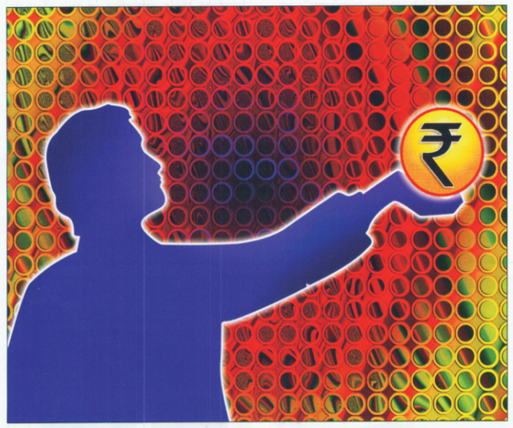
Nanotechnology in life sciences industry

A profitable venture?

Nano Science and Technology Initiative (NSTI) contributed $15 million for the development of nanotechnology over five years. It enabled funding of about 100 research projects, set up six centres for nanotechnology and one for computational materials science across India. With this, does the pharma industry see a lucrative prospect?



Chandreyee Bhaumik

Attempts are being made by the Indian government to speeden new developments in nanotechnology, and several technologies from the laboratories are to be commercialised in this respect. Nanotechnology, an important aspect of biotechnology, is assuming interest, both in the industry as well as in academia. The concept of nanotechnology was proposed and popularised by the noted American physicist, Dr Richard Feynman. It encompasses the ability to arrange and rearrange molecular structures, which aims to bring a change and thereby impact the way everything is manufactured. If we can pack 100 atoms into a cubic nanometre, and each atom can be any of the approximately 100 elements, then there is something like 100^{100} different ways in which we can arrange the atoms in just a single cubic nanometre. However, this is not an easy affair since there is no general consensus that will determine and direct how to achieve this.

In 2007, India had initiated a programme with a budget of $255 million that would aim to promote nanoscience and nanotechnology. Further, several public and private research institutes are working on carbon nanotubes and nanoparticles. Again, it can be said that considering the strategic importance of R&D in this area, the Department of Science and Technology (DST) has been levying tremendous thrust on nanomaterials. The Indo-US joint forum on science and technology has identified this area of research for intense co-operation. Besides, Government of India's Nanomaterials Science and Technology Initiative (NSTI) offers a forum for greater cooperation. As part of this scheme, Government of India has plans to spend ₹ 1,000 crore on R&D in nanotechnology over the next five years.

Coming to the forefront

Nanotechnology is a multidisciplinary field bringing forth a convergence of basic sciences and applied disciplines like biophysics, molecular biology and bioengineering. Commenting on this, K V Subramaniam, President and CEO, Reliance Life Sciences, affirms, "It has impacted various fields of medicine including cardiology, ophthalmology, endocrinology, oncology, pulmology, immunology and highly specialised areas like gene delivery, brain targeting, tumour targeting and oral vaccine formulations. Nanotechnology also provides intelligent systems, devices and materials for better pharmaceutical applications." In the same vein, Subramaniam avers, "Nanomaterials, particularly nanoparticles and nanocomposites, currently dominate the nanotechnology market. The largest end-user markets for nanotechnology are environmental remediation, electronics, energy and biomedical applications." It is also seen that nanotechnology is relevant to the pharma industry. Commenting on the use of nanotech in pharma sphere, Subramaniam continues, "In the pharma industry, application of nanotechnology to provide new drug delivery systems is an emerging area, requiring lesser investment and expected to be a high profit-making proposition. Cancer and central nervous system disorders are the fastest growing application areas. Hence, nanotechnology has generated significant interest in the pharmaceutical industry."

Discussing the scope of nanotechnology in biotechnology, Dr Santhosh Kumar, Medical Advisor, Anglo-French Drugs & Industries Ltd, explains, "Today's highest resolution, the nanoworld, reveals structures inside cells, molecular components of structures and even ongoing processes in living organisms. Nanoscale devices and materials help scientists to interact with a variety of biological events down to the molecular level. These applications benefit life science research, clinical diagnostics, drug development and many other areas."

According to Nanotechnology in Healthcare, a novel study from *The Freedonia Group, Inc*, a Cleveland-based industry research firm, demand for nanotechnology medical products will increase by over 17 per cent per year to $53 billion in 2011. Again, the increasing flow of new nanomedicines, nanodiagnostics and nanotech-based medical supplies and devices into the US marketplace will boost demand to more than $110 billion in 2016.

