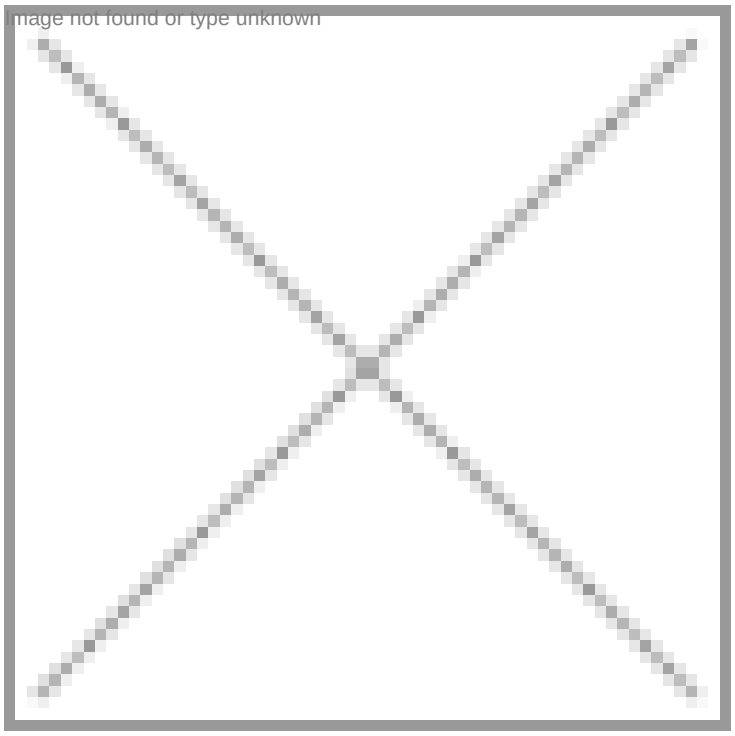
BioSpectrum the business of Bio & Health Sciences

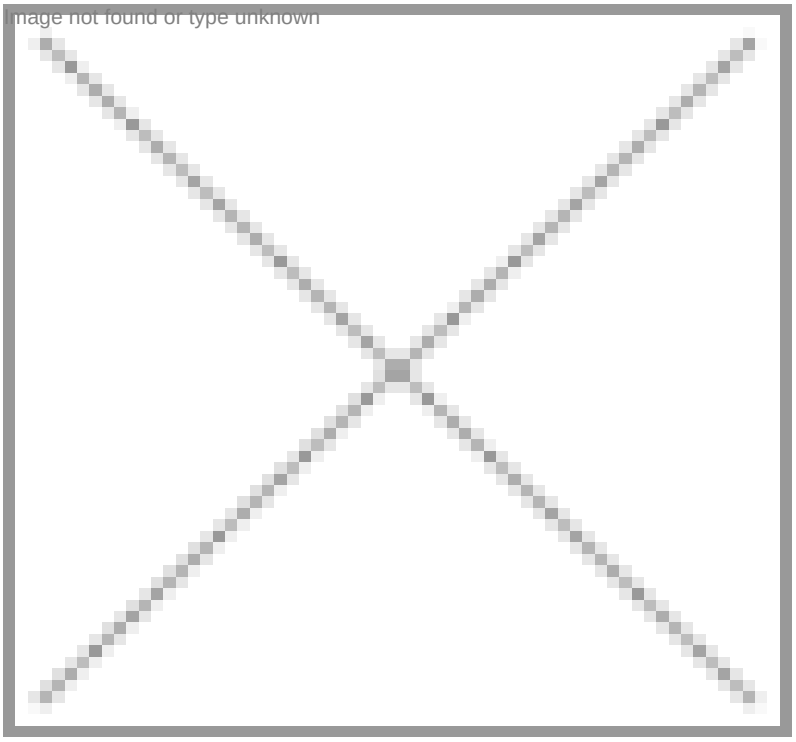
Biotech manufacturing in India on a roll

06 November 2007 | News



Biotech manufacturing in India on a roll

India is fast emerging as a favored destination for biopharma manufacturing



Indian companies like Biocon, Bharat Biotech, Biological E, Serum Institute and Shantha Biotechnics have world-class facilities for biopharmaceutical manufacturing. Earlier there was some reluctance to award contracts to Asian biopharma manufacturers because of concerns of IP and regulatory compliance. But now some of the Asian countries are changing and becoming very competitive in biopharma manufacturing. "Indian firms are expanding and scaling up manufacturing capacities to become global players and the West is increasingly becoming comfortable with the IP, quality, regulatory filings and the infrastructure here," said Gautam Das, COO, Syngene.

