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India's R&D-The Future Forward

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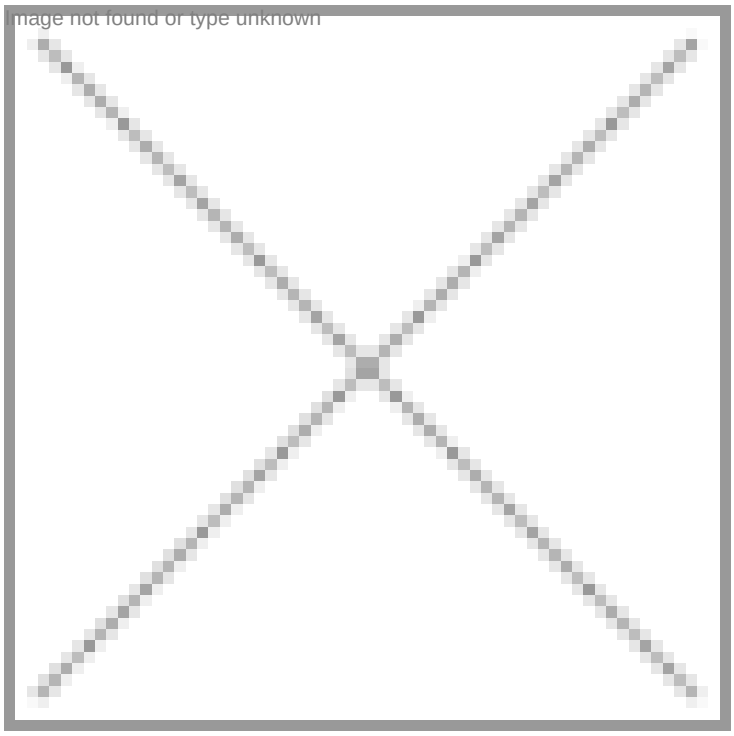

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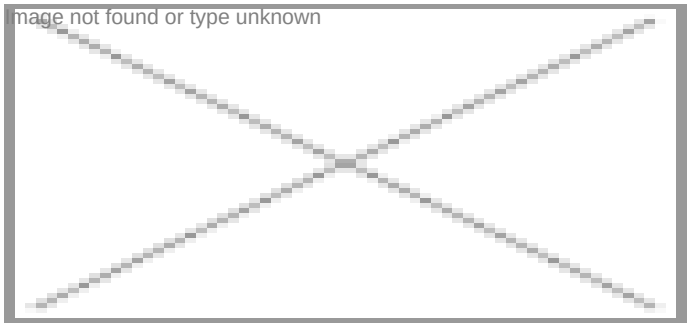

India has what it takes to become an R&D hub in the coming decade. We just need to tackle the roadblocks

India is fast emerging as the preferred R&D destination for many companies across the globe, outpacing cut-throat rival, China. Faced with increasing drug development costs and commercialization on one hand and drying pipeline on the other, global companies have now chalked out elaborate plans for India not just because of the low costs it has to offer but due to faster and cheaper time-to-market opportunities, a larger and diverse patient pool and the availability of a sizable number of scientists. It has been estimated that the cost to conduct a trial in India is 50 percent lower than that of a developed market.

Indian companies have realized this and are making massive R&D investments. Results of a recent survey demonstratedthat R&D spending by India's 25 leading drug makers grew nearly 17 percent in 2008-2009, with a number of firms increasing their investments by over 40 percent. The total spending on R&D was Rs 321 crore, according to a news agency.

However, India still has a lot to do. Its spending on life sciences R&D is paltry 0.9 percent of its GDP which is extremely low compared to nations like China or Brazil. In US this figure is 2.5 percent of the GDP. A recent McKinsey report says that India can aspire to become an innovation hub by 2020. But this requires globally competitive research infrastructure, world-class talent, funding, private-public partnerships and enabling regulatory environment.

To be the next R&D hotspot, India has to devise a strategy of promoting its R&D agenda. Essentially, change from the roots is required. Education system is a good place to begin. We need scientists and researchers who can think out-of-the-box and can in turn drive innovation. Moreover with drug development and commercialization costs sky rocketing, the industry should look at approaches that drive down R&D costs.

In the ensuing pages, BioSpectrum team has put together highlights of the key points that have emerged in discussions with the R&D heads across life sciences companies. Strategies to clear some of these roadblocks and drive the country's innovation agenda with efficient R&D will be deliberated at the BioSpectrum Technology Forum 2010 in Goa on February 16 & 17, 2010.