Elaborating on the current demand, Dr Kumar reiterates, "The critical need for new or improved therapies for many medical conditions will promote the adaptation of nanotechnology to an expanding number of biotechnologically driven pharmaceuticals. The total market for nanomedicines will command strong growth over the long term." Further, he continues, "Treatments based on humanised monoclonal antibodies, nanopolymers and nanoproteins will drive gains, with compounds for cancer, heart diseases, neurological disorders and viral infections leading to new product introductions and growth opportunities. Advances in nanotechnology will also contribute significant improvements to the quality and performance of medical diagnostic products.

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K V Subramaniam
President and CEO, Reliance Life Sciences

This industry is still at a nascent stage and would be driven primarily by the value proposition specific to each end use - engineering, medicine and materials sciences, in particular.

Time for a 'nano' approach

Practical nanotechnology is essentially and significantly the increasing ability to manipulate (with precision) matter on previously impossible scales, thereby presenting possibilities which many could never have imagined - it therefore seems unsurprising that few areas of human technology are exempt from the benefits which nanotechnology could potentially bring. Hence, this science finds applications in almost every field/business/science known.

Dr Mandar Kubal, Consultant Infectious Diseases and HIV Aids, Infectious Diseases and Pulmonary Care (IDPC),says, "The major problems with the medications available today are the bioavailability, solubility, toxicity, lack of targeted drug delivery system, to name a few. Also, for the industry at large, developing a New Chemical Entity (NCE) with the least of the above mentioned problems is time consuming and costly with the probability that it may never be approved for human use in the first place. If by applying the principles and components of nanotechnology, we can convert the negative points of the existing molecules, it would be much cheaper and more acceptable." He further provides a few numbers to show the importance and the scope for this subject. Dr Kubal says, "As far as the international pharma innovators are concerned, many of their top brands are coming off patent by the year end. The losses estimated are around $ 70 – 80 billion due to patent expiry. It would rather be prudent to invest money in nanopharmacy rather than an NCE to cover up the losses. Major corporations are hence investing heavily in nano R&D, to find practical applications for old concerns."

Taking a practical route

This industry is still at a nascent stage and would be driven primarily by the value proposition specific to each end use – engineering, medicine and materials sciences, in particular. Further, nanobiotechnology is being increasingly looked at from the point of view of direct delivery of drugs into the human body. Applications of nanobiotechnology are widespread. Dr Kubal categorises the application of nanotech in pharma arena. He discusses, "The major applications of the technology in pharma industry lie in smarter drug delivery systems, smart material for tissue engineering and also

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smarter diagnostic materials. Using this concept there is a possibility that many molecules that never progressed in clinical trials due to safety issue might see the light of the day and thus be available for clinical use. The dried up pipeline of drugs for many medical illnesses may suddenly find a lot of nano pharma gushing out of it."

This is one of the major areas of focus in the current environment. It involves using nano systems to deliver a particular dose of drug to the target. Dr Kubal clarifies this point and reiterates, "It may be a smarter drug delivery system of an older drug, e.g., Liposomal Amphotericin B, which is Amphotercin B delivered using a liposome as the vehicle and hence facilitating higher drug concentrations at relatively less nephrotoxicity than the conventional drug. Such preparations are now commercially available in India as generic versions too." Smarter drug delivery may also involve targeted drug delivery to the intended target organ/cell only thereby preventing unintended damage to nearby tissue and hence definitely the side-effects. Dr Kubal says, "One of the major areas where this is utilised is delivery of chemotherapeutic agents to the tumour cells only in case of cancers."

Aradhana Dixit, Senior Product Manager, Plethico Pharmaceuticals Ltd, believes that nanotechnology, biotechnology together with Information Technology(IT) can do wonders. Discussing the practical use of nanotechnology, she affirms that it can be extensively used for medicines. She opines, "Nanotechnology in medicine is currently being developed and involves employing nanoparticles to deliver drugs, heat, light or other substances to specific types of cells such as cancer cells."

Quick picks

Nanotechnology is enabling new applications in the areas of molecular imaging and early detection, in vivo imaging, reporters of efficacy, multifunctional therapeutics and research tools.

Pharma taking the front seat

The key benefit of nanotechnology in the pharma industry would be in the area of novel drug discovery as well as developing novel devices for treatment of various diseases. Discussing the advantages in this context, Subramaniam asserts, "One example of current nanobiotechnological research involves nanospheres coated with fluorescent polymers. Researchers are seeking to design polymers whose fluorescence is quenched when they encounter specific molecules. Different polymers would detect different metabolites. The polymer-coated spheres could become part of new biological assays, and the technology might someday lead to particles, which could be introduced into the human body to track down metabolites associated with tumours and other health problems. Again, another example, from a different perspective, would be the evaluation and therapy at the nanoscopic level, the treatment of Nanobacteria as done by NanoBiotech Pharma."

