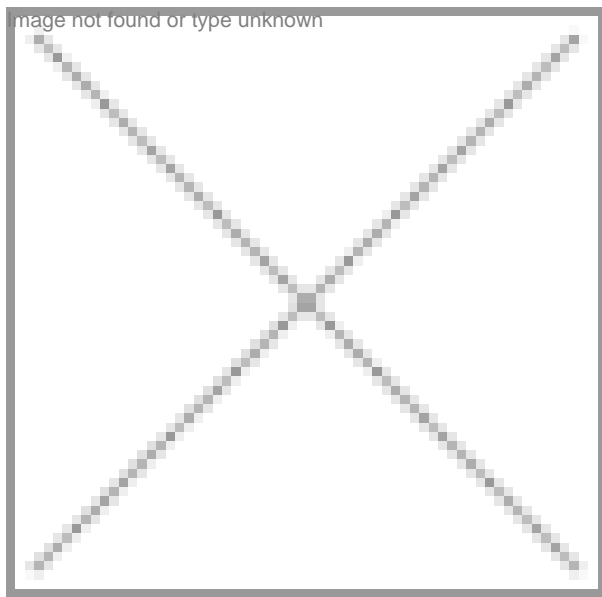


## Leveraging Nanobiotech Applications

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From enabling the delivery of engineered drugs to specific target tissues to multiple possibilities in stem cell research, nanobiotechnology is certainly the key to the future. Several researches in nanobiotechnology are going on in various research institutes, but the lack of efforts in conversion of basic research to product development,

“I think, we are still in infancy. Though nanocoated anti-cancer drugs like Doxil have been in clinical application in the US, we have not heard of any such breakthrough from India in the drug discovery field,” says Dr Samuel JK Abraham, director, Niche-in Center for Regenerative

Dr Anita Goel, CEO, Nanobiosym, says, “Medicine and nanomaterials may provide some of the first low hanging commercial fruits from nanotechnology. In medicine, for example, nanotechnology is enabling novel diagnostic as well as new approaches to therapy and drug delivery. In nanomedical diagnostics, I envision the impact of this technology to be somewhat similar to the cell phone industry. We saw a

paradigm shift in the telecom industry when computing and communications devices became portable. Likewise, I believe that we will see a similar shift in healthcare when the ability to detect and diagnose disease can be taken out of pathological labs and put in the hands of doctors, nurses, and healthcare workers. Well, at least this is the motivation and vision behind

our GeneRadar technology platform.â€?

Another major impediment to the sector comes from the long wait for the regulatory approvals. Therefore, the clear set of guidelines and regulator is required for this particular sector. Dr Jitendra N Verma, MD, Life Care Innovations, Gurgaon, says, â€œI really don't see much progress in the nanobiotech sector as far as commercialization is concerned. The conventional approach often leads to the hampering of approvals and sometimes the opinions may also be misguided. Eventually, this leads to the patent life being eaten up. The regulatory committees should understand this.â€? But, despite having a humble beginning, this technology is expected to replace the existing technology in a big way.

Dr VK Tripathi, CEO, Virtus Technoinnovations, Mumbai, terms the nanobiotechnology as 'disruptive technology'. While citing reasons for using that term, he says, â€œThis is a very powerful technology that will revolutionize the entire industry, but, at the same time, it will upset the entire Rs 11.26 lakh crore (\$250 billion) spa industry because of the cost-effectiveness that comes with it. It will certainly lead to replacing of the conventional methods by more effective ones.â€?

### **Recent trends in research**

The researchers have exploited the unique properties of nanomaterials for various applications including cell imaging and therapeutics for treating cancer. The size of nanomaterials is similar to that of most biological molecules and structures; therefore, it is used for both in-vivo and in-vitro biomedical research and applications.

The research by scientists at the Banaras Hindu University and the India International Advanced Research Center for Powder Metallurgy and New Materials has shown that silver nanoparticles show 'immense potential' in the prevention of blood clots. The scientists consider their discovery as an alternative to aspirin and other anti-platelet agents currently used to prevent blood clots in coronary artery disease, heart attack and stroke that often cause dangerous bleeding. Nanosilver appears to possess dual significant properties of being antibacterial and antiplatelet, with unique utilities.

Virtus Technoinnovations has developed a patented technology on Gene Repair Therapy (GRT) to stimulate dormant genes in an attempt to cure diseases like cancer and AIDS. The company is the first in India to develop a resveratrol formulation having a half life of three hours, slow release from intestine and non-trace amounts of upto 53nmols/L.

â€œIn one case we got even 40,000nmols/L of free resveratrol. Our formulation is a plant produce neither synthetic nor a plant extract and is free of heavy metals. We hence got a FDA manufacturing license as a nutrient product. Our excitement really rose because amongst large number of proven benefits of free resveratrol, one was that free resveratrol was toxic to cancer cells and protective to healthy cells during in-vitro and in-vivo animal studies.â€?

NCRM has successfully accomplished the in-vitro expansion of hematopoietic stem cells of human origin and from primates using such scaffolds. In the near future nanosurface coated human autologous fibroblast culture is likely to revolutionize the facial wrinkle treatment. At the moment conventional method of fibroblast culture is used to support the facial anti-wrinkle treatment in Japan which is gaining popularity. NCRM is working on enhancing the fibroblast culture work by using appropriate nanobiotechnology.

Another area of potential application will be in dental stem cells. In animal studies, corneal surface damages have been repaired using dental stem cells using temperature sensitive nano-coated surfaces.

â€œNCRM is planning to take this to clinical studies. These proven applications using our expertise where in three dimensional culture of corneal limbal stem cells have been accomplished by our team jointly with Sankara Nethralaya,â€? clarifies Dr Abraham, Life Care Innovations is doing pioneering work in developing nanobiotech products. The company has developed a nano drug for tuberculosis that is going to have global implications under the project funded by the Department of Science & Technology (DST), Government of India.

