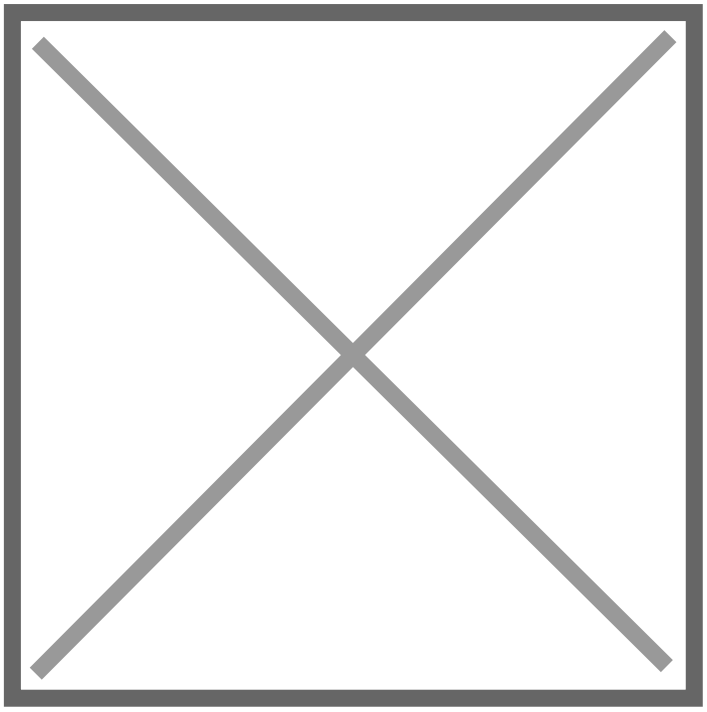
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Game Changers in Drug Discovery & Development: BioSpectrum Technology Forum 2011 Ã¢â?¬â?? Bangalore & Mumbai

14 November 2011 | News



After the thumping success of the BioSpectrum Technology Forum (BSTF) in Goa in 2010, BioSpectrum takes the event to two cities - Bangalore and Mumbai - in 2011

What is BSTF
Every year, BioSpectrum brings together research heads and scientists of biotechnology and pharmaceutical companies on a common platform to enable industry leaders to interact and share their views and opinions.

The BioSpectrum Technology Forum was taken to two cities this year to make it more accessible to delegates. While the first leg of the event was held on September 21 at Chancery Pavillion in Bangalore, the second leg was held on September 23 at Leela Palace in Mumbai. West Pharmaceutical Services sponsored the Mumbai event.

Elaborating the vision of the BSTF and role of BioSpectrum, Mr Narayanan Suresh, group editor, BioSpectrum, said in his welcome address, Ã¢â?¬Å?BioSpectrum mirrors the views of the industry and works closely with its leaders. Earlier, we were involved in policy advocacy and regulatory change campaigns. We then looked at moving to the next level and we did this by organizing events such as the BSTF that encourage interaction with industry leaders at different levels.Ã¢â?¬?

The theme of BSTF 2011
The theme for this year's forum was 'Game Changers in Drug Discovery & Development'. This topic was covered with five sessions - 'Next Generation Innovation', 'Computer-aided Drug Discovery', 'Strategies to Strengthen the Drug Pipeline' and 'Strategic Outsourcing of Drug Discovery: How to Leverage the Opportunity'.

Bstfsuresh	Drug discovery is an exciting area. In our BioSpectrum Asia-Pacific CRO Survey, many indicated that they will focus on drug discovery in the years to come and will send their work to Asia **Mr Narayanan Suresh** group editor, BioSpectrum

Session I:
Stem Cells & Gene Therapy

Panelists
Bangalore: Dr Rakhi Pal, scientist, Advanced Neuro-Science Allies, Mr Ambar Rao, director, Cryo StemCell and Mr Narayanan Suresh, group editor, BioSpectrum (moderator)
Mumbai: Ms Dipta Chaudhury, program manager, pharma and biotech practice, South Asia and Middle East, Frost & Sullivan

(moderator); Dr Milind Antani, head of pharma & life sciences, Nishith Desai Associates; and Dr Chandra Vishwanathan, head, regenerative medicine, Reliance Life Sciences

Dr Rakhi Pal**Dr Rakhi Pal,** scientist
Advanced Neuro-Science Allies

A lot of animal and clinical trials are available to prove their proliferation capacity. Scientists have tagged stem cells that were injected to show that neural stem cells from the injected site migrated to lesion site. Using imaging techniques, they have shown that the injected stem cells differentiated into astrocytes and neural cells. Parkinson's disease animal studies have shown increase in dopaminic output, and in vitro studies have shown that mesenchymal stem cells can differentiate into dopamine terminals and release dopamine.

