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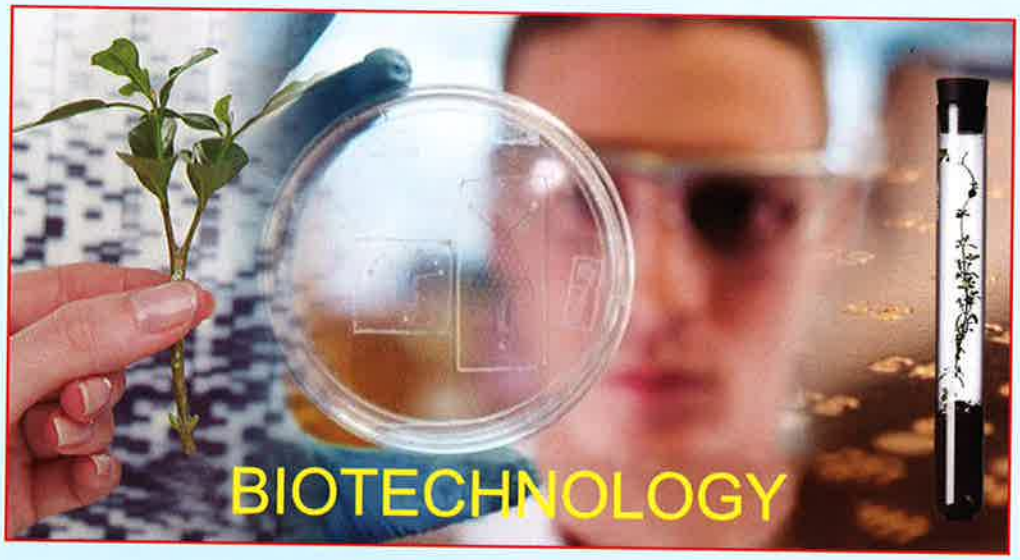
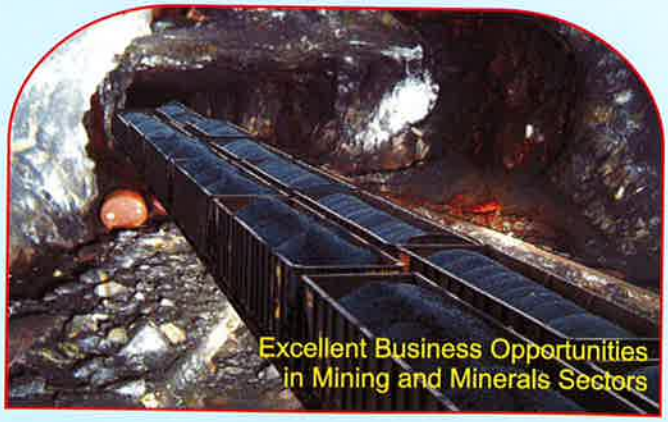
India's Biotechnology Industry's Rapid Growth; BIO India International Partnering Conference Scheduled at Hyderabad September 21-22

Canada-India Mining & Metals Forum to Meet at Toronto



MOU Signed on Cooperation in Geology and Mineral Resources



Business and Industry Leaders Upbeat on Eagerly Awaited President Obama and US Trade Mission's November India Visit; Billions of Dollars Deals in Offing

HIGHLIGHTS

The Strategy Is Not Generic

With Generics Industry Becoming More Competitive and Profit Margins Shrinking, Indian Firms Should Take Lead in Global New Product Development

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Innovator drug development entails multiple challenges. A newly marketed drug takes about 10 years and costs more than one billion US dollars. The high cost and long time is attributed to extensive research and development required for showing the safety and effectiveness of the new drug.

To add to that is the high risk of failure; a drug product could be rejected at any stage in development due to unacceptable properties—higher than expected risk or lower than expected efficacy. It has been suggested that the cost and risk can be reduced somewhat with better strategy and global development.

