# BioSpectum turns 7- High Impact Trends

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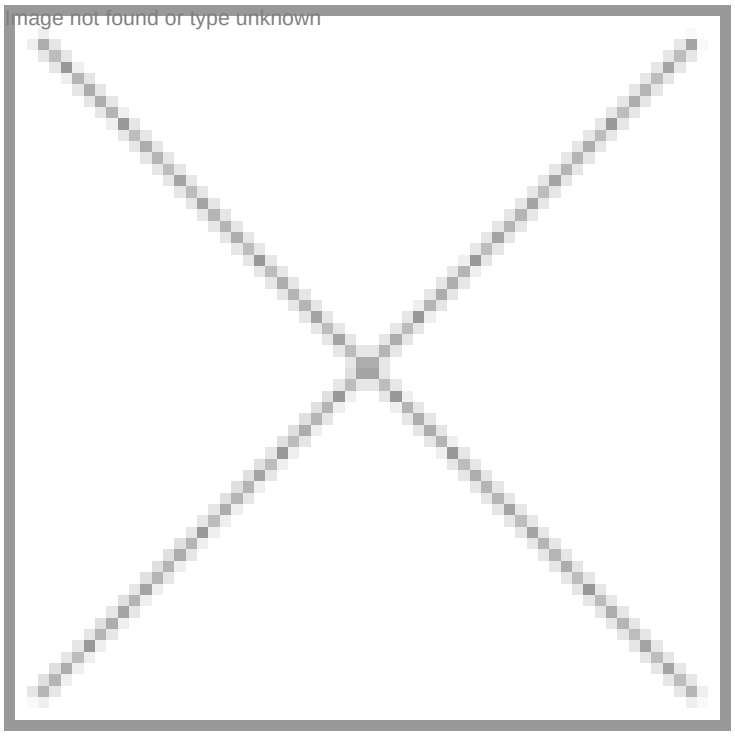


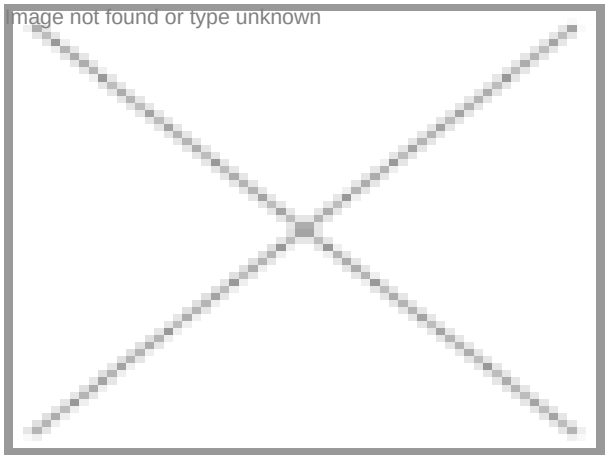


## Bt cotton

*Being the only GM crop in India so far, Bt cotton has been a success story*

The approval of Bt cotton for commercial release by the GEAC at its 32nd meeting in 2002 marked India's entry into GM club. It also led to a great deal of hope, curiosity and expectations for the future success of agri-biotech sector in India.

Initially frowned upon, GM cotton was a runaway success in India. The area under this crop and the number of farmers who adopted this technology increased significantly. The transgenic hybrids were developed by Monsanto's Indian partner-

MAHYCO (Maharashtra Hybrid Seed Company). The introduction of Bt Cotton significantly brought down the annual losses caused by bollworms, estimated at about $300 million (Rs 1,384 crore). Also, it has helped in cutting down the repeated spraying of insecticides valued at $700 million (Rs 3,229 crore), 50 percent of which is sprayed on cotton crop alone.

Despite the continued opposition by a small section, the Indian cotton farmers have accepted this technology in a big way and derived social and economic benefits.

## Human clinical trial for stem cells

*Recent approval of clinical trials of stem cell-based drugs by the Drug Controller General of India (DCGI) has created immense interest among global stem cell players to conduct their clinical trials in India*

Well-defined guidelines, efficient and speedy processes for approving clinical trials by regulatory bodies and availability of vast patient pool makes India a good destination for conducting clinical trials. ICMR and DCGI have drafted guidelines to conduct clinical trials in India in an ethical and scientific manner. ICMR has formed an expert stem cell committee to validate and recommend trials in India. DCGI recently made registry of all clinical trials mandatory with Clinical Trials Registry-India (CTRI) registry-so that all trials can be monitored for proper conduct as per international norms.

Availability of skilled manpower and initiatives taken by the government in creating good infrastructure for stem cell research are attracting foreign institutes and private companies for collaborative research with Indian institutes and private companies. The initiative taken by the DBT in creating a world-class stem cell research center in Bangalore is another positive step in nurturing value-added stem cell research in India. India has the opportunity to be a global force in biotechnology and stem cell research can be an important constituent of this aspect of global leadership in this frontier technology area.

## First recombinant insulin and a vaccine

*The two indigenously developed recombinant products were real technology breakthrough not only for the companies who developed it but also for India*

In 1997, Shantha became the first Indian company to develop, manufacture and market India's first recombinant vaccine, Shanvac-B, a vaccine for hepatitis B. Shantha's entry into market with its hepatitis B vaccine (Shanvac-B) drastically brought down the prices of imported vaccine from Rs 780 to Rs 50 in 1997 and to Rs 25 in 2003.