Mr Ambar Rao**Mr Ambar Rao,** director
Cryo StemCell

When we started cell banking, the level of understanding among the clientele was very poor or did not exist at all. Other challenges we faced were the logistics and regulation troubles. Over a period of time, we were able to establish a good stream of revenue with an increase in the number of clientele banking stem cells. Recently, we successfully transported stem cells for transplant to the Gujarat Cancer Research Institute. The sample was shipped in liquid nitrogen. We follow stringent norms in handling our products and we have, so far, done around 80-odd transplants for liver cirrhosis, myocardial infraction and other conditions where our application was put to use.

Dr Chandra Vishwanathan**Dr Chandra Vishwanathan,** head
regenerative medicine, Reliance Life Sciences

Science is changing and so is our understanding (of it). It was presumed that stem cells of the brain and the liver did not have regenerative qualities but now they are found to have such capabilities but in limited capacities. This provides some hope. The period between 1985 and 2002, known as the regenerative period I or phase- I, was dominated by the US because of excessive funding. Phase-II is the period after 2002 when stem cell research moved beyond the US to countries in Asia, such as Korea, Japan and India. It clearly shows that we are maturing in our understanding of stem cell, countries are investing in this field and governments are taking interest in funding.

Dr Milind Antani**Dr Milind Antani,** head of pharma & life sciences
Nishith Desai Associates

There is no law in India. There are guidelines that are not binding on the company or an individual. It is left to them to follow the guidelines. As far as the concept of informed consent for clinical trial participants or the receiver of stem cell therapy goes, it should not be just a piece of paper but should hold significant importance in India. This is a challenge and is often ignored by doctors in India.

Should India shy away from stem cell research for lack of regulations?
Panelists suggested the contrary and said India should be engaged in more research and the absence of a proper regulatory framework should not be a hindrance to commence future research work in the field. Too many rules will throttle research was the opinion.

Session II:

Next Generation Innovation

Panelists
Bangalore: Dr Pradip Majumder, CSO, Mitra Biotech; and Dr Binay Panda, chief officer and head, Ganit Labs

Mumbai: Dr Pradeep Nagalkar, head-quality control, Haffkine Bio-Pharmaceutical

Mr Pradip Majumder**Mr Pradip Majumder,** CSO
Mitra Biotech

By 2030, 11 million people will die of cancer, which means every year a population the size of Bangalore or Delhi is dying. We need to have some technology or device that can tell us which is the best way to select a particular medicine for a particular patient. At Mitra Biotech, we have developed Oncoprint, a technology that predicts the outcome of a particular medicine on a particular patient. We can predict whether a particular drug is functional, not functional or partially functional. We can also predict the functional, pathological and genetic outcome. But of course innovation to application is not a one-day thing, it is a marathon.

Mr Binay Panda**Mr Binay Panda,** chief officer and head
Ganit Labs

Today, we have the ability of using next generation sequencing to actually capture and study each step of the central dogma to interrogate and analyze it. We do not have to create new drugs, we have to reposition the drugs that are already in the market. The big pharma companies are repositioning drugs by using pharmacogenomics model. Bioinformatics is the buzz word in India. We need to analyze the genome which is relevant to the efficacy of the drug or come up with a complete different methodology to target a different pathway that was absent before.

Dr Pradeep Nagalkar**Dr Pradeep Nagalkar,** head-quality control
Haffkine Bio-Pharmaceutical

It is only in the last two to three decades that novel technologies in vaccines, such as conjugation, recombinant technologies and virus-like particle methods, were developed and found to be successful. The industry is likely to change dramatically over the next five to 10 years as many promising innovative technologies will reach the market. Adoption and application of new technologies must be driven by their ability to generate revenues and contribute to growth of a business by meeting important unmet needs. Technologies such as DNA vaccines, recombinant vectors, and alternative routes of administration address manufacturing, and scalable needs are the way ahead. Naked DNA is both cost-efficient and scalable since DNA can be manufactured rapidly. This approach could be particularly useful as a response to a pandemic outbreak.

Session III:

Computer-aided Drug Discovery

Panelists
Bangalore: Dr Kas Subramanian, CSO, Strand Life Sciences, and Dr Vellarkad N Viswanadhan, head, Department of Computational Chemistry at Jubilant Biosys
Mumbai: Dr Urmila Kulkarni-Kale, information scientist, Department of Bioinformatics, University of Pune; Dr Abhay Jere, associate vice-president, life sciences domain, Persistent Systems; and Dr Chetan Desai, director- operations, Karmic Life Sciences (moderator)

Dr Vellarkad N Viswanadhan**Dr Vellarkad N Viswanadhan,** head, Department of Computational Chemistry
Jubilant Biosys

Chemoinformatics is a critical part of computer-aided drug discovery that plays an important part in target drugability and validation. Early focus on candidate drug likeness properties, like potency and validation, was possible using informatics. Drug modeling has evolved to predict not only the potency in enzymes but also other chemical properties. Computer-aided drug discovery is also making an impact in the biological field, especially in the domain of monoclonal antibodies. Fragment-based drug design approach is what we follow where the idea is to look at the active site of the enzyme and see what specific functionality or groups bind to different targets. This concept is further optimized to give rise to a candidate drug.

