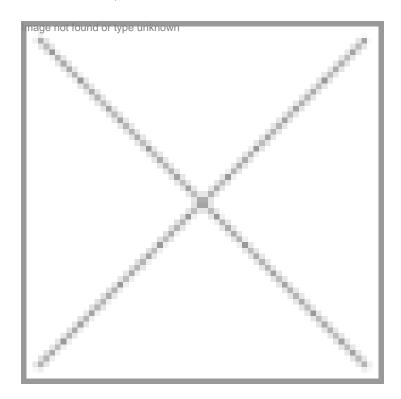


# FICCI picks 8 areas for BT tie-ups with China

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Collaborative R&D, speeding up of pre-clinical study, bioinformatics/chemi-informatics, free flow of biological materials, preferential incentives, exchange and technology transfer and human resource development are the major areas where Chinese and Indian biotech companies could collaborate for mutual benefit.

These potential areas of tie-up between Indian and Chinese biotech companies have been identified by a 13-member FICCI biotech mission to Beijing, Shanghai, Tianjin and Nanchang, led by Dr Krishna M Ella, chairman, FICCI National Biotechnology Committee, and CMD, Bharat Biotech International Ltd.

The FICCI Biotech

delegation ve Raina.

Chinese companies can outsource new drug discovery to India, whereas further drug development and pre-clinical studies can take place in China and India simultaneously. This would enable both countries to come together to become global suppliers of Innovation Based Drugs (India's costs are 1/8th and China's 1/5th compared with the cost incurred by the US.) China can help India in vaccine development, gene therapy and stem cell research as they are much ahead.

### Faster pace of pre-clinical study

In-vivo studies at the preliminary level would be faster in China as there are no ethical or long procedural issues for animal

experimentation in that country. Also, the animals for experiments can be obtained from China's national resource centers such as the one at Nanching University.

#### Bioinformatics/chemi-informatics

Data management expertise of India can be well utilized by Chinese biotech and pharmaceuticals players in order to get their labs GMP and GLP complaint.

#### Free flow of biological materials

There can be a free flow movement of biological materials, which include microorganisms and animals such as different strains of mice between two countries. If drugs are developed as a collaborated effort between India and China, these can be exported together to highly regulated markets such as the US, the UK and Australia. India can help export Chinese biotech products to these markets and China can help India export drugs/vaccines to China by collaborating at a research level for speedy approval from SFDA.

### Benefit of preferential incentives

Indian companies can take benefit of preferential incentives offered by SEZs to set up representative offices at some of the provinces such as Nanjing and Tianjin so that SFDA approval can be easily obtained.

### Exchange and technology transfer

There is scope for exchange and technology transfer of off-patented technologies to India, which have yet not been commercialized in China, and this may have a huge scope in the Indian market.

### Human resource development

Education in field of life sciences, biotechnology and clinical research (exchange program of scientists) in creating a total skill set has been identified as a potential area for collaboration. This is because India is good at GLP/GMP and data management whereas China has expertise in technology development and commercialization.

# **ABLE opens regional chapters**

The Association of Biotechnology Led Enterprises (ABLE), a collective face and voice of the Indian Biotechnology industry has decided to open its regional chapters in Hyderabad (South), Mumbai (West) and New Delhi (North) to establish a direct interaction with companies based in these cities.

Dr M Vidyasagar, executive vice president and head of advanced technology centre, Tata Consultancy Services will head the Hyderabad Chapter as hon. regional director. Dr Vidyasagar said, "I am delighted to see that ABLE is making a concerted effort to spread its wings beyond Bangalore, where its head office is currently located. With so many biotech companies in Hyderabad, I am sure we will be able to create a vibrant chapter here."

Alok Gupta, country head - life sciences & technology, YES BANK will head the Mumbai Chapter as hon. regional director. Gupta said, "ABLE is an excellent forum representing India's Biotech environment. In my role as regional director, I hope to showcase Mumbai's inherent strengths in life sciences and biotechnology, and further develop as a robust platform to aid development of the biotechnology industry in India."

Rajesh Jain, joint managing director, Panacea Biotec Ltd will head ABLE's New Delhi Chapter, as hon. regional director. Commenting on his plans for the New Delhi Chapter, Jain said "The Delhi Chapter will strive to further enhance ABLE's vision by offering a platform for establishing tripartite relationship between the industry, the government and academia specially for north India - the three important pillars for developing an economically successful and socially responsible biotech industry in India. The chapter would undertake proactive role in organizing regional, national and international seminars/symposium/workshops/group discussions to address critical issues relating to the growth of biotechnology."