Shasun Chemicals, Suven Life Sciences, Strides Arcolabs, Jubilant Organosys, Orchid Pharmaceuticals and many other large Indian companies have started undertaking contract manufacturing of APIs as part of their additional revenue stream. Top MNCs like Pfizer, Merck, GSK, Sanofi Aventis, and Novartis are dependent on Indian companies for many of their APIs and intermediates.

Today Indian pharma companies have upgraded their existing plants or built new plants which are not only GMP compliant but also approved by international drug authorities. Many mid to large-sized ones have achieved GMP approval of highly regulated markets such as the US, Europe, Australia, Latin America and Canada. The most stringent, the USFDA approval is distributed between large and mid size companies.

India triumphs in having maximum number of USFDA approved plants after the US. India has over 80 USFDA approved plants and all comply with WHO GMP. India is expected to have 30 percent more USFDA plants by 2008. The large portion of this increase will be shared by mid size pharma companies. Most of the companies are upgrading and building new facilities as per USFDA standards. Apart from Andhra Pradesh and Gujarat, Himachal Pradesh is the next favored state for setting up manufacturing plants. India comes fifth in terms of API manufacturing. It has established itself as low cost and high quality API production country. With product patent regime in its second year and several products expected to go off patent in the next 2-3 years, India is well positioned to capture the outsourcing opportunity.

With India emerging as a cost competitive outsourcing base for global majors, Jubilant Organosys, an integrated pharmaceutical and custom research and manufacturing services company, intends to be the preferred partner for custom research and manufacturing to global leaders in the pharmaceuticals and agrochemicals industry.

Jubilant Organosys recently signed a multi-million dollar long-term agreement with Syngenta for the supply of pyridines. The new contract will begin from early 2008 and it will cover an extension period of up to five years, during which Jubilant will continue supplying the products to Syngenta.

Recently Jubilant expanded its production capacity for pyridines and picolines to 42,000 TPA and this contract with Syngenta would significantly improve the use of the additional capacity. With this multi-year contract and increased capacities, Jubilant

emerges as the largest player in pyridines worldwide.

Jubilant Organosys have also acquired US-based Hollisterâ€“Stier Laboratories LLC for $122.5 million. This is said to be the largest overseas acquisition in contract manufacturing sector by an Indian company. The acquisition significantly strengthens Jubilant's global CRAMS business via entry into the high barrier injectables segment.

Hollister is an excellent strategic fit for Jubilant, as it augments the company's growth in the CRAMS business globally. This acquisition provides Jubilant with a platform within the fast growing injectables contract manufacturing segment.

The company had signed annual contracts worth $60 million. The contracts form part of the company's order book for the calendar year 2007. The contracts have been finalized with some of the leading global life sciences companies in the US and Europe. In addition to these annual contracts, the company as part of its normal business also executes half yearly, quarterly and monthly contracts and spot sales.

The company will also focus on twin strategies of investments in innovation and world-class manufacturing facilities. Currently, Jubilant is in advanced talks with other global life sciences companies and is confident of signing several other contracts for CRAMS over the next few months.

Over the last two years, Jubilant Organosys has invested close to $45 million on augmenting its manufacturing capabilities and strengthening its R&D backbone in customs research and manufacturing business.

Hyderabad-based Suven Life Sciences, a pioneer in Contract Research and Manufacturing Services (CRAMS), received NABL (National Accreditation Board for Testing and Calibration Laboratories) certificate by the Department of Science and Technology (DST) last year, for its biopharmaceutical research lab facility at Hyderabad with the standard ISO/IEC/17025:2005 (general requirements for the competence of testing and calibration laboratories). With this NABL certification, Suven is in a position to offer value added services within the business segment of CRAMS, Drug Discovery and Development Support Services (DDDSS) and Collaborative Research Partner (CRP).

