



## **BioIndia News / Updates**

**Free, bi-monthly newsletter for India's BioBusiness, BioScience, Regulatory and Clinical News; tracking news/trends in the India biopharmaceutical/pharmaceutical biologics industry**

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### **BioPlan Publications**

#### **Updated! 2nd Edition! China Top 60 Biopharmaceutical Manufacturing Directory**

New, comprehensive directory, review and analysis of the top biopharmaceutical facilities in China. Rank and profile of facilities are based on current capacity, staffing, commercial and clinical products, and future build-out plans.

The [directory](#) also highlights upcoming facilities, and includes data on key marketed and clinical trial products.

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### **BioBusiness in India**

Glenmark is expanding its biopharma manufacturing facility in Visp, Switzerland, with the addition of a 1,000 L bioreactor, with the facility 70% single-use, and expected to produce 6 batches/lots per year. *Source: BioPharma-Reporter.com; May 12, 2017*

Biocon recently awarded a 3-year contract to supply human insulin formulations for the country's Ministry of Health. The formulations will be made at its Malaysian facility: size of the contract was not disclosed. *Source: In-Pharmatechnologist.com, Jan. 27, 2017*

Aurobindo Pharma Ltd. acquired rights to 4 biosimilar products from TL Biopharmaceutical AG (Switzerland) and plans to construct a related manufacturing facility in Hyderabad. *Source: BioPharma-Reporter.com; Feb. 10, 2017*

Indian Immunological Limited, subsidiary of the National Dairy Development Board, launched Cysvax, a vaccine to combat tapeworms in pigs. An added benefit of the vaccine is its potential to help reduce the incidence of epilepsy in human in India, with untreated cases often resulting in epilepsy. *Source: The Hindu Business Line, Oct. 19, 2016*

COOLPORT, the first perishable air cargo center, opened at Kempegowda International Airport, operated by Air India SATS Airport Services Pvt. Ltd., a 50:50 JV between Air India Limited, and SATS Limited. It is a one-stop-show for temperature-sensitive imports and exports. *Source: Global Trade, Oct. 16, 2016*

Biocon's new \$250 million insulin manufacturing facility in Nusajaya, Malaysia, came online in late 2016. It is the co.'s first biopharma facility outside of India. *Source: FiercePharma, Oct. 21, 2016*

U.S.-based standards/testing organization, Underwriters Labs. increased its partnerships with Pharmexel to assist Indian pharma co.'s with compliance with manufacturing standards. *Source: Pharmabiz.com, Sept. 22, 2016*

Over 30% of Indian pharma co.'s expect to make investments in biopharma manufacturing in the next 3 years, and 38% cited insufficient government support for the industry, according to a survey by CPhI India Pharma Insights. *Source: BioPharma-Reporter.com, Dec. 6, 2016*

Baxter acquired Claris Lifesciences, also a major Indian manufacturer of injectable generic drugs, for \$625M. *Source: FiercePharma, Dec. 19, 2016*

R&D expenditures by Indian pharma co.'s increased 24% from 2015 to 2016, with this about 7.5% of net sales on R&D, according to a study by PharmaBiz. For comparison, the world's largest 15 pharma co.'s average spending 17% of net sales on R&D. *Source: PharmaBiz.com; Oct. 10, 2016*

## **BioScience in India**

National Institute of Immunology launched the world's first leprosy vaccine targeted to the indigenous Indian strain, *Mycobacterium indicus pranii*. It is also being tested as a vaccine against bladder cancer, warts, lung cancer and tuberculosis. *Source: Indian Express, May 9, 2017*

Panacea Biotec launched EasySix, a hexavalent combo vaccine for infants, and the world's first vaccine containing a fully liquid whole cell pertussis vaccine component. *Source: BioVoiceNews, April 10, 2017*

Indian Council of Medical Research halted the ReAnima clinical trial seeking to revive brain-dead accident victims using injections of mesenchymal stem cells and peptides with transcranial laser and median nerve stimulation. *Source: RT; Nov. 16, 2016*