### Matrix signs pact to acquire controlling stake in Mchem Group, China

Matrix Laboratories has announced that the company has entered into a Share Purchase Agreement (SPA) with the promoters of Mchem group, China for the acquisition of controlling stake of about 60 percent in the Mchem group.

The closing of the transaction is expected to be completed by the end of December 2005 and is subject to fulfilment of certain conditions/formalities and obtaining requisite approvals from the regulatory authorities.

The share purchase agreement is in line with the strategic intent and the memorandum of understanding that the company had signed earlier with Mchem to gain access to the comparative advantage that China provides in the sourcing of pharmaceutical chemicals and intermediates, and to establish a cost effective supply chain.

The acquisition of substantial stake in Mchem group will help the company to backward integrate into China for manufacture of intermediates and will help consolidate its position as a major supplier of Active Pharmaceutical Ingredients (APIs), particularly Anti-retrovirals (ARVs), worldwide.

### GangaGen signs pact with Elanco Animal Health

Gangagen Life Sciences (GLSI) has announced the signing of a collaborative research, license and commercialization agreement with Elanco Animal Health to develop anti-bacterial products derived from bacteriophages. Under the terms of the agreement, GLSI and Elanco intend to jointly develop and commercialize phage-based products for the control of dangerous bacteria that pose problems for human and animal health. Financial terms were not disclosed.

"This agreement is of great importance to GLSI, and to the health market in general," said Rainer Engelhardt, chief executive officer of GLSI. "The fact that a global leader such as Elanco has chosen to work with GLSI in the development and marketing of phage-based products as antibacterial treatments is a tremendous validation of our vision and progress, and of phage technology itself."

# ISO recommendation for HCL to manufacture medical electronic products

HCL, a leading global IT enterprise, has been recommended by TUV Germany for the ISO 13485:2003 certification for the manufacture of medical and electronic products. HCL is the first IT enterprise in India to have been recommended for this certification for manufacturing medical electronic devices that endorses compliance with international standards.

Commenting on this recommendation, Pradep Nair, vice president and head, life sciences practice, HCL, New Jersey, US said "An early adoption of the standard will give us an edge in the market. The certification assures our clients of HCL's ability to manage the right process and helps them achieve quantum improvements in all aspects of the life science project lifecycle."

### **BII introduces PG Diploma in Pharma Regulatory Affairs**

Bioinformatics Institute of India has recently introduced an innovative program in Pharma Regulatory Affairs. The course, PG Diploma in Pharma Regulatory Affairs, has been developed to educate professionals about the regulatory issues pertinent to the pharmaceutical and biological industry .The objective is to impart in-depth and latest knowledge required for a successful career in regulatory affairs.

According to Vijay Shukla, director, Bioinformatics Institute of India, "This is a highly specialized and well designed course which promises wonderful career options in the upcoming pharmaceutical industry in India. Pharma Regulatory Affairs professionals also has a very good demand, all over the world."

The program has six modules comprises of Pharma Regulation Practices and Procedure, Pharma Patents, IPR and Regulation, Pharma Regulatory Regime in USA, EU and India, Clinical Trials & Regulation, Good Manufacturing Practices, Quality Assurance and Regulation, Regulatory Compliance for Pharma and Biotech Products.

### ClinInvent implements Oracle Clinical to drive project efficiencies

ClinInvent Research has implemented Oracle Clinical software for faster and more accurate data management. This will help ClinInvent to achieve greater efficiencies and reduce costs of clinical trials. "The implementation of Oracle Clinical is a strategic initiative on our part to leverage our data management team's IT capabilities and to offer our international sponsors high quality data management." said Dr Arun Bhatt, president, ClinInvent Research.

"We decided on Oracle over other competing solutions as Oracle software is not only adopted universally, it is also 21 CFR Part 11 compliant, globally recognized and well supported by easy access to training," he added.

# Indian students participate in UN Convention on Biodiversity

Indian students participated in the negotiations of Model United Nations Convention on Biodiversity held from August 18-20,2005 at Giessen, Germany. As a part of the program "Biotechnology: law and policies in Europe" at Justus Liebig University, Giessen conducted by Hessen International Summer University (Hessen Ministry of Higher Education) DAAD (German Academic Exchange Service), the students discussed issues like access to plant genetic resources and protection of traditional knowledge at international level. There were about 25 participants from 17 countries including three participants from India - Priyank Gupta, Pushpendra Jaiswal and Pratyush Chandan. All of them are doing their B Tech, Biotechnology from Jaypee Institute of Information Technology, Noida, UP. As a part of the program the students also attended a seminar on biotechnology policy issues at European Union's parliament in Brussels, Belgium.