

CII predicts \$1500 M biotech industry by 2007

12 February 2004 | News



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The Biotech Committee of Confederation of Indian Industries (CII) strongly predicts the Indian biotech industry to be worth \$750 million by 2005, though the same in 2002 was \$150 million only. The industry would reach \$1,500 million by the end of 2007, the report said.

Raising the challenges ahead of BT industry in India, CII mentioned in its report that upgradation of toxicological labs, GMP certified facilities, import of animals for testing, and incentives for clinical research are desperately required. "Venture capital and investment, regulatory issues and mapping human resource requirementâ€"synergy between industry's needs and government's efforts are some areas that needs to be upgraded," urged Dr Sandhya Tewari, head, National Committee of Biotechnology, CII. She also suggested, that for the betterment of the growth rate in this area, the infrastructure needs have to be looked upon.

Biotech tools handy for pharma: Joshi

According to the Union HRD and science and technology minister, Dr Murli Manohar Joshi the Indian market would be soon flooded by a large number of new drugs and vaccines. "Some of them are in final phase for their clearance by regulatory authorities," the minister informed. Dr Joshi was addressing a gathering of captains and representatives of biotech industry in New Delhi. The biotechnology coupled with information technology is the new destination for industrial development with unlimited opportunities in this century, said Dr Joshi. He urged young entrepreneurs and researchers to venture into the field

of biotech sector for their growth as well as welfare of the society. Dr Joshi said the centre's liberalized policy has boosted R&D, facilitating the growth of knowledge-based industry such as drugs and pharmaceuticals, IT, and BT. He also underlined the need to take into account controversial issues like genetic engineering.

India, Malaysia getting closer

CII and The Malacca Indian Chamber of Commerce & Industry (MICCI), Malaysia have tied up to promote Malacca and India as ideal investment destinations for their business community. The MoU was signed to tap the tremendous potential existing in biotechnology, pharmaceuticals, infrastructure and information technology sectors.

Seed manufacturers will have to register their seeds

Very soon the Government of India will come up with the seed law amendment bill, which will make mandatory for the seed manufacturers to register their seeds under the seed law. This was disclosed by the Union agriculture secretary, RCA Jain, who is part of the Task Force constituted by the Ministry of Agriculture, Government of India, to develop a forward looking policy of agricultural biotechnology in India.



The Task Force headed by Prof. MS Swaminathan had met in Chennai for its last series of consultation where it interacted with the media to get their opinion and integrate them in a proposed policy. RCA Jain was responding to the existence of fake seeds in the market, like the illegal BT cottonseed, being manufactured by Gujarat based local company. Even though the hybrids used by this company are not

approved by GEAC (Genetic Engineering Approval Committee), illegal seeds have been sold in large quantities. "As per the new seed law, manufacturers will have to register their seeds. Even if the company gets authorization by GEAC, they have to get certification under the Seed Law," remarked Jain.

In yet another move, the government has plans to start 96 FM (Frequency Modulation) radio stations in the rural villages to spread the awareness on new technologies in agriculture and on Genetically Modified (GM) seeds and crops.

The task force with Prof. Swaminathan as the Chairman has representatives from Biotechnology, Environment, Health and Commerce, Secretaries Agriculture, as well as eminent biotechnologist in India. "The bottomline of this Task Force is how to use new tools of genetics in an environmentally safe way to contribute to the sustainability of agricultural productivity in future," said Prof Swaminathan.

The committee has set up five sub-groupsâ€"VC Chopra Committee, RCA Jain Committee, Mangla Roy Committee, Manju Sharma Committee and Dr Amita Patel Committee. The five committees will soon be submitting their reports and it is expected that the final report will be submitted in a month's time.

East Germany is India's biotech gateway to Europe

Lower wages, liberal labor laws and availability of skilled and trained personnel are the major plus points for Eastern Germany, a future destination for all biotechnology and manufacturing companies. Speaking at the "Eastern Germany: a gateway to Europe for Indian companies" at the 10th Partnership Summit, organized by CC, Horst Dietz, the president of the International Investment Council, Germany contended that East Germany has offered unique opportunities for biotech companies. Already over 300 life sciences related companies had taken roots in the region. They specialized in medical designs, tissue culturing, bioinformatics and protein technologies. Most of the Indian life science companies were looking at East Germany as their future destination for expansion.

