BioSpectrum the business of Bio & Health Sciences

A Case for Manufacturing

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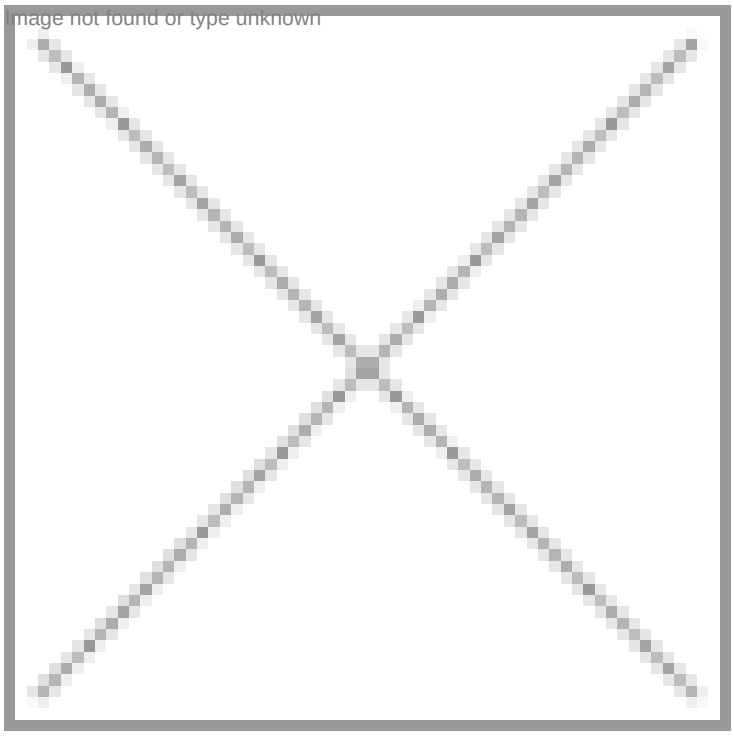
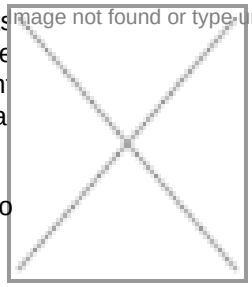


Newer opportunities can be tapped through bio-manufacturing services.



Decades of investment in Biotechnology Research have fueled a market for biopharmaceutical products that is expected to grow from about $35 billion in 2005 to over $70 billion by 2010. With over 300 large molecules currently in clinical development, therapeutic proteins and antibodies from recombinant technologies will soon become the leading source of new products and growth in pharmaceutical industry.

The exciting market opportunity presents the biopharmaceutical industry with a new challenge to manufacture enough products to meet the growing demand.

During the last two decades, India has emerged as a preferred destination for cost competitive quality production of pharmaceutical API and formulations. Today, India enjoys the distinction of having the maximum number of US FDA approved facilities anywhere in the world outside of the US and has proven its claim to be a major manufacturing hub and supply centre to the world. With the Indian IPR laws in place, the pharma manufacturing sector is expected to leap.

There is an acute shortage of bio-manufacturing capacity globally. And there is a case for the Indian biopharmaceutical company to offer manufacturing services as it can provide a competitive cGMP facility, with skilled manpower and scientific talent, along with a good cGMP culture, among several other things.

Nonetheless, investments in bio-manufacturing facilities involve considerable risk. A manufacturing strategy for a biopharmaceutical molecule must be determined early in the development process. Current regulatory position "Product by Process" does not allow choices to the developer to make alteration and / or change of manufacturing facility. This stance of US FDA and EMEA is the main issue of contention to allow (or not to allow) generic biologicals. An amendment to this position would open opportunities for contract manufacturers to participate on toll manufacturing contracts for original developer of molecules and for manufacturing and marketing a generic version of the same on the expiry of the Patents.

Till then, the risk of clinical or regulatory failure would be one of the key project uncertainties that would have to be factored in any investment decision. The commercial potential of the drug at this juncture is a significant unknown. The biopharmaceutical molecule manufacturing processes are far more complex than synthetic, less flexible to be adopted for alternate products. They involve both large investments and long lead times. Further, the current market size both in quantity and value terms outside the regulated markets is small.

It is also possible that potentially disruptive new technologies, such as highly productive expression systems or perhaps transgenic plants, may make existing manufacturing process obsolete. Biopharmaceutical manufacturers wishing to participate in this opportunity must make strategic choices regarding capacity, technologies, expression systems and capabilities in the face of these uncertainties.

Surely, Indian biopharmaceutical companies having developed a viable business model and capabilities across the full value chain from research-to-marketing would stand a better chance to participate in this opportunity as their current business would allow them to mitigate the associated risks.

Unlike therapeutic proteins and antibodies, which have limited market both in quantity and value terms in developing world, vaccines offer a large market in quantity and more friendly-regulatory environment. The active participation of organizations, like WHO and other National Health Agencies in developing countries, in the vaccination programs offers a ready market without considerable investment in marketing network.

India is already recognized as a key supplier of conventional pediatric vaccines for the global market and will consolidate further in the next few years by adding manufacturing capabilities to produce much needed newer vaccines using newer technologies.

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