Wockhardt, a hospitals-to-drugs chain produced India's first recombinant human insulin- Wosulin-in 2002, making India the first Asian country to develop, manufacture and market the product. Those days, there were only three manufacturers of recombinant human insulin. With Wosulin, India gained reputation on the global map. With this indigenously developed insulin in the market, multinational companies had to cut their insulin prices in India by 35-40 percent in January 2003.

## National Biotech Regulatory Authority

*The drafting of a bill for the establishment of a National Biotech Regulatory Authority has been a major landmark in the history of biotech industry of the country*

In 2004, a single-window system for promotion and regulation in the form of National Biotechnology RegulatoryAuthority (NBRA) was proposed by a task force headed by famous agricultural scientist, Dr MS Swaminathan.

This was seen as a major step towards generating the necessary public, political, professional and commercial confidence in the science-based regulatory mechanism in place in the country.

Although awaited eagerly by the industry, the bill is yet to come up before the cabinet for approval. But now the recent announcements suggest that government is expected to push the bill through to the end of this year.

An independent authority like NBRA will help regulate the large number of biotech related activities in the country. These activities include the vaccines, seeds, and biological products that require genetic engineering. The authority is expected to ensure that the biotechnology policies are strictly based on scientific assessment of risk. The need for a credible biotech regulator has been felt since last decade due to the lack of consensus on various issues related to GM technology.

## Biotech parks

*There has been growth in Bt parks in the country providing infrastructure to fuel the growth*

Establishment of Bt parks is an attempt both by the central and the respective state governments to bolster the R&D work and the infrastructure availability for the biotech industry. Over the past seven years, many states have taken up the biotech

park initiative-especially the states of Gujarat and Andhra Pradesh.

Gujarat is rapidly growing as far as Bt parks are concerned. The aim is not just to attract big players to the park but also to promote local companies. This includes The Akruti Gujarat Biotech Park which is a joint venture between the Gujarat government, The Chatterjee Group (TCG), and Akruti City Limited. It is also in the process of setting up an Agri-Biotech Park. Maharashtra is coming up with an International Biotech Park at Hinjawadi in Pune, a joint venture between Maharashtra Industrial Development Corporation (MIDC) and The TCG Real Estate and the Agri-Biotech Park in Jalna.

Andhra Pradesh is one of the first states in the country to kickstart the BT parks strategy. Other states include, Tamil Nadu, Karnataka, Himachal Pradesh, Rajasthan, Uttar Pradesh and Chattisgarh. Recently, the Orissa Government commissioned a state-of-the-art Biotech Pharma IT Park, spread over 64.86 acres, at Mouza-Andharua, Bhubaneswar on a public-private partnership (PPP) mode.

The park, the first-of-its-kind in Orissa envisages promotion of biotech, pharmaceuticals and IT industries in the state. The state government has recently selected Bharat Biotech International as the 'developer' for this prestigious project.

## Industry consolidation

*The industry gradually moved towards consolidation with an upswing in mega mergers, alliances and acquisitions*

The industry witnessed landmark convergence between pharmaceutical and biotech companies, not just globally, but even in India, thus paving the way for consolidation in the domain. A convergence between the pharma and biotech sector will gradually see both parties leveraging their strengths in drug development, commercialization, discovery and manufacturing capabilities thus delivering innovation and changing the whole landscape of M&A deals.

Globally, Big pharma's acquisition spree started making big news since 2008. In January 2009, Pfizer acquired biotech big-wig Wyeth for $68 billion (Rs 3.12 lakh crore), followed by Roche ending its long drawn hostile battle with Genentech by buying the remaining 44 percent stake, thus acquiring the latter for $46.8 billion. This was followed by Merck's announcement in March 2009 to acquire Schering Plough for $41.1 billion (Rs 1.88 lakh crore). Other big deals include: Eli Lilly's purchase of ImClone Systems last year, Japanese giant, Takeda Pharmaceutical's acquisition of Millennium Pharmaceuticals and Cephalon's takeover of Australia's Arana Therapeutics.

But the highlight was big pharma's growing interest in Indian companies. The landmark pharma-biotech deal being Sanofi-Shantha Biotechnics deal last year. Sanofi's vaccine's division, Sanofi-Pasteur, announced that it will pay â‚¬550 million (Rs 3,602 crore) for the Indian company. The former acquired ShanH, French subsidiary of Merieux Alliance, which holds a majority stake in Hyderabad-based Shantha. Similarly, Pfizer entered into an agreement with Aurobindo Pharma wherein the former acquired rights to 39 generic solid oral dose products in the US and 20 in Europe, plus an additional 11 in France. In a similar way, Pfizer also inked alliance deals with Ahemdabad-based Claris Life Sciences and Kolkata-based TCG Life Sciences. In a similar way, GSK and Dr Reddys' Labs entered into a marketing deal.

## First human genome sequencing in India

*A unique achievement in the field of science, the breakthrough paves the way for affordable healthcare and predictive medicine*

In December 2009, The Council of Scientific and Industrial Research (CSIR), India completed first ever human genome sequencing in India. With this achievement, the nation entered the league of select few countries like the US, China, Canada, UK, and Korea that have demonstrated the capability to sequence and assemble complete human genomes. This feat was unique in the sense that it was by a team of very young scientists. They finished the complete sequencing and assembling in much shorter time when compared to similar efforts elsewhere.

The sequencing of the first human genome in India in conjunction with Indian Genome Variation program opens newer vistas for low-cost affordable healthcare and predictive medicine in future for the masses. This also opens up newer possibilities in disease diagnostics, treatment and sustaining low-cost drugs in the market.