The forum is by invitation only. If you are an R&D head and want to participate you can register for invitation at: http://events.biospectrumindia.com/TechnologyForum2010/

A time to step up R&D

Innovation will be the key, if India needs to match up with global standards in R&D

Unfortunately, Indian scientists and researchers are more 'development-driven' rather than 'innovation-driven'. â€œThe system in India is such that it kills novelty. India has established itself in the world with generic versions of innovator chemical drugs and is looking at biosimilars in a big way. But then to be a global name you need to be an innovator. We need to create an environment of early innovation,â€? says Dr MK Sahib, director, Genomics and Biotechnology Research, Wockhardt.

This boils down to the education system of the country, which till date has been churning out a vast number of graduates but not skilled talent. Attribute this to the fact that the system propagates a syllabus that is more theoretical than practical. â€œStudents here should be trained to be different, challenge the old order and that is when innovation can come about. We should be open to new avenues and also permit people to be different. It is already taking place,â€? adds Dr Sahib.

Says Dr Ramani Aiyer, senior vice president, strategic development, Actis Biologics and former CSO, Actis Biologics India, â€œWe must make science more exciting to them. Churn out PhDs and young scientists. A lot of Indians go to the US not for the money but for the scientific problems offered there, essentially challenges.â€?

There is a paradigm shift in the dynamics of the industry from blockbuster drugs to customized medicines. This is when improving the infrastructure of the country comes into the picture. â€œWe have a huge manpower base in India but then the Government needs to increase investments in quality infrastructure,â€? says Dr Sahib. Compared to investments in pure pharmaceuticals, R&D in biotech requires a high-end infrastructure, which automatically means mammoth investments. â€œCosts of developing a chemical drug is low which also results in lower returns but for a biologic drug, the costs might be higher, but companies and the government should realize that the returns will be equally higher,â€? says Dr Sahib.

Dr Aiyer believes to the contrary and mentions, â€œThe government has put in their best to promote India R&D. It is the Venture Capitalists (VCs) and Private Equity (PE) players who should take a more risk driven approach to the industry.â€?

Dr Dhananjay Patankar, chief operating officer, Intas Biopharmaceuticals agrees with Dr Aiyer.

â€œ The DBT is exploring avenues to fund research, focus on the opportunity of bio-similar products and create infrastructure to scale-up human resources to support a shift to high-end research in the long term. The Center is also looking to support innovation from universities and a Bill to empower scientists and help them commercialize their innovations is expected to be passed by the end of the year.â€?

The industry also claims that the IP regime needs to be reviewed and the regulatory framework pertaining to pre-clinical and clinical trials needs to be harmonized. â€œI want the government to ensure that patents are enforced properly, which can be beneficial both to the MNCs and Indian companies. There are aspects like data exclusivity and incremental innovation, which needs to be more clear in their definition. Evergreening should also be looked at as a serious issue,â€? adds Dr Aiyer.

The future ahead
After its success with Information Technology and Telecom, life sciences is the next big growth story in India, as the marketis

looking attractive for offshoring and outsourcing. Contract Research and Manufacturing Services (CRAMS) also seem to be big on growth. â€œThe global clinical research outsourcing market is projected to touch $23 billion by 2011, with market research companies estimating that India will corner 15 percent of this in two years,â€? adds Dr Patankar.It has been estimated that by leveraging its capabilities, India has the capability to touch almost $8-10 billion by 2020 from R&D alone. Dr Aiyer is optimistic, â€œFive years down the line I am confident that India will come out with at least one NCE and the number can also go up to three. A number of molecules in India are already reaching phase-III. If we come out with an New Chemical Entity (NCE) it will be a great milestone in the western markets. We are on the threshold of this one,â€? he says.

Ways to enhance R&D

While R&D retains its position as a key driver in the success of India's life sciences industry, there emerges a strong need for research collaborations both within the industry and with the Government institutes in the form of public-private partnerships (PPPs). Significant research can also come about with collaboration between the industry and the academic institutions.

In order to provide an impetus to PPPs, the Indian Government has directed considerable efforts especially to promote flow of core scientific knowledge from the national laboratories and institutes of higher learning to the industry for further development and commercialization.

Companies too have taken the step forward in revamping their R&D team structures to make it compatible with the overall demands and needs of the industry.

Public-private partnerships

The Union government has been supporting start up firms with seed funding through the New Millennium Indian Technology Leadership Initiative (NMITLI) and Special Drug Development Research Initiatives. Six biotech parks are functioning in various states under the public-private partnership and 10 parks are in different stages of development across the country. Several world-class scientific institutions like the National Center for Biological Sciences (NCBS), the Indian Institute of Science (IISc), and the Center for Cellular and Molecular Biology (CCMB) further lend support to the sector.