Dr Kumar avers, "By 2016, nano implants will be widely employed in orthopaedic procedures and begin to gain experimental uses in tissue and neuron regeneration. By 2021, nanotechnology will serve applications that extend into most areas of critical and chronic care. Additionally, the development of monoclonal antibody and nanomaterial vaccines and, to a lesser extent, controlled-release nutritional preparations will create a large preventive medicine market."

While discussing the use of nanotech in the field of pharma, Dr Kumar opines, "The application of this patented nanotechnology enables the realisation of pharmaceutical forms that were up to now impossible. That means complex and cost-intensive manufacturing processes are needed to make these drugs available for the therapy." In this context, he adds, "With the help of the patented nanotechnology, they are able to convert the drugs, which were previously available only in parenteral form, into, eg, oral administration

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Advances in technologies, such as DNA microarrays, micro electromechanical systems and micro fluids, will enable the realisation of the potential of nanotechnology for food applications.

Aradhana Dixit
Senior Product Manager, Plethico Pharmaceuticals Ltd

forms. This signifies a huge progress for the patient's quality of life." Therefore, it can be said, by utilising this new technology, customers can receive the benefits that were till date hardly possible. Nanotechnology is able to reduce manufacturing costs, and improve the specificity and the effectiveness of the drug, moreover, the ability to reduce the side-effects of therapy.

Although still far from a cure, the area of healthcare where nanotechnology has made its greatest contributions is cancer. Nanotechnology is enabling new applications in the areas of molecular imaging and early detection, in vivo imaging, reporters of efficacy, multifunctional therapeutics and research tools.

Significant achievements by Indian pharma industry so far by using nanodevices are:

- Development of one dose-a-day ciprofloxacin using nanotechnology
- Tumour-targeted taxol delivery using nanoparticles in Phase II clinical trial stage
- Improved ophthalmic delivery formulation using smart hydrogel nanoparticles
- Oral insulin formulation using nanoparticles carriers
- Liposomal-based Amphotericin B formulation

Delving deeper

It can be said that one of the main goals of using nanotechnology for medical purposes is to create devices that can function inside the body and serve as drug delivery systems with specific targets and cancer detector.

In this regard, Dr Kumar establishes, "Current treatments for cancer using radiation and chemotherapy are invasive and produce debilitating side-effects. Nanotechnology has the potential to treat various forms of cancer by targeting only the cancer cells. Researchers at Rice University have developed a technique utilising heat and nanoparticles to kill cancer cells."

Investment patterns

Several Indian companies have already made the required moves to compete with multinationals. Therefore, they have begun to invest intelligently into R&D. Dr Kumar opines, "Ranbaxy, Torrent, Wockhardt, Dr Reddy's Laboratories, Sun Pharma and Piramal Healthcare etc together have made capital investments of over ₹ 200 crore. Cadila Healthcare, Cipla, Lupin and Aurobindo are making similar investments. By the end of the first decade of this millennium, the total investment into R&D will be to the tune of ₹ 500 crore."

While commenting on the investment pattern, Shruti Pande, Clinical Research Associate, International Clinical Research, Wockhardt Ltd, avers, "As with any new development, there are sceptics abounding on the fringes of nanotechnology. The science's real potential will take many years to come to fruition, but in the meantime much of the research is being hyped up. The true extent to which many of those becoming involved are there for the long haul, and an investment in nanotechnology is for the long term."

Helping hand from Government

The Government has been at the forefront of promoting nanotechnology industry in India through its three major funding agencies, namely Department of Science and Technology (DST), Department of Scientific and Industrial Research and Department of Biotechnology. DST launched the Nano Science and Technology Initiative (NSTI) in 2001 under the leadership of Prof. C N R Rao. Dr Kubal says, "Its aim is to make India a major player in this sector, and provided a total of $15 million for nanotechnology over five years. The NSTI funded about 100 research projects, and provided funding for setting up 10 core groups in nano science, six centres of nanotechnology, and one of computational materials science at different institutions across India. DST remains by far the largest funding agency. Government spending in nanotechnology through all its funding agencies amounted to less than $20 million in 2003-04 out of total R&D expenditure of about $3.03 billion (0.8 per cent of GNP of India). According to government figures, the government has spent approximately $50 million over the past five years to promote R&D in the area of nanotechnology.