"The famous Chemical Triangle in Germany was well known the world over for its quality research and production. Seventytwo universities and teaching schools in the region rich with R&D facilities also provided a healthy labor management environment," he said and added that the most significant financial incentive offered was 35 percent grant against investment in Eastern Germany by any investor. In the last 10 years, 2000 companies from 40 countries have located their manufacturing units in Eastern Germany.

India needs 50,000 professionals

Indian contract or research services segment has a potential of harnessing 50,000 professionals per annum over the next five years with a revenue realization to the tune of \$5 billion per annum, said Kiran Mazumdar Shaw, chairperson of Confederation of Indian Industry's National Task Force on Biotechnology. At present only 15,000 bio-scientistsare engaged mage not found or type unim the biotech sector.



The R&D outsourcing market in pharmaceuticals and biotechnology is expected to grow to \$18 billion in the next three years. Shaw noted that factors like pressure on big pharma to increase development capacity without increasing fixed costs, continuing time-to-market pressures and superior performance on time and quality by CROs will drive the outsourcing market in India. India currently has three million graduates, 700,000 postgraduates and 1500 Ph Ds qualify in the biosciences each year. "A research services model therefore has the potential of gainfully employing this valuable scientific human resource and generating revenues equivalent to \$100,000 per scientist, " she said.

Singapore seeks Indian hand

Indian industry looks at Singapore for ventures capitalists. Singapore looks for joint ventures with Indian companies in healthcare, biotech, medicine, research and development, which are striving towards success. The visiting health and transport minister of Singapore Balaji Sadasivan to India stated this. Balaji Sadasivan indicated at the CII Partnership Summit in Hyderabad that India has reached commanding heights in a multitude of fields and it is about time that India and Singapore integrate to form the unparalleled biomedical-healthcare collaboration in the world.

"Singapore is undergoing its 6th phase of development, which is driven by the knowledge industry. Today Singapore receives nearly two hundred thousand medical tourists annually. However, it aims to receive almost a million of them every year, considering the fact that ASEAN itself is home to 500 million people. Singapore can achieve these objectives very fast if it partners with India and the prior Singaporean experience proves the same," Sadasivan added.

Sanmar's biotech arm: Bangalore Genei

The future of biotech initiatives of the Chennai-based Sanmar Speciality Chemicals Ltd, which recently acquired Bangalore Genei Pvt Ltd, will depend of the growth of latter. MS Sekhar, managing director, Sanmar Speciality Chemicals Ltd said, "Our future plans in biotechnology will be driven by the growth plans of Bangalore Genei and their execution. The future plans are to penetrate into international markets as well as to develop new products and expand the contract research business. This will obviously call for additions to staff and investments in labs, for which we are adequately prepared. "

Now it's the turn of DNA parks

We have Information Technology parks. Biotechnology parks are coming up. Now it is the turn of the combination of twoâ€"Bio-IT parks, called DNA/Bioinformatics Park. The proposed DNA/Bioinformatics Park is an initiative of the Department of Information Technology (DIT) and ministry of communication and information technology (MCIT) to facilitate the export of Bio-IT solutions and attract foreign direct investment in the field of information technology and health sciences.

"In India the Bio-IT market is pegged at \$15 million, which is poised to grow to \$120 million by 2006 against the total global market size of \$25 billion that is growing at 20 percent annually," said Kamalkant Jaiswal, IT secretary, government of India. Addressing a gathering at "Pune's potential to be the knowledge capital of India" organized by TiE chapter of Pune, he said, "The government has already engaged a team of global consultants to identify the nature and scope of infrastructure and services that such a park could offer to its users/tenants. The consultants will advise the government on the adoption of global best practices and methodologies with respect to such initiatives and partner the government in identifying a suitable partner for public private development of the park. "

CDISC to set up India chapter

Clinical Data Interchange Standards Consortium (CDISC), USA, a non-profit organization committed to the development of clinical research organizations' standards world over is looking at setting up its chapter in India.

Dr Chandresh Shah, director, business development and pharma practice, CDISC, who was in Pune to participate in a convention on clinical data management informed BioSpectrum that discussions are on. And coordinating committee for setting up the Indian chapter has been initiated. "It will take some time. But I am hopeful of an Indian chapter of CDISC in near future."

CDISC is an open, multidisciplinary, organization committed to the development of industry standards to support the electronic acquisition, exchange, submission and archiving of clinical trials data and metadata for medical and biopharmaceutical product development. The mission of CDISC is to lead the development of global, vendor-neutral, platform independent standards to improve data quality and accelerate product development in the industry.

