

DIRECTORY OF

Top 60 Biopharmaceutical Manufacturers in India

A comprehensive industry review: Profiles of established, and rapidly growing, organizations involved in biomanufacturing.

SEPTEMBER 2008



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Preface

This directory is an on-going project to provide in-depth information and insights into the rapidly growing and changing Indian biopharmaceutical industry. To the best of our knowledge, this is the first directory of its kind. As the Indian biopharmaceutical industry continues to expand, the information in this directory will, necessarily, become outdated.

As such, we will have on-staff researchers to keep it up-to-date. However, our readers' input will be invaluable in that regard. If you have comments or corrections, please forward them to us.

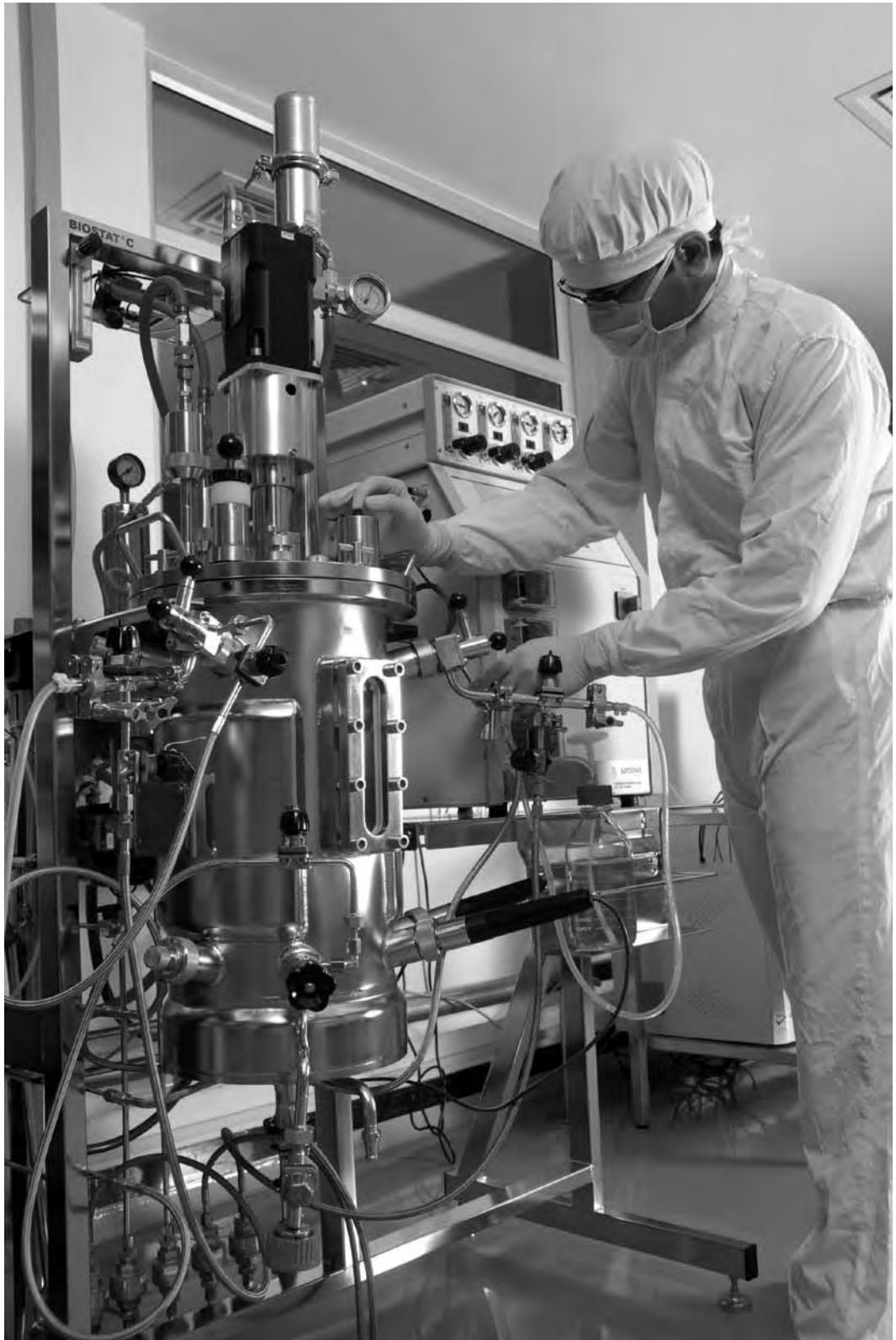
The ranking of companies is based on information publicly available. Financial estimates in some cases are based on factors such as the number of employees, facility size, and available partnership resources.