High Quality Generic Drugs

India has made a name in the global pharmaceutical industry as the source of high quality and inexpensive generic drugs. But developing an innovator drug is very different from reverse engineering a marketed drug. However, expertise developed in generic drug creation can be used for new product development as well. India boasts of one of the world's largest pool of engineers, chemists, doctors and researchers. What it lacks can be created with strategic planning and training. However, to fill gaps one needs first to identify the same.

Intellectual Property

While excellent labs in biological sciences exit, India has generated very little internationally recognized intellectual property. Academic and non-profit institutions harbor fresh talent that can lead to new inventions. Academic centers can use public-funded non-profit resources to explore new areas without limiting the scope of the research to commercially defined boundaries. New inventions need not only be recognized in a timely fashion but must also be protected and then appropriately transferred to the commercial developers for further development.

Technology Transfer

In India, the process for technology transfer is still in its infancy. Very few academic institutes have professionals trained in technology transfer and commercialization. Industrial labs dedicated to discovery are few

and mostly lack the corporate support for long-term research projects. The first place India needs to work on is in its technology transfer processes. System for nurturing entrepreneurship and sharing profits needs to be developed vastly.

Limited Preclinical Facilities

The preclinical facilities in India are severely limited in the scope of services they offer not only because of religious considerations where certain animals are restricted, but also because most of the preclinical experience is limited due to lack of clear preclinical requirements under Indian laws. The preclinical requirements for new drugs have been evolving rapidly over the last decade with the FDA expecting far more complex, indication-specific non-clinical studies. There is need not only of building infrastructure for specialized animal and tissue culture experiments but more facilities meeting the GLP requirements so that there are more in-country options for generating such data. For now, most complex experiments need to be outsourced to other countries.

Regulatory Processes

The regulatory processes in India are going through rapid transition and harmonization with those in the USA and Europe. However, since most of the industrial experience comes from creating generic products, *Indian companies lack training in regulatory processes for developing non-generic new products*. Regulatory process is perhaps the most critical area where India lacks on most fronts. Indian regulations for conduct of clinical trials, manufacturing, and safety event reporting are similar to those defined in the ICH guidelines.

A few years back Indian regulators announced that they would favorably decide on applications already approved by the US and European regulators. But most of these harmonization efforts still miss some critical elements to assure approval of safe and effective new medicinal products. Most of these are because of lack of resources at the regulatory bodies.

Interactions with Regulatory

Key areas of development in regulatory environment are transparency of application review process, pre-defined time-lines for review, formal meetings between regulators and sponsors to discuss critical development steps, auditing and monitoring capabilities of the regulatory agencies, and open dialogue between regulators, sponsors and public to define new regulations and processes.

Indian industry lacks robust interactions with its regulators containing the above elements and as such lag behind their US-based counterparts. Strong and transparent interactions with the regulators not only help in creating globally acceptable products but also speed up the overall development and reduce the risk of failure.

So, with the above shortcoming how does an entrepreneur based in India develop globally acceptable new non-generic products?

How does one take advantage of the global knowledge-base while taking advantage of the indigenous resources?

New Product Development

New product development should go through a series of strategic steps. It starts with searching for and licensing promising technologies for further development. Biological technologies can be invented anywhere in the world and developed elsewhere. Due to lack of local resources for new technologies, it might make sense, at least in the near future, to license new technologies from outside India. Of course, if a local technology in the area of interest is available, it should be selected but by not limiting themselves to smaller geographical locations, Indian companies gain access to good technologies of international repute.

Steps in Developing Product

Next comes various steps in developing the product. A medical product needs good scientific rationale, well-defined experiments, and non-compromising quality control. The US FDA maintains one of the most comprehensive free online resource for good quality processes and strategies for developing new products at its web-site (www.fda.gov). An investment in training personnel in US requirements for a given product will not only help overcome several knowledge shortcomings but also lead to a globally acceptable product. The product development plan should be living document that adapts to new findings and changing requirements. Companies have successfully moved product faster through the development pipeline by conducting global trials. It's a lot easier to conduct many preclinical studies in China and early stage clinical trials such as Phase I trials in USA and Western Europe. The product development plan should maximize all incentives – regulatory and logistical – available all over the world for the successful development of a given product.