Institute of Microbial Technology reports having developed technology for manufacture of insulin, streptokinase and hepatitis B vaccines, with expectation of reducing their costs by 3x-4x. *Source: Times of India, Oct. 16, 2016*

Sun Pharma and the International Centre for Genetic Engineering and Biotechnology formed a collaboration for development of a vaccine targeted against all four stereotypes of dengue virus. *Source: Times of India, Oct. 19, 2016*

Tuberculosis cases continue to increase in India, with now an estimated 10.4M patients, more than any other country and over 1/4th the worldwide total. An estimated 480,000 related deaths annually are reported, despite govt. efforts. *Source: New York Times, Oct. 13, 2016*

Sanofi India signed a memorandum of understanding with the National Institute of Pharmaceutical Education and Research, Kolkata, to promote academic pharma excellence and research. Sanofi will assist in revising post-graduate training and provide research opportunities. *Source: Business Standard, Nov. 18, 2016*

## **Regulatory and Clinical in India**

Mylan and Biocon finally received full permission to market their Herceptin 'biosimilar' in India, marketed as CANMAB by Biocon and Hertraz by Mylan, Hoffmann-La Roche had been successful in stalling market entry for 3 years. *Source: FiercePharma, March 3, 2017*

Central Drug Standard Control Organization (CDSCO) developed a new system for granting export certifications for recombinant proteins and vaccines that promises sponsors a clearance within 10 days. *Source: FDAnews Drug Daily Bulletin, Feb. 14, 2017*

The central govt. largely abandoned prior planned financial support for new pharma API manufacturing facilities construction, cutting funding from \$750M to \$95M. This had been the centerpiece of Indian govt. strategy to counter Chinese dominance in APIs manufacture, a threat to India's generic drug industry. *Source: FiercePharma, Oct. 6, 2016*

The Drug Controller General of India changed regulations formerly requiring Phase III trials, with foreign products approved in major Western markets, only needing Indian Phase III trials where deemed necessary. *Source: The Indian Express, Oct. 18, 2016*

CDSCO will seek to align India's pharma GMP regulations with those of the World Health Organization (not major market countries, e.g., US or EU, GMP regulations). *Source: FDAnews, Oct. 18, 2016*

CDSCO halted plans to open an office in China that would have supported Indian GMP inspections of Chinese API facilities, due to inability to recruit suitable staff. *Source: LiveMint, Nov. 18, 2016*

Zikavac, a zika virus vaccine from Bharat Biotech, is entering Phase I clinical trials in India. The co. claims to have the first zika vaccine to enter clinical trials. *Source: FiercePharma, Oct. 12, 2016*

Among 500 drugs combo products examined by the Drug Controller General of India (DCGI), 200 were deemed "irrational." Drug combos have proliferated as a means to avoid price controls. *Source: Business Standard, Nov. 16, 2016*

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**Upcoming Biomanufacturing Meetings**

[ACN- International Conference on Environment, Agriculture and Biotechnology \(ICEABT\) - 3 Sept 2017, Pune, India](#)

[Drug Discovery India 2017 - 14-15 Sept 2017, Bengaluru, India](#)

**BioIndia International Conference 2017 - 21-22 Sept 2017, Hyderabad, India**

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## Articles

[Trends in Biopharma Contract Manufacturing in China and India](#); Pharmaceutical Outsourcing; June 2017, V. Xia and R. Rader

[2 part series - Chinese & Indian Expectations For GMP Biologics Exports - A Comparative Assessment](#); BioProcess Online; July 2017, V. Xia, L. Yang, E. Langer

[Chinese And Indian GMP Biologics Exports: Surveying The Current Landscape](#); BioProcess Online; June 2017, V. Xia, L. Yang, E. Langer

[China Biopharma: Is a Wave of GMP Exports in Our Future?](#); PharmaFocus Asia; May 2017, V. Xia, L. Yang, E. Langer

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## Comments/Suggestions/Resources

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