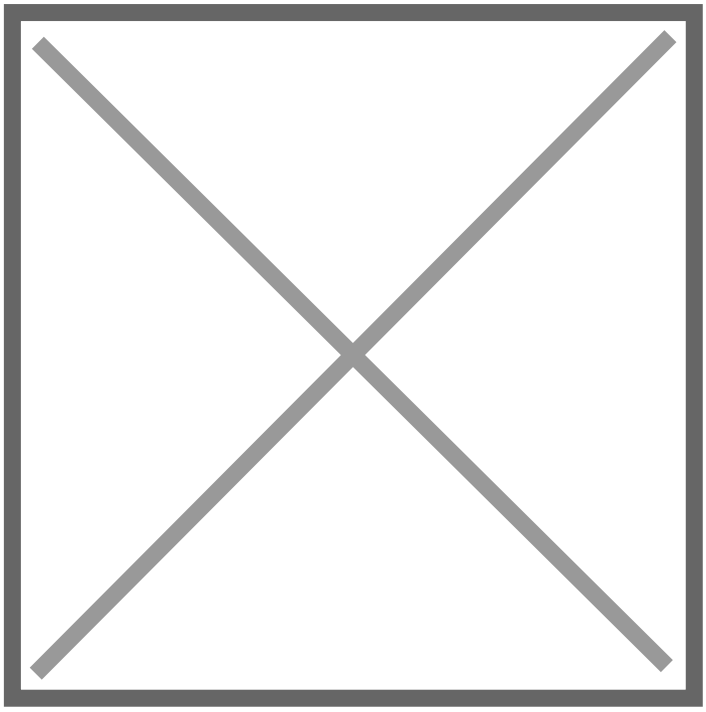


Kemwell eyes biologics frontiers

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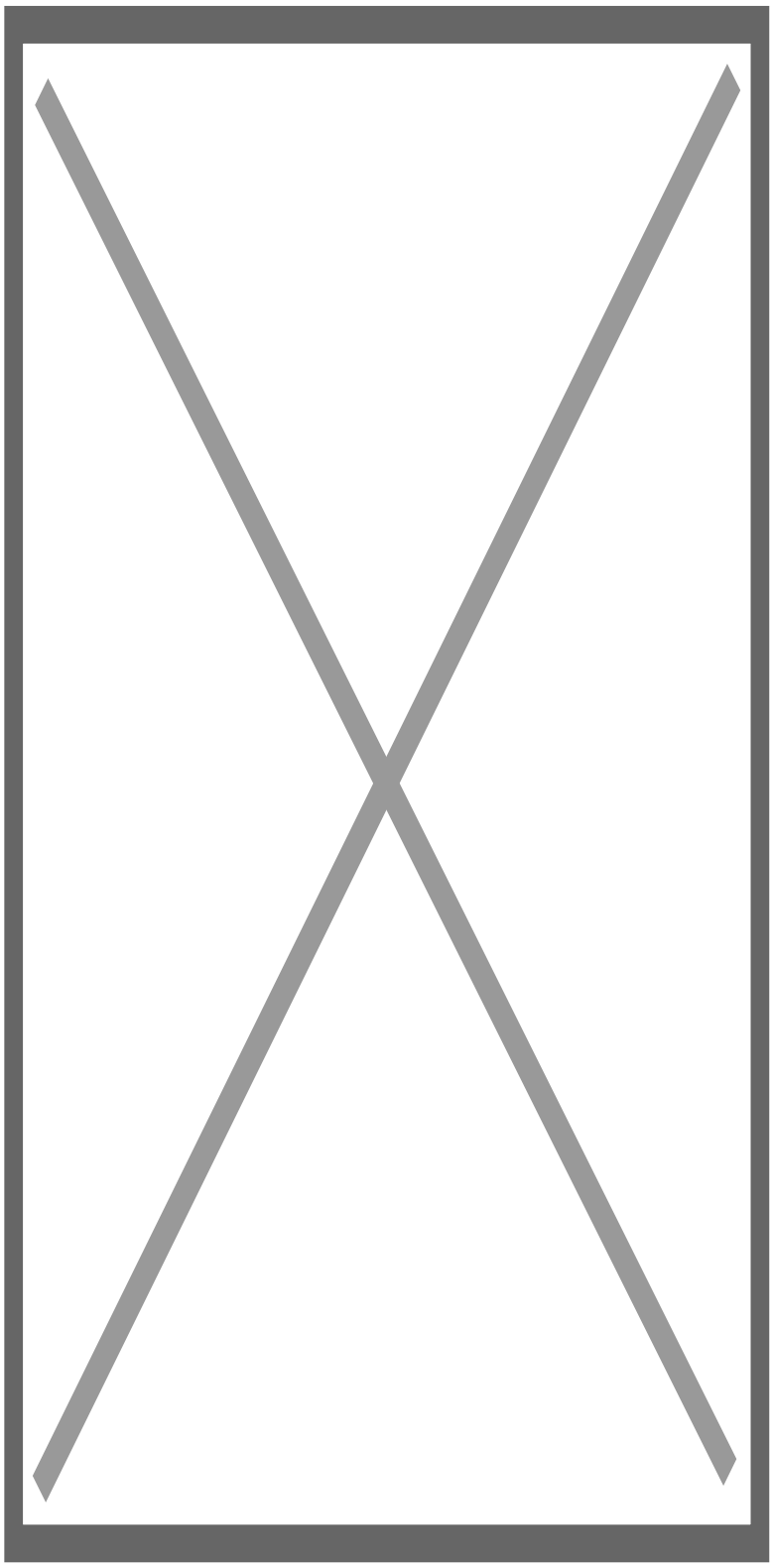