Synchron has 36 bed facility

Synchron Research Services Pvt Ltd, an Ahmedabad-based clinical research organization started as a small company by a group of pharmaceutical professionals in 1998, has the facilities for 36 beds with adequate recreation and dining facilities to participating volunteers. Shruti Shukla, senior manager, business development, Synchron said that the organization has been functioning with a set of detailed Standard Operating Procedures for all phase I-IV clinical trials and data management activities. Data management operations are completely validated as per the regulatory requirements. Having its own bioequivalence center in Ahmedabad, she said Synchron has tied up with Nizam's Institute of Medical Sciences, Hyderabad for conducting Phase I studies. Synchron has conducted more than 150 biostudies mainly for European and USA clients.

Synchron is conducting phase III clinical studies of Covance in India, which are part of global trials. The company has set up state-of-art facilities at Bangalore, which looks after phase II to phase IV clinical studies, including Data Management and is fully equipped with necessary hardware and software including SAS, Dell Servers, Computer Systems.

ACE offers CRO course

For the first time the Academy for Clinical Excellence (ACE) is conducting a diploma course for professionals in clinical research. The courses will be conducted only on Sundays. And will run till August starting from February.

Samyukta Ajay, director, ACE informed that the course is open for graduates in medicine, pharmacy, microbiology or any other science stream. The syllabus comprises six modules and a dissertation that will have to be completed over one year. The program on diploma has been developed and will be delivered by eminent clinical research professionals from pharmaceutical industries, CROs and academia.

"We have also undertaken tailor made programs for three companies. Besides organizing courses at Mumbai we do conducted courses at Hyderabad and Ahmedabad. For basic courses the intake will be 60 and for advanced courses we stick to only 40," said Samyukta Ajay and added that due to traveling assignments in the clinical research, people might be opting for clinical data management.

Thermo Electron grows

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Thermo Electron LLS India Pvt Ltd has increased the turnover of its Bioscience Technologies Division to Rs 24.96 crore from

the last year's revenue of Rs.16.45 crore. Ajit Tamhane, director, sales and marketing, bioscience technologies, Thermo Electron LLS India Pvt Ltd, informed that during the year ended December 2003 the company sold 80 Microplate systems in Yemen, Saudi Arabia and Bangladesh.

Briefing about the achievements of Thermo Electron LLS India in 2003, Tamhane said "We started offering a unique facility called customs bounded warehousing for instruments, to help us to supply the equipments to our customers in the scientific and clinical sector within 48 hours of receiving the order." Explaining about the strategy for the year Virendra Tipnis, managing director, said "After completion of warranty, Thermo Electron will be commencing a major maintenance contract with the second National AIDS Control Program to maintain 500 ELISA systems. We are committed to support all our customers not just for sales but most importantly excellent after sales support and this has developed confidence about Thermo's brand in them."

C3i launches India operations

New York-based C3i Inc announced the launch of its global operations center in Hyderabad. A service provider for customer management consulting, integration and ongoing support services to the life sciences industry, this is the company's first facility outside US.

Set-up in a record time of three-and-a-half months, according to Joel Morse, CEO and Co-founder of C3i, good technical infrastructure and skilled labor pool available in Hyderabad made C3i choose Hyderabad over competing locations in Phillipines and Canada. "Our Hyderabad operations offer a great competitive advantage with a 24-hour support capability," said Michael Jakubiak, the company's global implementation director. He was elaborating on the cost advantage and the strategic decision to locate to Hyderabad. The BPO center set up essentially to support the sales force of its clients will start with Roche in India.

In Vanenburg IT Park, the company has a 99-seater facility with the first batch of 50 analysts under training. "We will scale up pretty fast," informed Morse. According to him, with multi-million dollar deals in the next 18 month pipeline the company will increase its revenues by at least 50 per cent. And that's just half the story. "Re-engineering of existing C3i business will see hundreds of jobs moving to Hyderabad from other three C3i locations in New York and New Jersey," he said adding that by December 2004 C3i will be employing 300 people in India. The company currently has 500 people on its roll worldwide and delivers end-to-end seamless solution to over 30 pharmaceutical, biotechnology and products companies in North America. At its India center, along with handling the inbound calls the team will also assist in implementing the Siebel solutions for its new customers.