Discussions with Sponsors

Indian regulators have no formal process for discussions with the sponsors. Meetings with regulators help the sponsor design better clinical trials, appropriately address manufacturing concerns and trouble-shoot issues arising from on-going studies.

While Indian regulators do allow informal one-on-one meetings, the processes to request, conduct and record such meetings do not exist. There also is no formal process for periodic meetings with the reviewers or request comments about critical times in the overall development timeline such a pre-IND, end-of-Phase 2, and pre-NDA. There is no predefined format for such meetings and as such their utility is limited.

International Supervision

To overcome this challenge, Indian companies could benefit by conducting their new drug projects under international supervision. Both the FDA and EMA offer several avenues for formal discussion with the regulators no matter where in the world the trials are conducted so long as it is done under a formal application with them.

Among the two, FDA is perhaps far more transparent and accessible for high-quality timely discussions. By filing an IND with FDA for their product being developed in India, the Indian companies could get access to FDA's immense scientific expertise.

Global Perspective

Developing global products requires global perspective. First step is getting rid of the generic mindset. Pharmaceutical products take long time to develop. A program should be developed with long-term ambitions. Second, quality issues could kill a

product even if it seems very promising. Parameters to define high quality of research should be designed and strictly implemented. These included demonstrating compliance with GLP and GCP principles, ethical practices, and regulatory requirements.

Since local resources for training and consultation are lacking, it might be good idea to involve international experts in global processes. Due to excellent and inexpensive communication channels, availability of experts is no longer limited by geographical and time boundaries.

Global New Product Development

As the generics industry gets more and more competitive with time, and profit margins shrink, Indian companies have to step up and take the lead in global new product development. India currently harbors a lead

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Russian Biotechnology Firms Keen for Tie-Ups with India in R&D Area

HYDERABAD, India—India's remarkable growth of its Biotechnology Industry, especially its research and development of products, has been attracting more and more developed countries for tie-ups in R&D area.

Russian biotech sector, too, is keen on partnering with Indian biotechnology companies to take up joint research and development of products.

The biotechnology associations of both countries are currently engaged in identifying areas for collaboration and technology transfer.

"We are working on creating a platform for joint activities between the Indian and Russian biotechnology sectors. The effort is currently on to create a common platform and bringing together various stakeholders, including the companies, onto the platform," according to Mr. Rraif G Vasilov, Chief Operating Officer of the Russian Biotechnology Association (RBA).

Immediate Focus Areas

According to Mr. Vasilov, the immediate focus is on agri-biotechnology, pharmaceuticals and vaccines.

"Russian biotechnology sector is already strong in certain areas and we are planning to expand the presence of the companies in Russia to other geographies.

The Indian biotech sector, too, has been working on development of new products. We are willing to transfer the technologies that are developed in Russia to the Indian partners. Though it would take sometime before we roll out any products through the joint initiative, the process has begun," Mr. Vasilov said.

A delegation of Russian biotechnology sector is expected to visit India shortly to evaluate the options for collaboration and also offer technologies available in Russia.

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over its global competitors thanks to its almost two decades of pharmaceutical industrial development. But that lead is shrinking fast as other countries try to catch up. Good strategic planning could not only maintain that lead but also keep it for a long time.

EDITOR'S NOTE:—Dr. Mukesh Kumar leads the Regulatory Affairs and Quality Assurance departments at Amarex, a full service pharmaceutical product development company based in Germantown, Maryland, USA (www.amarexcro.com). He is also the Global Managing Director for Amarex Biosciences, India, a pharmaceutical product development company based in Delhi. His key expertise is in regulatory affairs, clinical trials and multi-national project management for medicinal and diagnostic products. He has been involved in about 100 clinical trials in more than 40 countries, has made several hundred US FDA submissions, and arranged a number of meetings with the US FDA.

He is a well-known expert in global regulatory affairs and has been an invited speaker at several professional and academic organizations worldwide. Dr. Kumar can be reached at mukeshk@amar excro.com or mkumar@ amarexbio.com.