Kemwell eyes biologics frontiers

Kemwell, the leading provider of contract manufacturing and development services for the top 10 pharmaceutical companies in the world and manufacturers of five of the top 10 pharmaceutical brands in India, is now making its foray into biologics.

Kemwell India, the Bangalore-based contract manufacturing organization is all set to launch its aggressive growth strategies and expansion plans in the year ahead. Having consolidated its position in commercial manufacturing in India and worldwide, this 20-year-old contract manufacturer is all set to venture into biologic manufacturing. It is setting up India's first biologic contract manufacturing facility in Bangalore with the support of Boehringer Ingelheim, Germany, world's largest biopharmaceutical contract manufacturing company. As a part of its strategy, the company is also planning to set up shops in the US and Europe.

Kemwell has made three alliances in the past one year. The most recent one is with Boehringer Ingelheim. In November 2008, Kemwell had set up a research and development (R&D) facility in Bangalore, in partnership with GlaxoSmithKline, London, for developing oral healthcare products. In April 2009, Kemwell formed a strategic pact with the CMO Patheon (Toronto), for client referral and marketing services. The latter deal provides Kemwell with aseptic and high-potency manufacturing. It gives Patheon low-cost manufacturing for solids, semi-solids, liquids, and related development services in India.



With an employee strength of over 500 in India and 175 in Europe, and with revenues crossing Rs 300 crore, Kemwell has emerged as one of the top contract manufacturers in India. However, this success was not earned overnight. It took 26 years for the founder to turn Kemwell, initially an API manufacturering company bought from an IISc scientist with a turnover of Rs 20 lakh, and making losses of Rs 6 lakh annually, profitable.

It took some time, and a lot of effort to bring the company to the present level, says Subhash Bagaria, the founder and chairman, Kemwell. “After taking over, we started doing our own branded products, and we were making more losses. A close friend in GSK advised me to close it down since the competition was too high, and we were very small. We closed it, and then, we thought of starting contract manufacturing. Since that day, we are doing contract manufacturing and nothing else. The moment we closed API business and our own products, the company stopped making losses,” he adds.