â€œThe clinical studies have been completed and now we are waiting for the Drug Controller General of India's approval. The three formulations have been already approved and the fourth one is waiting for the approval,â€? informs Dr Verma.

â€œThese studies were carried out in collaboration with the University of South Africa, and CSIR in South Africa. What makes this drug unique is that in comparison to the general DOT program where drug is taken everyday, it will have to be taken thrice a month only. The results of phase II clinical trial are awaited by the South African Medical research institute for the release of the drug in their country,â€? adds Dr Verma.

Mumbai-based NanoBio Chemical, which was founded in 2006, focuses on nanobio applications in textiles and also the customized synthesis of complex peptides and biochemical solutions.

### **Biotech company Bharat**

Biotech is developing a novel topical oestrogen hormone replacement therapy and the New Delhi-based Panacea Biotec is working on novel drug delivery research using mucoadhesive nanoparticles.

DNA is the natural nanoscale material that carries the genetic information. This quality makes it an obvious choice for the researchers working in nanobiotechnology. Therefore, a lot of research is being done in this field by taking the DNA as the base molecule and the availability of novel techniques simplifies the study process.

There have been many new developments related to nanobiotechnology applications in the field of diagnostics as well. The Defence Research and Development Organization (DRDO) has developed diagnostics tools for TB and typhoid, using nanobiotechnology. Gene-Radar developed by US-based Nanobiosym, is a mobile phone like device in which a small drop of blood, saliva or water is placed. The machine can then display what disease the person has. It detects signatures of DNA and RNA as well.

The commercialization of Nanoxel, an injectible vial for dispensing the cancer drug paclitaxel, by Dabur in India and abroad has also opened doors to various possibilities. Nanoxel is a cremophor-free polymeric nanoparticle formulation of Paclitaxel with no hypersensitivity reactions, which allows administration to patients without pre-medication as is required with Cremophor paclitaxel.

### **Revenue support**

The funding for nanotechnology applications is largely from DSIR, DST and DBT. The Nano Science and Technology Initiative (NSTI) by DST in 2001 under the leadership of Prof. CNR Rao allocated Rs 1,000 crore (\$250 million) for nanotechnology research from 2007.

Also a Mission on Nano Science and Technology (Nano Mission) was launched in May 2007, to foster, promote and develop all aspects of nanoscience and nanotechnology, which have the potential to benefit the country. Recently in the budget for 2010-11, Indian government has increased the funds for the Nano Mission from Rs 70 crore to Rs 100 crore.

“At the early stages when you are doing fundamental scientific research, government can be an ideal investor in promoting the basic science and technology agenda. As the innovation starts to get closer to commercialization, then venture capitalists and private equity players have a unique role to play to commercially scale up a technology and to capture market share,” opines Dr Goel.

However, the lack of specific allocation of funds for the R&D in nanobiotechnology sector seems to hamper the growth of this sector. “There is a need for the allocation of funds separately for nanobiotechnology and specifically for the product development and clinical trials. Then only we can see some visible progress in this field,” suggests Dr Verma.

### **PPPs and nanobio products**

Nanobiosym is planning to set up multi-purpose nanotechnology innovation parks, the first-of-its-kind in India. Gujarat and Himachal Pradesh have signed MOUs with the company to establish the NanobiosymTech Park in India.

While commenting on this Dr Goel says, “For truly game changing technology platforms, I think the public-private partnership mechanism is an ideal way to bring disruptive technologies into market. For example, a developing country would have to spend huge amounts to develop its healthcare infrastructure to be at par with the developed world. But, by investing in game changing technology platforms like the cell phone or our Gene-Radar nanoscale molecular diagnostic platform, governments can drive technological change and leapfrog their healthcare delivery capabilities, because they do not have to build out the same overhead infrastructure that is required by the conventional technology platforms.”

NCRM has been working on close to 240 different nanomaterials and technologies in specialties such as ophthalmology (corneal regeneration), orthopedics (cartilage injury repair), and hematology (expansion of hematopoietic stem cells). This has been made possible because it is an Indo-Japan joint venture organization and has an access to collaborators technological strength in terms of both nano products and processing methodologies.


“Though we have got two projects funded by the government bodies through our collaborators; one with Institute of Pathology, Indian Council of Medical Research, New Delhi, and other with Sri Ramachandra University, we usually go for such fundings after filing IP rights,” shares Dr Abraham. “We are also collaborating with public institutes such as IOP-ICMR, Anna University-KBC, and Tanuvas. But, the PPP initiative in India has to be given more emphasis, and it has to be result oriented as well,” he further adds.


Life Care Innovations has partnership with PGI Chandigarh, Punjab University and IIT for the development of nanoliposomal drugs. However, Dr Verma feels the need for more partnerships between the academia and industry in this particular sector to get enough products in the market. “The research going on in the academic and research institutes has not reached to

the manufacturing stage and it gets lost there only due to lack of coordination between the public and private sector," observes Dr Verma.

Mumbai-based company, Nanocutting Edge Technology, has been doing a lot of innovative projects related to nanobiotechnology, in partnership with Agharkar Research Institute, Pune. Nanobiotechnology is projected to play a critical role in patient-specific therapy; however, this transition will depend heavily on the evolutionary development of a systems biology approach to clinical medicine-based upon technology analysis and integration.

As Dr Goel says rightly, "There is certainly a lot of buzz out there about nanotechnology and thus one has the additional burden of proof to separate fact from fiction and the real applications from the far-off ones."

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**Rahul Koul and Jahanara Parveen**