Surviving the competition

Nanobiotechnology is a novel sector and among other challenges funding is an issue. As Subramaniam says, "Public sector funding is increasing in this area. Big pharma companies have so far been lukewarm to investing in these technologies. This may be overcome by industrial collaboration, consolidation and licensing agreements between nanobiotech players, government institutions and pharma/biotech companies."

Further, market development is taking time due to lack of regulatory guidelines and public concern over the potential health and environmental impacts of manufactured nanoparticles. Subramaniam explains, "There are some

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ethical, scientific, social and regulatory issues posing various challenges in practical realisation of pharmaceutical nanotechnology. Some major health risk associated with such devices includes cytotoxicity, translocation to undesired cells, acute and chronic toxicity; unknown unpredictable and undefined safety issues, environmental impact of nanomaterials and non-biocompatibility." Explaining the concerns in detail, he says, "Some ethical issues are altered gene expression, ultimate fate and altered or permanent anomaly in cell behaviour/ response on short/long term exposure. There are no specific Food and Drug Administration (FDA) directives to regulate pharmaceutical nanotechnology-based products and related issues."

Rulebook details

The notion that companies must innovate to survive has become more commonplace as competitive pressures and economic volatility define the business landscape. Dr Kumar shares his opinion in this regard. He says, "For challenges affecting the nanotechnology industry, three general categories are intellectual property issues, regulatory issues and pharmacovigilance. Combined, these have the potential to create a perfect storm for the industry if not properly addressed."

Intellectual property assets are the lifeblood of companies in all industries. Dr Kumar reiterates, "By 2011, the pharma industry faces the potential loss of approximately $70-$80 billion of drug revenues as various blockbuster drugs go off-patent." He cites several critics' opinions and says, "Critics argue that Big Pharma either fell asleep at the wheel by not building nanotech capabilities early enough or that they were more focused on shareholder profits than on innovative therapies. As a result, some are even changing their business model to include outsourcing of various functions to stay competitive." This is where leading biopharma or specialty pharma companies may have a slight advantage. In particular, those focused on nanotech-enabled discovery, development or platform technologies that increase benefits while reducing costs are now in a position of strength for licensing, outsourcing or other collaborative opportunities with Big Pharma. The challenge for Big Pharma will be to swiftly adapt to a new business model that has the right balance of in-house and outsourced processes. They will also need to make efficient use of resources to identify and incorporate nanopharmaceuticals and processes into their pipeline. This will be virtually impossible for companies that have cut their tech-scouting staff and risked giving away cheap buying opportunities to competitors. The challenge for small/medium biopharma and specialty pharma will be to figure out the best way to get on Big Pharma's radar.

Discussing the regulatory issues, Dr Kumar cites a study and says, "With regard to regulatory issues and pharmacovigilance, safety and toxicity concerns continue to mount. An estimated $147-billion worth of nano-enabled commercial and consumer products were sold in 2007 and this amount it predicted to top $3.1 trillion by 2015, according to Lux Research, a market analyst firm."

Binocular vista

This segment holds an immense potential. Subramaniam says, "Nanotechnology industry is currently estimated to be around $ 12 billion globally. It is expected to grow multifold over the next ten years."

While discussing the future scope of this segment, Dr Kumar says, "Nanotechnology also has the ability to get us closer to personalised medicine. Targeted therapeutics with smart drug delivery devices and theranostics will drive this trend forward. On the surface, these two trends are not likely to have a favourable impact on pharma's current business model, but they could if pharma adapts its business model to align more closely with scientific and market trends. The market will demand these technologies based on benefits and costs as compared to today's alternatives. Areas of nanotechnology advances with a direct benefit to pharma and biopharma are those that will not only further improve efficacy and reduce side-effects of existing drugs, but that will enable a faster discovery process to eliminate non-efficacious drugs much earlier and with less investment."

Thus, in this regard it can be said that the companies that have decided to outsource these upstream processes will still need to understand what they are dealing with and incorporate the necessary processes and collaborative efforts with regulatory agencies to move the product along the development pathway.

In short, it can be considered that recent development, market realisation of various pharmaceutical nanotools and global interest shown by scientists, governments and industries ensure that there is tremendous potential and scope of nano-based drug delivery system in the near future. In this strain, Dr Kumar categorises, "There is no doubt to presume that in next ten years market will be flooded with nano-enabled delivery devices and materials." MPh

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