Because the Indian biopharmaceutical industry is in a growth phase, some of the organizations profiled are emerging as industry participants. These companies are included because, based on their human resources, their internal expertise, or their financial capabilities, they may have the potential to rapidly enter this market with their own biological products.

We wish to acknowledge the contributions of many individuals in India, and around the world, who have reviewed and evaluated the content of this directory. Without their support, this project would not have been possible.

In particular, we wish to thank Abhijeet C Kelkar, of D2L Pharma, (Bangalore). Mr Kelkar was instrumental in gathering the information and ensuring the accuracy and content of this directory.

Eric S. Langer
Managing Partner
BioPlan Associates, Inc.
September 2008



Photos Courtesy of Intas Pharmaceuticals.

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Photos Courtesy of Intas Pharmaceuticals.

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Indian Biopharmaceutical Companies: The Development of Modern Biotechs in India

Overview: Indian Biopharmaceutical Industry

India's interest in the Biopharmaceutical/Biotech market dates back to 1925 when *Haffkine Institute (Plague Research Laboratory)* began production of vaccines in Mumbai. In 1953, *Unichem* entered production and began exporting hormonal products. At that time, India was primarily dependent on foreign companies to meet the country's growing demand for basic medication due to its rapidly growing population and frequent epidemics.

Later in the 1960s, many companies were established for production of vaccines. Some prominent ones included the *Serum Institute of India*, *Biological E*, *Bharat Serums and Vaccines*, *VHB Life Sciences* and *Chandra Bhagat Pharma Pvt. Ltd.* Simultaneously, the focus also shifted towards the enzyme market, and companies such as *Biocon* and *Advanced Enzymes* entered into enzyme production. *Biocon*, established in 1978, became the first Indian company to manufacture and export enzymes to the U.S. and Europe.

India has moved from complete dependence on foreign multinationals to becoming a major supplier of vaccines to the global market, which remains a major segment of the Indian biopharma market. The Indian local vaccine market is currently in the region of USD\$100 million and is growing at the rate of more than 20% per annum.

India is the largest producer of Recombinant Hepatitis B vaccine in the world today. *Serum Institute*, which started in the early 1960s, reports itself today to be the second largest manufacturer of vaccines, and claims that 1 of every 2 kids in the world is vaccinated by Serum's vaccine.

Most of the major Indian companies involved in biopharmaceuticals are largely confined to the areas of traditional biotechnology like fermentation and vaccines. The domestic Indian biopharma segment involved in recombinant DNA production is still evolving. Until the 1990s, the Indian recombinant product market was completely dominated by global majors such as *Novo Nordisk* and *Eli Lilly & Co.* India's entry into recombinant products started with the launch of rHU-Erythropoietin (Hemax®) into the Indian market in 1993 by *Hindustan Antibiotics*, followed by the Hepatitis B vaccine from *Shantha Biotech*, and a year later by *Bharat Biotech*, another Hyderabad-based company, which also entered the hepatitis vaccine market.

A further breakthrough in recombinant products was with the launch of recombinant Hepatitis-B vaccine (Biovac-B®) by *Wockhardt* and (GeneVac-B) by *Serum Institute* in 2000 and 2001, respectively. *Wockhardt* also launched its Recombinant erythropoietin (Wepox®) in 2001, and r-DNA human insulin (Wosulin®) in 2003, Asia's first recombinant insulin.

The Indian biopharma sector became the largest sector of biotech industry in India with a growth rate of 31.8% in 2006 and accounted for a 72.2% share with revenues of USD \$1.05 billion.

A majority of the Indian biotech industry's contributions come from its biopharmaceutical segment, but also includes other segments such as bioagriculture, bioinformatic, bioservices, and bioindustry. The majority of exports in the biotech sector are made by biopharma companies. Today, India ranks 11th in the world and 3rd in the Asia-Pacific in terms of company count with over 300 biotechnology-related firms.

Current Trends in Biopharma – India Changing the Paradigm

At present, the biopharmaceutical industry in India is mainly comprised of three segments: recombinant drugs, monoclonal antibodies (mAbs), and vaccines. Much of the industry focuses on manufacturing biotech drugs through the fermentation process.

Most of the early companies were into the vaccine business, which led to market saturation and increased competition in the domestic market; now with proven quality and cost effectiveness, these same companies are looking to tap the global markets for a broader array of biologics. The focus is now on obtaining a share of the underdeveloped market, as well as supplying the World Health Organization (WHO), UNICEF, and other non-government organizations. The industry is also setting its sights on the therapeutic needs of developed countries in North America and Europe.