Pure play strategy

The company’s strategy has been to continuously grow itself in contract manufacturing and nothing else. Kemwell never looked at putting its own brands in the market and competing with its customers. Bagaria believes, “It is best to be a pure play player in contract manufacturing. And that is the reason why we are getting so many orders.”

“As the contract manufacturing market is maturing, CMOs worldwide are becoming more competitive, striving to make a global presence, and providing expert one-stop shops. To sustain in this intensely competitive market place, we have maintained ourself as a pure play partner with high-level niche capabilities and options for collaborations and alliances,” adds Bagaria.

Building long-term relationships for commercial products is necessary for any large CMO to sustain long-term growth. Kemwell has long-standing relationships with innovator companies such as AstraZeneca, Bayer, GSK, J&J, Novartis and Pfizer, for the Indian market. And to meet the enlarged pipeline of projects, Kemwell has expanded its manufacturing capacity in the last few years, and the number of its employees now is more than double. Kemwell will continue its commitment to pure-play contract manufacturing, and build on its extensive experience in manufacturing. The company sees high opportunities for supplying monoclonal antibodies in future. It is committed to provide these services in a timely and cost-effective manner.

Europe focus

With a long-term aim of establishing itself in Europe, the company acquired Pfizer’s manufacturing facility in Uppsala, Sweden. The facility approved by US Food and Drug Administration (FDA), the European Medicines Agency (EMEA), and Japan’s regulatory authority, supplies products to over 80 markets, including the US, Europe and Japan.

The strategic acquisition resulted in significant growth in Kemwell’s contract business, and provided it the access to

technology and quality standards on a continuing basis. The Swedish facility serves as the base for QP release testing into the EU, and also works hand-in-hand with the Indian facility. The addition of Pfizer's manufacturing capabilities to its operations have allowed Kemwell to transfer some of the learning and experience, from Europe to India, and has enhanced in the expansion of its contract manufacturing business. The acquisition also provided Kemwell with a global site to serve its customer base, in addition to its four sites in Bangalore, thus significantly reducing customers' sourcing risks.

Late last year, the manufacturer's oral solids facility in Bangalore was declared GMP-compliance for supplying to the EU. Kemwell has also completed the construction of its new oral solids facility dedicated for exports to the US, Europe and Japan. The new plant will increase current capacity by over 10 times.

Kemwell's tablet facility has a capacity to make 500 crore tablets annually. The company currently has manufacturing contracts for 40 crore which is about 10 percent of the capacity of the plant. Kemwell has secured contracts with a couple of European pharma majors, and has begun tech transfer from the EU. "We are in talks with few companies to utilize the remaining capacity," informs Subhash Bagaria.

