in the fields of oncology, infectious diseases and platform technologies. It has also filed an IND for monoclonal antibodies in the US at the end of last year. By early 2007, the company has initiated trials on monoclonal antibodies and is working on four monoclonal antibodies mainly focusing on cancer and genetic disorders. Most of these would be ready by the end of 2007.

Shantha is also planning to develop a single dose Hepatitis B vaccine, which will not only reduce the pain but also ensure that the subjects do not miss the doses, as it happens with the currently available vaccines. It may take another 2-3 years to launch this vaccine. It is also working on typhoid conjugate, pneumococcal, cellular pertusis and serum free vaccines for DPT. Rotavirus vaccine will also be an important part of the company's portfolio, which is likely to take four years for development.

The company is also planning to develop JE vaccine, vaccine for varicella-zoster and heat stable vaccines. Shantha has tied up with Cambridge Biostability, which is a university spin-off company. The company hopes to be in a position to launch heat stable vaccines in another 2-3 years.

Shantha has expanded its current facilities at Hyderabad by adding three new blocks including facilities for mammalian cell culture, viral vaccines and warehouses to stock vaccines. It has opened its new cGMP compliant state-of-the-art high speed vaccine vial filling sft facility, which will have a capacity to fill and finish 3,00,000 vials a day. Set up at a cost of Rs 25 crore, this 80,000 sft is part of Shantha Biotechnics' strategic expansion plans focused on servicing existing and growing market demands for its range of vaccines. Apart from hepatitis B, DPT-Hep B and tetanus toxoid, the vaccines under development like Human Pappiloma Virus (HPV) and Rotavirus and the soon to be launched pentavalent vaccine will be formulated and blended in this new facility.