Suven Life Sciences recently underwent USFDA inspection at its facility in Hyderabad for the manufacture and supply of Active Pharmaceutical Ingredients (APIs) under cGMP. Based on the inspection and the review thereafter, the USFDA classified Suven's facility at Pashamylaram as acceptable for manufacture and supply of APIs. So far Suven Life Sciences has filed 8 Drug Master Files (DMFs) from this facility, which is now USFDA compliant under cGMP. With partner ANDA approvals Suven can supply the APIs in future thus generating new revenues in due course of time.

Last year, Kemwell, a Bangalore-based contract manufacturing and development services company, acquired Pfizer's manufacturing plant in Uppsala, Sweden. The facility produces salazopyrine known as the first designer drug used to treat arthritis and irritable bowel syndrome (IBS). This is not the only acquisition made by Indian life sciences companies and will neither be the last. Nicholas Piramal has done an acquisition in the UK and Dr Reddy's Labs has bought a Roche facility in Mexico. However, the acquisition by Kemwell is a good indicator that medium-sized Indian companies also have the opportunity to be global players. According to Anurag Bagaria, vice president of Kemwell, the acquisition enabled the company to gain the vital European footprint for its contract manufacturing ambitions.

Being close to the customer is a mantra being heard increasingly in the life sciences sector. The Kemwell acquisition of the Pfizer plant, which is approved by the USFDA, the European EMEA and the Japanese regulator, is also believed to have been driven by this mantra. "We service 80 countries from our Uppsala facility and this acquisition has helped in increasing our credibility in the international market," said Bagaria. Though the contract with Pfizer is a long term one, Kemwell is in a position to manufacture other drugs as well in this facility. "We will use this facility to do the lab tests for medicines manufactured in India and to be sold in EU. We continue to look for more acquisitions in Europe and the rest of the world," added Bagaria.

At present over 80 Indian pharmaceutical formulation plants have received USFDA approvals. Companies such as Lupin, Biocon, JK Pharma, and Ranbaxy got the USFDA approvals for manufacturing few of their fermentation products. Also global majors like GSK and Aventis are setting up manufacturing bases here.

Serum Institute of India is widely recognised as a world-class contract manufacturer and is able to deliver a wide range of products and clinical assistance to companies on a market competitive basis. In particular, Serum Institute has developed a complete process of fermentation, purification and manufacture of polysialic acid and the Development and Manufacturing Agreement (DMA) provides the framework for this process to be taken forward to enable production on a competitive commercial basis.

Lipoxen PLC, a UK-based biopharmaceutical company specialising in the development of differentiated biologicals, vaccines and anti-cancer therapeutics drugs, entered into a Development and Manufacturing Agreement with the Serum Institute of India. Pursuant to the DMA, Serum Institute develops the technology for the manufacture of polysialic acid and its derivatives to the USFDA standards on a commercial scale to meet the demands of the company's collaborative partners and for pre-clinical and clinical trials purposes.

Serum Institute of India is setting up a biotech Special Economic Zone (SEZ) at Pune with an investment of $265 million. About one billion doses of various vaccines are expected to be produced on an annual basis from this SEZ. Oncological products for the US and EU markets are also expected to be manufactured at the new facility. The premises has been pre-qualified by the WHO.

Bharat Biotech, Dr Reddy's Labs, Intas Pharmaceuticals, Panacea Biotec, Shantha Biotechnics, and Wockhardt are some of the other companies that are manufacturing rDNA products in India. Others like Glenmark Labs are serious about setting up manufacturing facilities for recombinant biotech products. Haffkine Bio-Pharmaceuticals, Hindustan Antibiotics, Shreya Life Sciences, and US Vitamins have been into formulation business so as to produce for mass consumption. Biological E, which is looking at increasing its revenue from the biotech area, is increasing its capacity and setting up a modern vaccine facility in Hyderabad. Indian Immunologicals Ltd (IIL), a major player in animal vaccines manufacturing, has been making investments in infrastructure development in the last few years. Pune-based Venkateshwara Hatcheries, a leading poultry vaccine manufacturer is entering manufacturing human vaccines. Venkateshwara Hatcheries is investing about $40 million in phases.