The Council of Scientific and Industrial Research (CSIR) led institutes such as National Chemical Laboratory (NCL), Pune, Center for Drug Research Institute (CDRI), Lucknow and IMTECH, Chandigarh have been the vanguard of the public private partnerships.

IMTECH has collaborated with about 32 companies including Ranbaxy, Cadila Pharmaceuticals, Lupin Labs and Panacea Biotech for contract research projects. Recently, CDRI, Lucknow entered into a contract research collaboration with Biocon â€œThere are many successful stories related to drug development in CDRI with pharma industries in private and public sectors. Out of 16 new drugs/products developed in India, CDRI alone has shares of 11, which shows the important role of CDRI in pharmaceutical sector,â€? says Dr Rajendra Prasad, head and deputy director, business management, CDRI, Lucknow.

The sharing of ideas and facilitating the technology transfer along with the technical expertise forms an important part of PPPs in R&D. PPP remains one of the important needs of current times and there is a need for the industry to come forward and recognize the potential of Indian scientists and their capabilities in R&D,â€? says Dr Rajesh Gokhale, director, IGIB.

Similarly, the DBT's National Biotechnology Development Strategy involving schemes like SIBRI, BIPP and especially the BIRAP to promote the R&D in biotech industry, has been one of the motivating factor for many SMEs. DBT-funded institutes such as NCCS, Pune, NII, New Delhi and CDFD, Hyderabad have also made some concrete efforts in this direction. One such example is the DBT-funded project on developing HRP-II/ p-LDH based diagnostic kits for the differential detection of malarial parasites by Bangalore-based Bhat Bio-Tech in collaboration with National Institute of Malaria Research, New Delhi. In agribiotech sector too, there are many examples of collaboration such as Mahyco with University of Agricultural Sciences, for Bt brinjal and SIBRI funded project on the stress resistance strategies in maize (Zea mays) by Nuziveedu Seeds Hyderabad in collaboration with ICGEB, New Delhi.

The HUGO opens personalized medicine pathway

As the genome initiatives got under way, the need for an international coordinating body was felt by the scientists-That ishow the Human Genome Organization (HUGO) was conceived in April 1988, by Sydney Brenner at the first meeting on genome mapping and sequencing at Cold Spring Harbor, US. Victor Mckusic was its first president. HUGO was established to foster collaboration between genome scientists around the world. What began in 1990 as a 15 year, $3 billion international scientific project has advanced faster than was ever imagined. Ever since the mapping of the human genes under the first Human Genome Project completed in 2003, genomic discoveries are pointing the way to new drugs and tests that disrupt processes

at the molecular level and that predict one's risk for a disease.

Based out of Geneva, Switzerland, HUGO has members drawn from 23 countries and has been at the forefront of efforts to coordinate the mapping of the genome across the world. The HUGO's Pan-Asian initiative is a consortium of 90 geneticists and 40 institutions from 10 Asian nations, namely China, India, Indonesia, Japan, Malaysia, Philippines, Singapore, South Korea, Taiwan and Thailand. It collected samples from 1,928 unrelated individuals representing 73 groups of people from 10 countries and 10 linguistic lineages from member countries as well as from two non-Asian population groups of Africo-American and Caucasian ancestry. According to the study, modern humans evolved in Africa and spread across the world, adapting locally to the selective pressures of climate, food sources and pathogens.
In India, the first Human Genome Meeting was held in Hyderabad in September 2008. Now the recent completion of firstever human genome sequencing as a part of HUGO project in India by scientists at IGIB, Delhi, is being closely seen as a step towards personalized medicine.

These developments, especially in India, have raised hopes for new drugs for diabetes and heart diseases developed with the help of new genetic information. Pharma and biotech, agriculture, and forensics are just some of the few areas that have been improved by the discoveries made.

Leadership strategies in R&D

Innovation in life sciences is not for the faint-hearted

R&D organizations are now striving for greater empowerment and less hierarchy. The role of an R&D leader is witnessing a paradigm shift towards an entrepreneurial drive and competitive spirit.

Senior R&D leaders today, are expected to play a greater external role, representing the company within the public and the industry by positioning the company as an attractive partner in open innovation.

There is widespread agreement among HR experts that R&D leaders need to improve their leadership competencies, specifically their drive for entrepreneurship and competition, ability to create vision and set strategy, and competency in executing for results.

