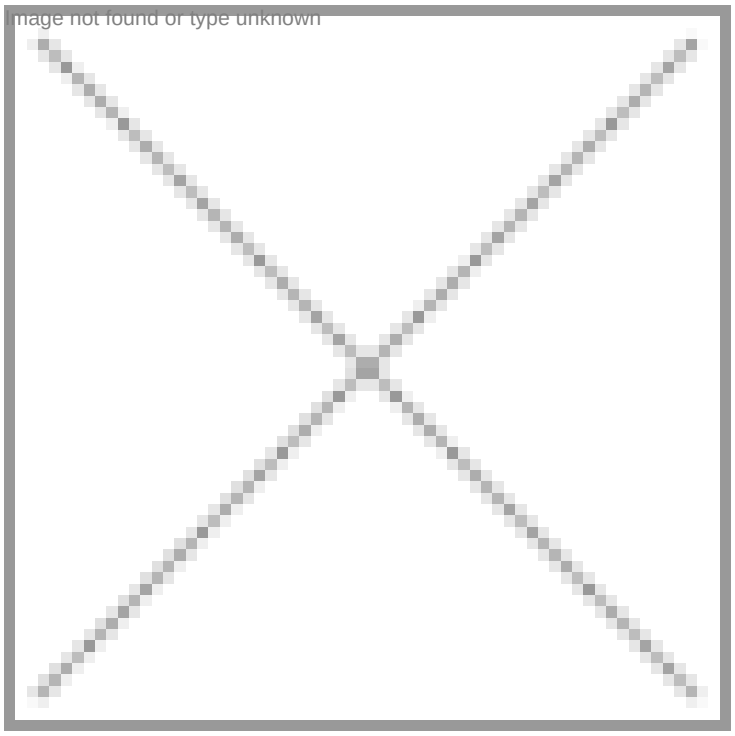
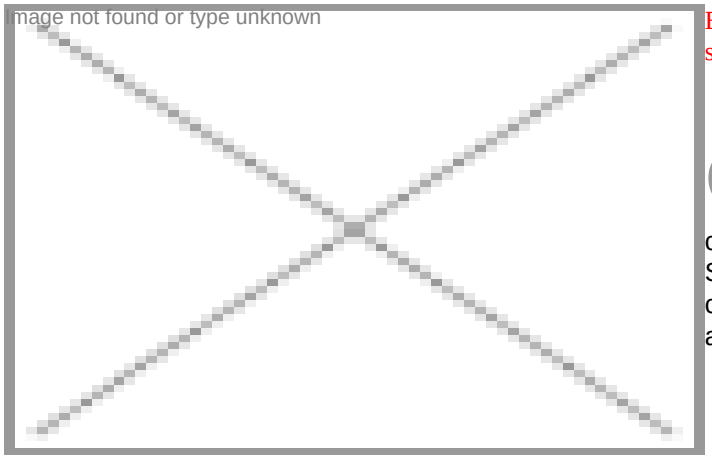
BioSpectrum the business of Bio & Health Sciences

Vaccine research laps up Indo-US deals

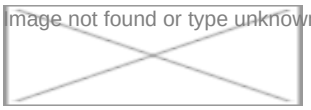
13 February 2012 | News





Both India and the US are making collaborative efforts in life sciences. The vaccine sector has particularly benefited from the

Over the past five years, a significant number of joint R&D projects have been inked between India and the US in the vaccine segment. One of the most recent such collaboration has been signed between Indian vaccine major, Serum Institute of India, and US vaccine giant Merck. The collaboration, which was inked in August 2011, will help develop and commercialize pneumococcal conjugate vaccine (PCV) for



While the governments have been proactive in forging long-term deals, such as joint R&D projects, human resource development, exchange of visits, joint workshops and academia-industry interaction, biotech companies from both countries have also made efforts at their level. Apart from Serum Institute of India, Biocon, Bharat Biotech and Shantha Biotechnics have entered into alliances and partnership with US companies or organizations in areas such as vaccines and biopharma.

While India has received continued help from the US in various domains of science and technology, there are several advantages that India has to offer to the US. The factors that favor India include its large pool of skilled and cost competitive

manpower, advanced chemical synthesis technologies, manufacturing practices conforming to the US and EU norms, and global recognition as producer of low cost, high quality bulk drugs and formulations. Also, the well developed, integrated scientific infrastructure offers major benefits.