Biocon leverages its India cost-base together with its extensive expertise and technology platforms to offer competitive, high quality, custom manufacturing services to a global clientele. Its full set of manufacturing capabilities, include mammalian cell culture fermentation, microbial cell culture fermentation, synthetic chemistry, formulation development for solid dosage (tablets and capsules) for immediate and modified release, injectables (vials, cartridges, lyophilized and pre filled syringes) and a fill finish facility. "Inspected by the USFDA on more than one occasion, the facilities are internationally benchmarked making it partner of choice for companies seeking innovative solutions for their medication delivery needs," remarked Dr Gautam Das, COO, Syngene. Last year Biocon inaugurated a multi-product biologics facility in Bangalore. The facility is designed to manufacture a broad range of novel and biosimilar therapeutic products through large scale cell-culture fermentation for the treatment of cancer, auto-immune and metabolic diseases. "We are focusing on our contract manufacturing business and it is also the growth driver for Syngene," said Kiran Mazumdar Shaw, CMD, Biocon.

Biocon had set up a multi-product biologics facility at Biocon Park, Bangalore. Biocon established Biocon Biopharmaceuticals Private Limited (BBPL) in collaboration with CIMAB, representing the Centre of Molecular Immunology, Cuba. The state-of-the-art cGMP compliant facility is designed to manufacture a broad range of novel and bio-similar therapeutic products through large scale cell-culture fermentation for the treatment of cancer, auto-immune and metabolic diseases. The facility is also designed to cater to contract manufacturing needs of international biopharmaceutical companies. The l.2 lakh-sft building spread over three floors comprises process, laboratory and technical support areas. The new facility represents a significant advancement in terms of technical sophistication over Biocon's existing facilities and comprises three distinct modules--cell culture module for monoclonal antibodies and other cell culture products; aseptic formulation and filling module for sterile products in vials, cartridges, lyophils and syringes; and quality control module.

Wockhardt has a contract-manufacturing relationship with Amylin and many other leading pharmaceutical companies, such as Aventis and AstraZeneca. It has manufacturing plants in India and the UK, which are certified by the USFDA and the UK's MHRA.

Bharat Biotech has state-of-the-art manufacturing plants meeting stringent standards laid down by internationally recognised institutions such as USFDA, UKMCA and WHO. And its production capabilities extend to vaccines and biotherapeutics. Bharat Biotech had set a precedent in this emerging area with the manufacture of HibTITER (Haemophilus Influenzae b Conjugate Vaccine) for Wyeth Lederle. This was the first time that a vaccine was moved out of the US for manufacturing in India. BBIL is also manufacturing a cancer therapeutic for US-based Agenix.

Shantha Biotechnics also offers high quality contract manufacturing services well supported by its experience in QC, QA and R&D. It has state-of-the-art facility conforming to cGMP for manufacturing biopharmaceuticals and quality control facility to cater to the in-process and finished product testing. From the very beginning Shantha has invested in building manufacturing capabilities and infrastructure to meet the most stringent regulatory requirements for manufacturing of biologicals.

Reliance Life Sciences (RLS) has started contract manufacturing and contract research of biopharmaceuticals. RLS currently offers a complete range of contract manufacturing and contract research services to address the products discovery and development needs of the customers in the biotechnology industry. Its contract manufacturing services ranges from bioassay

development, process development, analytical testing to clinical lot and commercial batch manufacture.

Asia is, no doubt a major center for manufacturing chemical-based pharmaceuticals. It is a favored destination for contract manufacturing. But the biopharma manufacturing is small. According to a recent report published by HighTech Business Decisions, "Biopharmaceutical Contract Manufacturing: Best Practices Pricing Study 2006", between 2002 and 2006, the size of the biopharmaceutical contract manufacturing market has doubled, reaching more than $2 billion in 2006.

Some of the major biotech manufacturing facilities in India

Biocon

Biocon had set up a multi-product biologics facility at Biocon Park in Bangalore. The state-of-the-art cGMP compliant facility is designed to manufacture a broad range of novel and biosimilar therapeutic products through large scale cell-culture fermentation for the treatment of cancer, auto-immune and metabolic diseases. The l,20,000-sft building spread over three floors comprises process, laboratory and technical support areas.

The new facility represents a significant advancement in terms of technical sophistication over Biocon's existing facilities and comprises three distinct modules -- cell culture module for monoclonal antibodies and other cell culture products, aseptic formulation and filling module for sterile products in vials, cartridges, lyophils and syringes, and quality control module. Inspected by the USFDA on more than one occasion, the facilities are internationally benchmarked.