Foundation laid for biotech incubator in Hyderabad

Dr Murli Manohar Joshi, union minister for HRD, S&T and Ocean Development, laid the foundation stone for India's first biotechnology incubator in Hyderabad. Andhra Pradesh Chief Minister N Chandrababu Naidu, B Gopalakrishna Reddy, minister for SSI and biotechnology, Andhra Pradesh and Dr (Mrs) Manju Sharma, secretary, DBT, were present on the occasion. Dr Joshi remarked that Hyderabad was emerging as "incubator for incubators".



Encouraged by the potential for growth of biotechnology based industries in Andhra Pradesh, DBT, the department of industries and commerce (Andhra Pradesh) and the Council of Scientific & Industrial Research (CSIR) have entered a strategic linkage to set-up a biotechnology incubator at Shapoorji Pallonji Biotech Park with an investment of Rs 23 crore. The incubator is expected to be fully operational within two years. The Indian Institute of Chemical Technology, Hyderabad would be establishing and commissioning the incubator. It will also source technologies from various national laboratories and other academic institutions.

There are more than 25 biotechnology incubators in the world with USA, Canada, France, Germany, China, Japan and other European countries making effective use technology incubation concept. India has also entered this concept and the biotech

incubator being located in SP Biotech Park will serve as an example for more such incubators in the future. "There is urgent need to set up biotech incubation centers in the country and the Genome Valley Biotech Incubation Center bridges this critical gap in the essential infrastructure for the growth and development of biotech sector," informed Naidu.

Magene launches biotech learning programs …

Hyderabad-based Magene Life Sciences Pvt Ltd launched an integrated, inter-disciplinary, corporate learning programme in biotechnology with the first batch from Sartorius India Pvt Ltd. "The basic course designed to include hands-on-training, GLP, and introduction to modern biotechnology aims for a holistic approach to biotechnology. A module has been designed to cover the basic tenets of the related areas like microbiology, cell biology, genetics, biochemistry, molecular biology, immunology, bioprocess engineering and tissue culture," said Gita Sharma, director & CSO of Magene Life Sciences Pvt Ltd.

The course costs anywhere between Rs 30,000 to Rs 50,000 per head and forms a part of the survival strategy for the company.

Magene is aiming to make its mark in the niche bioservices sector. It offers testing services for the companies, which have developed new molecules. With the lab capacity of testing 96 molecules at a time the company is focusing on generic protein therapeutics. "We have already developed two molecules to the pilot stage and will be taking them to pre-clinical trials in March this year subject to regulatory approvals," said Sharma. The product catering to cancer patients is likely to be launched in mid 2005.

â€l to ink deals with three major drug companies

According to Sharma, at least 30 odd products will be off patent in 2005 and the company is gearing up for developing a majority of these molecules. "By February, the company is likely to announce the closure of agreements with three major Indian drug companies for testing their molecules," said Sharma stating that Magene is in the final stages of negotiation. She added that the company will also be doing similar work for two US and one German company and in the event some IP is generated it will share the IPR with the outsourcing company.

With customer acquisition in the final phases the promoters expect Magene to recover the investment of Rs 7 crore in its very first year of operation. However, the scaling up plan is underway requiring the doubling of existing investments, informed MP Chary, Magene Chairman. Chary is the angel promoter of the company.

The company with the current manpower base of 26 scientists will also work in the area of new drug discovery.

Dr Reddy's organizes international symposium

Dr RA Mashelkar, director general, CSIR, inaugurated Pharmacophore 2004, an international symposium on the theme "Innovating Drugs: Emerging Perspectives". Pharmacophore 2004 was organized by Dr Reddy's Research Foundation (DRF) and sponsored by Dr Reddy's Laboratories. Over two hundred eminent scientists from across the scientific community of India attended the symposium to share ideas of mutual interest and to inspire young scientists and others in the Indian pharmaceutical industry to take to pharmaceutical drug discovery and research.

Pharmacophore 2004 attended by about 150 delegates had a range of presentations on various issues in drug discovery. In his inaugural address, Mashelkar gave a hint of things to come. "Drug and pharma industry in India is set for restructuring," he said elaborating that it will be forward engineering that will work for the industry and not the reverse engineering as it worked in past. Mashelkar informed that they have submitted a report to the government for a new regulatory authority and it won't be long before it comes into existence. He called for patent literacy and said a scientific approach with good legal systems can help elevate the status of India in the global pharmaceuticals market and contain the problem of spurious drugs. "The bottomline is people should get quality medicines," he said.