Dr Rajesh Jain, joint managing director, Panacea Biotec and president, Committee on Biotechnology, who was recently part of the India pavilion at BIO, says, â€œDuring my interaction with the prominent people there, I must say that they gave tremendous response and respect to the Indian industry. They rate Indian science is at a high pedestal.â€?

Also, the present slowdown in the US economy has opened a world of opportunities for Indian companies, mostly in terms of collaborations and alliances. Companies in the West are cutting down R&D budgets and, hence, will look at emerging nations such as India to outsource their R&D

Speaking on the collaboration with Serum Institute, Ms Julie L Gerberding, president, Merck Vaccines, says, â€œExpanding vaccine access to emerging and developing markets is top priority and we feel strongly that this collaboration will be a giant step towards impacting the devastation of

Merck and Serum Institute will form a product advisory committee to oversee the activities required to develop and seek approval for PCV, and pursue the World Health Organization's (WHO) pre-qualification. Under the terms of the agreement, Merck, through an affiliate, will receive specific rights to market PCV in certain designated territories and Serum will receive specific rights in other territories. Both companies will contribute to the development and

Another vaccine major from India, Bharat Biotech, has entered into a public-private collaboration for development of its rotavirus vaccine, Rotavac, in collaboration with the Department of Biotechnology, Government of India; Bill and Melinda Gates Foundation; Programme for Appropriate Technologies in Health; Centers for Disease Control, US; National Institutes of Health, US; NIAID, US; Society for Applied Studies; Translational Health Sciences Technology Institute; the Indian Institute of Science, India; the All India Institute of Medical Sciences (AIIMS), India; and Stanford University,

The vaccine is priced at around 50 ($1) and India licensure is expected in 2014, while WHO pre-qualification is expected in 2015 for supply to UN agencies. It is currently undergoing phase III clinical development for safety and efficacy in 10,000 subjects, one of the largest such clinical trial

Past, present, future

Indo-US collaborations in science and technology (S&T) go back to the 1950s when scientists from both countries inked joint R&D deals in areas of agricultural research. By 1960s and 1970s, there was an augmentation of S&T collaborations, when American scientists joined hands with premier institutes in India such as the Indian Institute of Technology (IIT) and the National Council of Education, Research and Training (NCERT), New Delhi. This subsequently led to the establishment of the Joint S&T Sub-Commission in 1974.

A US-India Fund (USIF) was established in January 1987 with funding of 217 crore, which supported more than 50 workshops and 300 research projects in science and technology over a period of 11 years.

Partnerships between the two countries have been an ongoing process. On October 17, 2005, an agreement was signed following which India's Prime Minister Dr Manmohan Singh and former US President Mr George Bush agreed to set up a bi-national S&T commission. This would build upon the bilateral agreement on science and technology signed in October 2005, and provide a framework for a vigorous public-private partnership. The commission would have an open architecture and encompass existing and ongoing bilateral programs that included DST-NSF program of co-operation, an Indo-US S&T forum, an Indo-US collaborative program in nano-technology and an Indo-US vaccine action program.

Major Indo-US collaborations

- MoU on November 7, 2002, between Biotechnology Industry Organization, Pharmaceutical Research and Manufacturers of America, the US-India Business Council, and the Confederation of Indian Industries to establish the US-India biotechnology alliance with an objective to promote cooperation between businesses in India and the US in the area of biotechnology.

Bharat Biotech has also invested 200 crore (~250 crore in clinical trials. The Hyderabad-based company, which clocked an annual turnover of 298.34 crore in FY 2010-11 (BioSpectrum-ABLE Top 20 survey 2011) also has a collaboration for its malaria vaccines with the International Center for Genetic Engineering and Biotechnology (ICGEB), New Delhi; PATH, US; Global Alliance for Vaccine Initiative, US; and Malaria Vaccine Initiative, US.

On similar lines, Shantha Biotechnics has had a collaborative deal with PATH and the US National Institute of Health (NIH) since 2007 for the development of a rotavirus vaccine. The technology in this case has been licensed from the NIH. Also, animal vaccine major Indian Immunologicals (IIL) has a spree of collaborations with institutes in the US, including those with the Harvard Medical School, US, for the development of polysaccharide vaccines and with Veterinary Technologies Corporation, US, for brucellosis vaccine. It also has a partnership with the Center for Disease Control (CDC), US, for hepatitis A and rabies.