India is the second largest manufacturer of vaccines used by children, with *Serum Institute* as a major contributor in the world vaccine market. In 1999, *Serum Institute* was recognized as the largest producer of Measles and DTP vaccines in the world.

Recognizing the potential of Indian companies, several foreign companies are working with domestic Indian manufacturers for inclusion into the Indian market. For example, *Acambis Plc.*, a UK-based vaccine developer, has a manufacturing and marketing agreement with *Bharat Biotech* for its investigational vaccine against Japanese Encephalitis.

Focusing on development of more complex combination vaccines, the following domestic companies have developed vaccines for a variety of uses:

- *Panacea Biotech* partnered with *Chiron Vaccines* (US) to develop a fully liquid pentavalent combination vaccine for five infectious diseases: diphtheria, tetanus, whooping cough, Hepatitis-B and H.Influenzae type b;
- *Shantha Biotechnics* launched its four-in-one vaccine, Shantetra, against four life-threatening infections including diphtheria, tetanus, pertussis and hepatitis B; and
- *Serum Institute* is manufacturing an indigenous DTP and Hepatitis B combination vaccine, Q-Vac.

India is working toward self-sufficiency and greater independence from foreign companies for product innovations or technology. It now exports vaccines to more than 100 countries around the world. Some Indian companies are experiencing significant growth, such as *Biocon*. It has developed expertise in solid state fermentation, which is 4 to 20 times more effective than in-liquid state fermentation. *Biocon* is the only company in the world, which has the technology to make drugs using genetically engineered microorganisms in a solid-state fermenter.

ABOUT THE DIRECTORY

This comprehensive Industry review of the Indian biopharmaceutical industry profiles established, and rapidly growing organizations involved in biomanufacturing.

Companies include manufacturers of protein therapeutics and vaccines.

ABL Biotechnologies Limited
Advanced Enzyme Technologies Ltd.
Avesta Biotherapeutics and Research Pvt. Ltd. (ABRPL)
BDR Pharmaceuticals Pvt. Ltd.
Bharat Biotech International Limited
Bharat Serums and Vaccines Limited (BSV)
Bhat Bio-Tech India Pvt. Ltd.
Bio-gen Extracts Pvt. Ltd.
Biochem Pharmaceutical Industries Ltd.
Biocon
Biological E. Limited
Biovel Life Sciences (P) Ltd.
Cadila Healthcare Ltd. (Zydus Cadila)
Cadila Pharmaceuticals Limited
Chandra Bhagat Pharma Pvt. Ltd.
Chemtech Laboratories Ltd
Claris Lifesciences Limited
Dabur Pharmaceuticals Ltd.
Dr. Reddy's Laboratories
Emcure Pharmaceuticals Limited
Fermenta Biotech Ltd (FBL)
Glenmark Pharmaceuticals
Gufic Biosciences Limited
Haffkine Bio-Pharmaceuticals Corporation Limited
Health Biotech Pvt. Ltd
Hindustan Antibiotics Limited
Indian Immunologicals Ltd.
Intas Biopharmaceutical Limited (IBPL)
KDL Biotech Ltd.
Life Medicare & Biotech Pvt.
Lumis Biotech Pvt. Ltd.
Marksans Pharma Ltd.
Mediclone Biotech
Nicholas Piramal India Limited
Panactea Biotech
Phikon Biotech Pvt. Ltd.
Ranbaxy Laboratories Limited
Reliance Life Sciences Pvt. Ltd.
RPG Life Sciences Limited
Saamya Biotech (India) Ltd.
Samarth Pharma Pvt. Ltd.
SCL Group (Saurav Chemicals)
Serum Institute of India
Shantha Biotechnics Ltd.
Shasun Chemicals and Drugs Limited (SCDL)
Sudershan Biotech Limited
Themis Medicare Ltd
Titan Biotech Limited
Transgene Biotek Limited
Unichem Laboratories Ltd.
USV India Ltd.
Varda Biotech (P) Ltd.
Venus Remedies
VHB Life Sciences Inc.
Vins Bioproducts Limited
Virchow Biotech (P) Ltd. (VBPL)
Viswagen Biotech Pvt. Ltd.
Wockhardt Biopharmaceuticals
Yashraj Biotechnology Limited
Zenotech Laboratories Limited

ABOUT BIOPLAN

BioPlan Associates, Inc. has been providing biotechnology and healthcare publishing and marketing research services to the industry since 1989.

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