

Inno Biologics paves way for contract manufacturing in Malaysia

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Drug manufacturing accounts for 25 percent of company costs and achieving agility in the production process has now become essential for pharma companies hoping to align their supply chains with constant shifts in global product demand. In addition to offering efficiencies in cost, capacity and time-to-market, contract manufacturing organizations (CMOs) provide innovative, state-of-the-art process and production technologies to support the rapid technical transfer of products from R&D to commercial manufacturing.

Looking at the opportunity and potential, Inno Bio Ventures, an initiative of the Ministry of Science, Technology and Innovation (MOSTI), Malaysia, decided to venture into this niche sector by setting up Inno Biologics, in 2002.

It won the BioSpectrum Asia Pacific Bioscience Industry Emerging Company of the Year Award for 2010.

Contract manufacturing has emerged as a major business opportunity for companies in the developing world mainly in Asian region. The global CMO market has grown from \$12.8 billion in 2002 to \$20.5 billion in 2008. The Asian CMOs share of global market is predicted to double from 10 percent in 2009 to 20 percent by 2013. Analysts expect the sector to see a CAGR of 11 percent.

Inno Biologics has set up 1000L facility that was designed and built by the world's leading cGMP EPCC service provider, Pharmaplan of Germany using the modular concept. The biomanufacturing complex began its operation in July 2006. The

facility was built to conform to the US Federal Drug Agency (US FDA), European Medical Authority (EMA) and Pharmaceutical Inspection Convention (PIC) regulations. Even Malaysia's National Pharmaceutical Certification Board (NPCB) has audited this facility.

The establishment of Inno Biologics signifies the first Malaysian entry into the highly regulated global biomanufacturing market. With this initiative, Malaysia is now ready for the challenge of establishing its footprint in the contract manufacturing sector and contributes to creating new economic opportunities in the regional biotech industry.

Set up with an initial investment of \$20 million with 10 employees in 2003, Inno Biologics received BioNexus status in 2006. The BioNexus status offers a number of benefits such as 10 year tax exemptions, various grants and removal of restrictions on employing expatriate, to entrepreneurial companies that are involved in research and development.

Partnerships for success

Besides getting government support, Inno Biologics has signed a cooperation agreement with Boehringer Ingelheim, a top pharma company. Through the partnership, it offers its clients access to Boehringer Ingelheim's enhanced manufacturing technology platform, protocols and support and well-established bioprocessing services for various stages of process development and biomanufacturing. Inno Biologics will have non-exclusive access to Boehringer Ingelheim's comprehensive manufacturing technology platform for cell culture products, including its state-of-the art BI HEX cell expression system. This strategic partnership provides Inno Biologics with the advantages of offering a complete range of services from the clinical stages up to the commercialization with a seamless transfer of technology.

Inno Biologics is involved in many projects with clients in developing and producing monoclonal antibodies for both therapeutic and diagnostic application. The company has secured partnership agreements with several international firms. Current ventures include a deal with an Indian drug developer, Avesta Biotherapeutics & Research to produce biopharmaceuticals over a five-year contract term. The contract signed with the Indian firm signifies its agile strategy to gain international recognition for Inno Biologics, and this will motivate the company to strive forward, and actively pursue its mission to be the world leading business organization in providing biopharmaceutical development and services.

Inno Biologics has grown in the last couple of years and emerged as a medium scale global CMO specializing in mammalian cell culture manufacturing of biopharmaceuticals for phase I-II clinical trials. Right now, it employs 95 people that includes 35 scientists and 17 engineers. With exclusive partnerships in place and more in negotiation, Inno Biologics' access to high standard of technology is set as an important differentiator from other competitors.

As a CMO for clinical materials, Inno Biologics aims to bridge the gap between R&D endeavors and commercialization activities. The company provides an array of R&D services including cell line development and engineering, hybridoma technology and antibody production, mammalian cell culture medium and development, cell banking, protein expression and verification, process flow modeling, biotech project management and clinical material production (cGMP environment).

With the research funding from MOSTI, Malaysia, Inno Biologics is focused on development of therapeutic/diagnostic antibodies against colorectal cancer markers. The company has acquired through licensing two murine antibodies from Cuba's Center for Molecular Immunology (CIM). Using a proprietary technology from CIM, the Inno has successfully humanized the antibodies and in the process conducting immunogenicity and toxicology studies in animal models.

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Working with other collaborators like Malaysian Nuclear Agency and National University of Malaysia (UKM) Medical Center, the company hopes to enter into clinical trials for these two products in the near future. Beside these two antibodies, Inno Biologics has successfully generated monoclonal antibodies against oral cancer biomarkers with Cancer Research Foundation (CARIF) and antibodies against drug of abuse, such as amphetamine, methamphetamine, morphine and cannabis.

Inno Biologics has embarked on a collaborative project with Malaysia Genome Institute and National University of Malaysia to develop an expression vector using DNA elements resulting from genome-wide analysis. This is in order to improve yield from the mammalian system. The company also entered into a collaborative agreement with CEVEC Pharmaceuticals, Germany, to generate producer cell lines using CEVEC's novel human cell line as the host. This cell line is expected to generate protein with the native human protein having similar post-translational efficiency and hence better bioactivity. With its strengths and expertise in manufacturing operations, process development and regulations, Inno Biologics expects to be the contractor of

choice that is committed in providing cutting-edge technology and business processes. With these offerings the company is set to meet the emerging needs of the industry as an ideal partner for outsourcing contract manufacturing.

Future prospects

"We are very optimistic about our future in this industry. Considering the current market demand, the biomanufacturing industry looks extremely promising. The market for contract manufacturing was \$2.5 billion in 2006 with an expected growth rate of 10-15 percent until 2011," says Dr Mohammed Nazlee Kamal, CEO, Inno Biologics.

Sharing his views on the future plans of the company he says, "Inno Biologics has aggressive plans to expand production capacity in tune with the market demand. Such initiatives would utilize the latest manufacturing technology including disposable technology. This will allow the company to become more competitive on costs thus attracting more interest from not only small biotech companies but also from mid to large pharma companies."

On receiving the award Dr Mohd Nazlee Kamal, says, "Inno Biologics is honored and inspired with the recognition of being awarded with the the BioSpectrum Asia Pacific Emerging Company of the Year 2010."