The makings of a leader
â€œInnovation cannot be taught and it requires many enabling attributes to provide the right â€œecosystemâ€?. Other than requisite infrastructure and scientific tools, it requires research drivers (â€œdrug huntersâ€?) who have independent decision making authority, close communication between interdisciplinary scientific/commercial teams, access to domain knowledge (best obtained through collaborations) and an organizational structure which is lean, challenging and highly incentivized for success. Innovation in life sciences requires high investment, patience and is certainly not for the faint-hearted,â€? says Swapan Bhattacharya, managing director, TCG Lifesciences.

Elaborates Dr Sami Guzder, R&D head, Avesthagen, â€œCritical thinking, and innovative approaches in problem solving seem to be lacking among the research groups. Trained, experienced personnel impact project completion that translates to increased efficiency and lower overhead. R&D leaders need to be able to recognize the right projects, people and collaborative models that will lead to the right decisions.â€?

He suggests that the Indian biotech companies should streamline processes for increased efficiencies, should ideate innovative approach to problem solving and promote co-development (Public and /or Private) as a business model to reduce costs and enhance R&D efficiency.
The other main focus is on improving the decision-making process in R&D. Although most are skeptical about the possibility of shortening late-stage clinical development, companies are now looking for ways to optimize the decision making in discovery research and preclinical and clinical development so that better and faster decisions can be made.

â€œFaster and better-quality decision making will be gained through empowering people lower in the hierarchy, those who hold the most current scientific expertise and by bringing them together in multidisciplinary teams, says Dr Ganesh Sambasivam, co-founder and CSO of Anthem Biosciences.

Team consolidations have become an extremely popular method of improving R&D efficiency by optimizing the structure and objectives of working groups. Many companies have undertaken substantial reorganizations throughout 2008 and 2009.

Dr Ganesh Sambasivam feels the life science industry needs people from diverse backgrounds and different skill sets. Different functional teams should come together and this will lead to cross pollination of ideas. He urges that the 'out of the

box thinking' is very crucial for increasing R&D efficiency.

Companies and their Initiatives
Companies that acknowledge the need for change recognize the value of their internal talent and put in place a fast and effective grooming process. They are also now waking up to the reality that they must set up strategy to attract international talent to fill in the talent gap that is persisting in the industry which also means that attracting expatriate talent is important if the region is to keep up the pace with the leading clusters and companies in the global life science industry. Says Dr Ganesh, â€œWhile India's educational system does not support an edge on technology and strength in drug discovery, the returnees from US and EU bring good skill-set in technology.

For large companies, an integrated and proactive HR function is critical, together with a mindset whereby HR leaders work with line managers to take ownership for identifying and growing the right kind of talent.

Woes of indigenous R&D

The pressure to reduce R&D development time and cost is on

With the current cost of drug development at $1.3 billion, the pressure is on to reduce R&D development time and cost without sacrificing clinical success rate.

Drug development times, especially the clinical phase, have almost tripled in the last four decades, pushing up development costs sky high. Added to it is the fact that the number of new drugs have not significantly increased despite investment on technology by several pharmaceutical and biotechnology companies. In recent years, drug developers have been under significant pressure to introduce new products while confronting escalating R&D costs, blockbuster patent expiration and heightened regulatory scrutiny.

According to Dr Suresh Menon, CSO, Novartis, â€œThe average drug development time is 10-15 years, clinical trials take half of this time and involves 60 percent of the total cost. To reduce drug development costs by Rs 200 crore, drug developers must reduce the time taken to develop the drug by 20 percent. And in order to save Rs 200 crore, developers would expect a clinical success rate reduction of 20-25 percent, a massive drop considering the success rates are relatively low even with a generous budget.â€?

Making R&D affordable
Although â€œAffordable R&Dâ€? has not traditionally been a concern for biotech and pharma R&D departments, the current economic climate has brought expense reduction programs into research labs. Most leading drug makers have recently undertaken or are in the process of implementing broad cost reduction programs.

â€œMaintaining a high level of productivity is critical for drug makers to successfully continue introducing new products. Many affordable R&D programs fail because they reduce current expenditure at the expense of future drug development. Therefore, broad cost initiatives are required to maintain sustainability,â€? Dr Sami Guzder, R&D head, Avesthagen says, â€œAn important factor influencing R&D cost is the adoption of right technology and science.â€?

Dr Jitendra Kumar, VP, Technology Incubation Center, IKP Knowledge Park, says â€œTechnology Business Incubators's (TBI) should be able to effectively connect start-ups with relevant R&D institutions and established companies to help them achieve synergies within such partnership. Also, TBI's should be able to catalyze product development and spin-offs from national laboratories by providing business mentorship to teams built around technologies developed, effectively reducing cost and enhance value of the R&D.â€?