The Lab Water Division of Millipore India Pvt Ltd had the unique distinction of rolling out its 1,000th WaterPurification System

(WPS) from its manufacturing facilities in Bangalore. The 1000th WPS is an Elix 10 UV model and will be installed by one of the leading pharma companies based in Hyderabad.

The WPS range from Millipore Corp., the leaders in membrane and filtration tech-nology, finds diverse applications in the pharmaceutical, R&D, biotechnology, clinical and educational segments. Applications range from HPLC, GC-MS, PCR, 2D Electrophoresis, and ICPMS to sample preparation, equipment feed and glassware rinsing. The need for ultra pure water is critical in such applications as impurities in water can distort research results and QA/QC analysis in pharma companies. While 1,000 WPS have been rolled out from Millipore India's production facilities, the installed base is over 3,000 systems in



India. Globally, its Elix and Milli-Q range of WPS have been installed across 300,000 labs. Millipore claims that its A10 version can remove impurities and total organic carbon contaminants to less than 5 particles per billion (ppb).

Scientists develop oxalic acid-free tomatoes

After creating protein-rich potato, It's time for tomatoes. A team of scientists has succeeded in producing tomatoes, which are free of oxalic acid, a compound that causes kidney stones at National Center for Plant Genome Research (NCPGR) New Delhi.

Informing about the technology, Dr Shubra Chakrabarty, of National Center for Plant Genome Research (NCPGR), "The tomato was produced by incorporating a gene from an edible mushroom into the plant." She led the research.

The centre has patented the mushroom gene and also plans to use the same technology to create "kesari" dal, which will be free of neurotoxin that causes nervous system disease in people who consume this dal, she said. Human beings cannot degrade oxalic acid present in many plants like tomatoes, spinach, groundnut and soybean. Oxalic acid reacts with calcium in the body and gets accumulated in the kidney causing stones, Chakrabarty said a session on the research work of young women scientists.

The team isolated a gene "Oxalate Decarboxylase" from edible mushroom and transferred it to tomatoes, leading to production of oxalic acid free plants. The trials have been carried out for about three years and the team planned to present the proposal for its commercialization to regulatory bodies in about one year, Chakraborty said.

Dabur's anti-cancer drug goes into Phase 2

Dabur Pharma is all set to embark Phase 2 clinical trials on its peptide-based anti-cancer molecule DRF 7295. The company recently got the approval of the Drug Controller-General of India for conducting the trials. As per the company's experience with this molecule in first phase of clinical trials, the results have been encouraging. And the company is targeting to complete the phase 2 trials within 12-24 months.

Dabur has also completed the phase 1 trials on its new drug delivery system (NDDS) for Paclitaxel, an anti-cancer drug. The trial results regarding Paclitaxel nano particles have shown that the NDDS has good efficacy and safety profiles. Dabur is open to licensing the inventions out for further development and commercialization. Some leading pharma MNCs have shown primary interest in these candidate drugs. The company, however, is likely to defer licensing deals until the phase 2 trials are over, as it reckons that value addition in research would help it clinch more remunerative deals.

Dr Reddys gears up for its Oncology product

Dr Reddys Laboratories is gearing up to bring out its oncology product. According to Dr Uday Saxena, the company's Chief Scientific Officer its Oncology product DRF 1042 is in pre-clinical trials and the results of animal-testing are very promising. Saxena was speaking on the sidelines of Pharmacophore 2004 symposium (January16-17, 2004) the two-day event

organized to celebrate the 10th year of Dr Reddy's Foundation.

Saxena informed that the company's R&D spending has increased to Rs 165 crore against a mere Rs 6.5 crore as research budget in 1993 when the discovery research programme was initiated."

NRCC picks Ocimum's Biotracker

Ocimum Biosolutions announced that National Research Council of Canada (NRCC) has chosen Biotracker as its Lab Information Management System (LIMS) for their DNA sequencing facility at Halifax. Ocimum's CEO, Anuradha Acharya commented, "This sale represents an affirmation of Biotracker as one of the leading LIMS solutions in the world for the Pharmaceutical and Life Sciences community." NRCC is Government of Canada's premier organization for research and development. The IMB lab in Halifax where the solution will be deployed houses the most active DNA sequencing facility in Canada, with a steadily increasing capacity to generate and analyze sequence data.

Biotracker is a multi-platform GLP compliant LIMS for the biotechnology and pharmaceutical industries. The software enables life sciences and pharmaceutical labs to keep an accurate track of samples, reagents, instruments, processes and output from the time these samples or resources are acquired right through to the final stage of research.