Biological E

Biological E has three manufacturing facilities in Azamabad, Hyderabad. The state-of-the-art facilities are designed to manufacture a broad range of products under each of its therapeutic segments like solid dosage forms, vaccines and sera, bulk actives, injectables, liquid orals in different locations which are WHO cGMP certified. The units have the production capacity of 2 lakh samples per day.

Serum Institute of India

Serum Institute of India is setting up a biotech Special Economic Zone (SEZ) at Pune with an investment of $265 million. About one billion doses of various vaccines are expected to be produced on an annual basis from this SEZ. Oncological products for the US and EU markets are also expected to be manufactured at the new facility. The premises has been pre-qualified by the WHO. Serum Institute develops the technology for the manufacture of polysialic acid and its derivatives to the US Food and Drug Administration standards.

Bharat Biotech

Bharat Biotech has state-of-the-art manufacturing plants meeting stringent standards laid down by internationally recognized institutions such as the USFDA, UKMCA and WHO. Its production capabilities include vaccines and biotherapeutics. Bharat Biotech had set a precedent in this emerging area with the manufacture of HibTITER (Haemophilus Influenzae b Conjugate Vaccine) for Wyeth Lederle Ltd.

Panacea Biotec

The new Greenfield construction Vaccine Formulation Plant (VFP) has been introduced in Baddi, Himachal Pradesh. The plant has been commissioned with several filling lines for bacterial and viral vaccines complying with WHO, cGMP norms for liquid vaccines in pre-filled syringes, liquid and lyophilized vaccines in vials. The total production capacity of this facility is one billion doses per annum. The three-story production block is spread over approximately 30,140 sft construction area at each floor. The plant also has a two-story block of warehouse-cum-cold storage facility admeasuring approximately 26,910 sft on each floor.

It also has a 50,000-sft vaccines formulation facility in New Delhi, a WHO cGMP approved facility with WHO pre-qualification for oral polio and recombinant Hepatitis B vaccines. With a built-up area of more than 50,000 sft, it has three vial filling lines -- two lines dedicated to oral polio vaccines both trivalent and monovalent and one line dedicated to Hepatitis B and combination vaccines. Provision has also been made for a separate filling line for pre-filled injection devices. Also any injectable preparation can be filled in vials. The injectable vaccine facility is also expected to be WHO pre-qualified for combination vaccines during the current fiscal.

Wockhardt Ltd

Wockhardt has set up a global-scale biopharmaceuticals manufacturing powerhouse, the Wockhardt Biotech Park in Aurangabad. This state-of-the-art complex comprises six dedicated, manufacturing facilities, and is designed according to the USFDA and EMEA standards. It has eleven world-class manufacturing plants in India, the UK and Ireland. The new SEZ is spread over 107 hectares of land. The SEZ house manufacturing facilities for Active Pharmaceutical Ingredients (APIs), biopharmaceuticals, and a research and development center.

Shantha Biotechnics

Shantha Biotechnics has a facility at Medchal near Hyderabad where it manufactures products like Shanvac-B (Hepatitis B vaccine), Shanferon (Interferon Alpha-2b) and also Shankinase (Streptokinase drug). It has state-of-the-art facility conforming to cGMP for manufacturing biopharmaceuticals and the quality control facility to cater to the in-process and finished product testing.

Indian Immunologicals Ltd

The total area of the Indian Immunologicals Ltd (IIL) complex at Hyderabad is 213 acres.

The veterinary vaccine plant is one of the largest plants in the world with the state-of-the-art technology, WHO-GMP and ISO-9002 certified. The modern plant at Hyderabad has an installed production capacity of 25 million quadrivalent doses of FMD vaccine, which is the largest in Asia and the facility at Ooty manufactures rabies vaccine.

Jubilant Organosys

Jubilant Organosys has state-of-the-art pilot and commercial scale multi-purpose pharmaceutical manufacturing plants conforming to cGMP guidelines and approved by various regulatory authorities such as the USFDA and TGA. It has 6 large-scale commercial multipurpose plants at Gajraula (100 km from Delhi) and 4 at Nanjangud (near Mysore in Karnataka), which operate on DCS systems. The Nanjangud facility has USFDA approval. Both these facilities put together have 135 reactors ranging from 1 KL to 12 KL. Total reactor volume is 600 KL.

Jahanara Parveen with
Shalini Gupta in New Delhi