Aditya Burman, managing director, OncQuest Laboratories says, â€œEfficiency is more important than affordability. Basic collaboration is an essential element in research. In fact, the government has been encouraging it for a while. The political landscape of Indian academia and industry, combined with the fight for grant money, has always fostered competition far more than collaboration. Our scientists hold a lot of good work within themselves. A lot of collaboration is also needed among larger and smaller life science companies.â€?

Dr Ganesh Sambasivam, co-founder and CSO Anthem BioSciences says, â€œThe outsourcing model has become very popular in recent years especially in India and China. India has 75-80 CROs and in China the number is double. For a big company, outsourcing R&D to India brings down their drug development cost by one third.â€?

Drug development alliances are also increasingly being used to leverage resources and cut R&D costs. Drug development

deal values are expected to triple over the next few years as developers seek partners to reduce in-house spending.

IP for effective R&D

Clarity in definitions is the starting point

In the decade to come it will be innovation alone, which will determine a company's competitive advantage over its rivals, its monetary returns and revenues, its bargaining power and further incentives in research for its scientists. Having a powerful tool in the form of an efficient IP management strategy and synchronizing it with the DNA of an organization is a pre-requisite to innovation.

Says a well-renowned IP expert, Shamnad Basheer, â€œThere is no dearth of innovative mind in India. Unfortunately company cultures do not foster an environment to bring that idea to fruition.â€? Barring top MNC companies, Indian companies are new to the IP game plan. â€œHaving a strong IP culture, integrating it in the overall strategy will mean that each and every person involved has the incentive to innovate and invent,â€? adds Basheer.

Effective management of IP
In many cases, the root problem lies in the fact, that scientists are not recognized for their inventions. Says Dr Milind Antani, head, Pharma, Life Science and Healthcare Practice at Nishith Desai Associates, â€œUsually the ownership rights of the invention by a research scientist employed remain with the company and not the individual. Companies need to recognize the individual invention of its scientists in some form. Recognizing such efforts would motivate and encourage scientists to look for innovations.â€? However, this comes about when only when the company has a strong IP management system in place.

â€œOnce you start giving emphasis on IP and its role in strategy planning you are adding value to your discovery, recognize key markets for your products and also catch-up with potential competitors,â€? adds Basheer.

Against this picture, awareness becomes key factor. Says Dr Alka Mehta, IP expert from the Intellectual Property Cell at Cipla, â€œTraining the R&D personnel to understand the patents and its importance in strategy planning for development, frequent discussions with the R&D team to update the IP situation on the products under development, exchange of ideas among R&D, medical, marketing and IP department for new technology and its demand in current and future business prospects and frequent discussions among various departments which are key decision makers for the business is important.â€?

A company needs to be aware of not just their patents but trademarks, copyrights, internal processes, manuals, various technologies and trade secrets as well. â€œEffective portfolio management of IP enhances the competitiveness, assists in becoming a market leader and improves the economic performance,â€? adds Dr Antani. An emerging trend in IP management is patent landscaping which tells a company its next step in R&D. Patent landscaping helps in identifying and analyzing its patent portfolio pertaining to a technology area critical to the business needs.

Once a company has a strong IP in place, its valuation increases. This becomes significant when it comes to commercialization of that IP especially when it comes to licensing, brand acquisition or a company acquisition altogether. Efficient integration of IP will also help a company form a clearer picture of the patentability of its product, the possible infringement situations and most importantly the cost factor involved. â€œAll the teams including the IP team need to sit down together right from the start and evaluate the risk and infringement factors and the strategy to adopt in case of an infringement,â€?claims Dr Kausalya Santhanam, founder-SciVista IP & Comm. It is only then that they can evaluate whether to maintain its IP in certain geographies across the world, whether to allocate or withdraw money for a stipulated number of years.

Efficacy of India's IP regime
With effect from January 1, 2005, India switched from a process patent regime to a product patent regime by which only the product and not the manufacturing process of the product would be patented. Once this was in place, the country saw a surge in research work and clinical trials, a churning out of quality scientists and researchers and most importantly, many MNCs who had shut shop during the process patent regime came back to India and geared up to launch their patented drugs in the market. This resulted in India becoming a prime destination for drug discovery opportunities. â€œMore incentive and business opportunities for Indian companies with R&D base is now available,â€? adds Dr Mehta.

However, there are certain hiccups in the IP regime. Basheer puts in a valid point, â€œI think the system is too complex and needs to be simplified. The patent system should be such that it allows a wider participation of scientists and the common man. Even a layman should be able to evaluate the patentability of his invention,â€? he mentions.

â€œThe system is yet in development phase so it would take some years to give fruits. The NCE policy is yet to be decided plus the Patent Database is not yet created to its fullest extent,â€? agrees Dr Mehta.