Philanthropic organizations such as the Bill and Melinda Gates Foundation have also been instrumental in forging joint research collaborative deals between the two countries in the recent years, especially in the area of vaccines. They urged the stakeholders to intensify progress on vaccinating the population, especially children. During their visit in March 2011, Dr Bill and Ms Melinda Gates announced grants to fund late-stage clinical trials to Pune-based Serum Institute of India and Hyderabad-based Bharat Biotech for pneumonia and rotavirus vaccines. The foundation is expected to grant around $30 million for late-stage clinical trials of rotavirus vaccines.

In 2009, Syngene International, a subsidiary of Indian biotechnology major Biocon, and Bristol-Myers Squibb (BMS) opened a dedicated R&D facility for the latter at the Biocon Park in Bangalore. The 200,000 square-feet facility is dedicated to augmenting BMS's work in discovery and early drug development. Work at the facility spans drug discovery and development process from initial hit to lead optimization, early pharmaceutical development and clinical nomination to phase I and II clinical studies.

Panacea Biotec also has an in-licensing arrangement with the National Institute of Health, US, for use of a peptide-based product for generation of hair follicles and hair growth. Another company, Transgene Biotek is co-developing cancer drugs based on siRNA with an US-based company.

- Co-operation in nanotechnology: In June 2005, an agreement was signed to establish a co-operative research program in the field of nano-technology between Rutgers University, the International Advanced Research Center (IARC) at Hyderabad, and the NEI Corporation, which is a Rutgers spin-off company in New Jersey.
- Indo-US science and technology (S&T) umbrella agreement on October 17, 2005, with special emphasis on sharing of intellectual property rights.
- Establishment of Indo-US bi-national S&T commission in 2006 for fostering R&D and scientific exchanges between universities and research institutions.
- Indo-US co-operation on emerging and re-emerging infectious diseases and disease surveillance to study TB, malaria, avian influenza, nipah virus and severe acute respiratory syndrome.
- US-India HIV/AIDS private sector corporate initiative: Following on India's recent scale up of resources and renewed political commitment to fight HIV/AIDS, the former US President, Mr George Bush, announced an additional US contribution of around 35 crore ($7 million) to expand resources available to fight HIV/AIDS in India.
- Indo-US vaccine action programme with priority areas, including viral hepatitis, typhoid, E. coli, rotaviral diarrhoea, acute respiratory infections, tuberculosis, leishmaniasis, malaria and HIV.

(Courtesy Embassy of India, Washington DC)

Industry bodies in proactive mode

A number of associations are playing a significant role in attracting global attention to the Indian biotech industry. They include the Confederation of Indian Industries (CII), Federation of Indian Chambers of Commerce and Industry (FICCI), the Associated Chambers of Commerce and Industry of India (ASSOCHAM) and Association of Biotechnology Led Enterprises (ABLE). These associations have been organizing various events focused on promoting Indo-US collaborations in biotechnology.

The bilateral Indo-US Science and Technology Forum (IUSSTF) has been working with government departments, such as the Department of Science and Technology, Department of Biotechnology and US Department of Energy, along with industry associations to effectively bring together government agencies, corporate houses and industry associations and the academia of both the countries.

FICCI's Center for Technology Commercialization (CTC) has assisted more than 150 innovators to provide a platform to showcase their creativity on a local and global level and helped them generate revenue worth 350 crore (DST-Lockheed Martin India Innovation Growth Programme). The CTC also played an instrumental role in commercializing about 30 Defense Research and Development Organization (DRDO) technologies, and talks are on for about six more DRDO technologies. FICCI also signed a memorandum of understanding with the Maryland Department of Business and Economic Development.

The CII sent its 10th Biotechnology Mission to BIO 2011, which was organized at Washington DC from June 27 -30, 2011. The 50 delegates visited prominent life sciences institutions, such as the NIH, Johns Hopkins University and the University of

Maryland, where they got opportunity to interact with eminent scientists and leaders. The CII mission members also had interactions with budding entrepreneurs in a special program designed for one-to-one interactions called BioBiz. The CII also promoted the advancements of the Indian biotechnological panorama through the India pavilion at BIO 2011 in association with ABLE and facilitated by the DBT.

â€œFICCI is playing a great role to promote Indo-US collaborations in the area of biotechnology because more than 80 percent of the merger and acquisition investments were seen in the five major sectors,â€? concludes Mr Arnab Kumar Hazra, director, biotechnology, FICCI.

Nayantara Som in Mumbai
(with Rahul Koul in New Delhi and Manasi Vaidya in Bangalore)