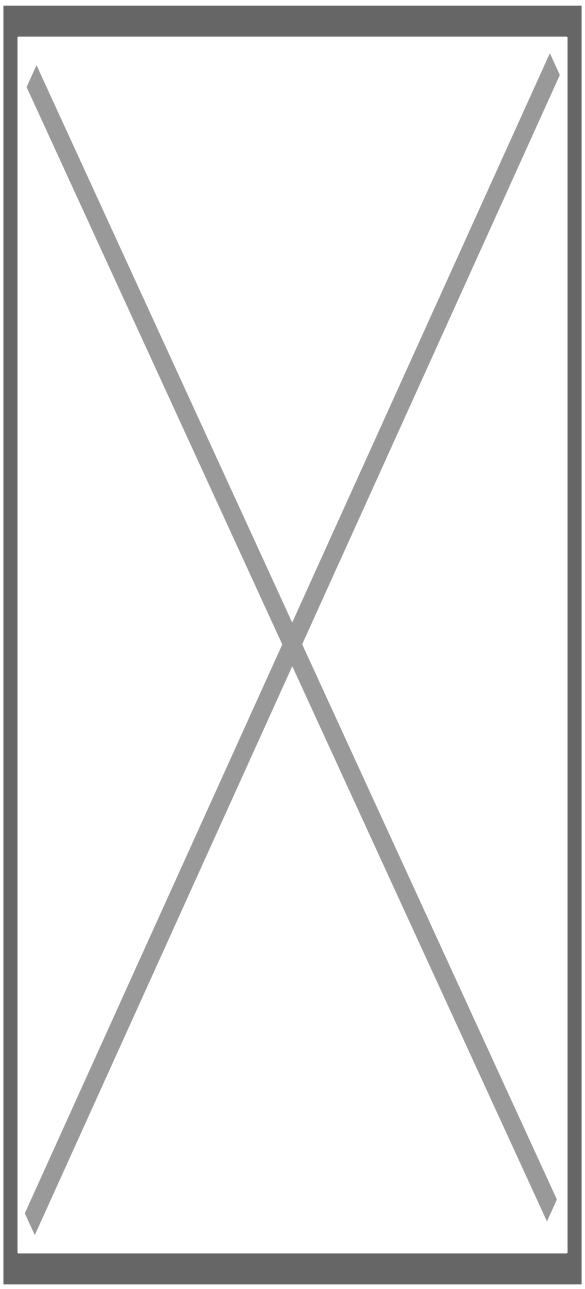


Foray into biologics

In a strategic move towards building its strength in the popular biologic segment, Kemwell is setting up India's first biologic contract manufacturing facility in Bangalore. With an investment of approximately Rs 250 crore and in partnership with the German pharma giant, Boehringer Ingelheim, Kemwell is all set to manufacture biopharmaceuticals.

"In biologics, there is no contract manufacturing facility in India. We are setting up the first unit with know how from Boerhinger Ingelhiem (BI), the world's largest contract manufacturer in biologics. Biocon, Shantha, Serum and Panacea have biologic manufacturing facilities, but they are all composite companies. They do research, processes as well as manufacturing," observes Bagaria.

The facility will initially be on a small scale. It will have three lines of fermenters of 2,500 liters. In India, except Reliance Life Sciences, no other company has 2,000 liters of production capacity. The new facility will manufacture products for the US and European markets. The know-how from Boehringer Ingelheim is claimed to help Kemwell in marketing.



With this collaboration, Kemwell complements its early clinical supply services ranging from full-service process development, manufacture, formulation, and fill and finish at the cGMP manufacturing facility in Bangalore. It also allows one-stop-shop through access to Boehringer Ingelheim's cell line development with the BI Hex technology platform, followed by a preferred access to the large-scale commercial production of Boehringer Ingelheim at its facilities in Europe.

"Most importantly, Kemwell and Boehringer Ingelheim will provide the customer with the state-of-the-art technology from Europe along with the benefit of low cost manufacturing from India," says Anurag Bagaria, vice-president of Kemwell.

Kemwell's new 15,000 sq mt, facility is designed for process development, fermentation, purification and formulation of biologics for early-phase preclinical and clinical studies. The facility in construction will consist of a cGMP drug substance manufacturing facility, a sterile fill and finish facility for drug product with a floor for process development laboratories to support production of protein therapeutics from mammalian-cell culture or microbial fermentation. Kemwell has facilities dedicated for tablets, semi-solids and liquids manufacturing as well as pharmaceutical development services on the same site, and can thus synergize its current competencies by using existing trained personnel in analytical and quality services at the new facility.

According to Anurag Bagaria, the Rs 300 crore company could add another Rs 250 crore from the biologic facility, when it gets ready in the next four years. The plant would be completed by the end of 2011. The search for new customers have already begun.

The biologic facility will have 100-120 technical and some marketing staff. It would offer expertise in toxicology and clinical development and partner with Indian CROs (clinical research organizations), to manage these studies. Some scientists are being trained by Boehringer Ingelheim.

"We believe that the future growth will be driven by the expansion of customer projects, and by our entry into new market segments like biomanufacturing of recombinant proteins and monoclonal antibodies. Increasingly, both pharmaceutical and biotechnology companies are relying on CMOs, as an integral part of their overall manufacturing strategy," says Anurag.

Jahanara Parveen