Dr Chetan Desai**Dr Chetan Desai,** director, operations,
Karmic Life Sciences

Over the years, drug discovery has seen a paradigm shift and now we see more focus on target-based therapies. Informatics had a critical role to play in the new age of drug discovery.

Dr Kas Subramanian**Dr Kas Subramanian,** CSO
Strand Life Sciences

The way drugs are being developed, cost of every successful drug is rising, while the number of new drugs is decreasing, which is unsustainable. The advantage of simulation is that once you run a simulation in your predictive model, it will tell you how every other sub system is behaving. Just to give an example, we designed a system to predict the impact of different therapeutic doses it shows which dose will have the maximum impact. There will be certain hypotheses that will fall off as a consequence of integrating what you know about the disease and everything else that we already know. There will be cases when you cannot distinguish. At this point, we have to carry both the hypothesis along till we get to the point where distinguishing between them becomes important, but once in this format, it will enable one to distinguish between two competing hypothesis, so we have to manage uncertainty as a part of the process.

Dr Urmila Kulkarni-Kale**Dr Urmila Kulkarni-Kale,** information scientist,
Department of Bioinformatics, University of Pune

Bioinformatics is a young discipline and recently completed 25 years of existence in India. It has bridged the gap between life sciences scientists, physicists and IT professionals.

Dr Kas Subramanian**Dr Abhay Jere,** associate vice president-life sciences domain,
Persistent Systems

We, at Persistent Systems, believe that personalized genomics is the way ahead and the future of science. Next generation sequencing has various applications, which include DNA analysis, Transcriptome and RNA, Metagenomics, Agrigenomics, ChIP and Methylome Sequencing, Small RNA sequencing and bacterial and microbial sequencing.

When we sign MoUs with universities, we organise meetings with students so that they understand the seriousness of the project.

What does the future behold?

Dr Urmila Kulkarni-Kale said, Ã¢â?¬Å?Bioinformatics has become an integral part of the life sciences industry. Immunoinformatics is, on the other hand, growing. As far as funding in both these fields are concerned, there is no problem.Ã¢â?¬?

She said there should be more collaborations between the academia and the industry. She also spoke on game changers in vaccine design and discussed the issues surrounding design and development of vaccines and put emphasis on reverse vaccinology.

Session IV:

Strategies to Strengthen Drug Pipeline

Panelists

Bangalore: Dr Kavita Iyer, COO, InbioPro, and Dr V N Balaji, CSO, Jubilant Biosys

Mumbai: Dr H Sivaramakrishnan, CSO, Piramal Life Sciences; Dr Sanjeev Saxena, CEO, Actis Biologics; and Mr Rajiv Pillai, vice-president, life sciences practice, Ernst and Young (moderator)

Dr Kavita Iyer**Dr Kavita Iyer,** COO
InbioPro

The total share of pharmaceutical market is growing at 21 percent and with many products going off-patent, sales of biosimilar products is estimated to be at $107 billion. Biobetter development is something that we will concurrently do along with biosimilars. There might be this misconception that reduced research and development costs will translate into reduced pricing of the drugs, but that is not the case.

The idea of biobetters is not that they are cheaply priced as they can cost up to 120 percent to 150 percent of the innovator brand unlike biosimilars that are sold at less than 50 percent of the innovator brand.

Dr VN Balaji**Dr VN Balaji,** CSO,
Jubilant Biosys

Target is most important for drug discovery. People have spent billions in accessing targets, many of which companies are no longer in operation or have diversified. Most of the targets discovered so far are from the academia and not the industry, and that too after rigorous research. Need for validated drug targets will help drug discovery. Different validatory targets at cellular level and tissue level with appropriate biomarkers is the goal to find new targets.

Mr Sanjeev Saxena**Mr Sanjeev Saxena,** CEO,
Actis Biologics

Indian biotech is still in its nascent stage. A lot of work is on in Biopharma but in the process we are creating a human resource pool, which is important for the discovery and development of new molecules.

Funding for drug discovery is still a challenge, and there is a dire need for the investor community to change their mindset towards the biotechnology industry. Investors mainly look at RoIs and refrain from investing in biotech because of huge time lines. They need to realize that returns in biotechnology can be huge.

Dr H Sivaramakrishnan**Dr H Sivaramakrishnan,** CSO,
Piramal Life Sciences

Despite a depletion in drug pipeline, in 2010, 28 new entities were accepted by the USFDA. Till June 2011, around 15 NCEs have already been approved by the FDA.

People have realized where they went wrong 15 years ago when research in target-based therapies started and they have made a lot of progress since then. I am confident that the industry will go up in the coming years.

Mr Rajiv Pillai, vice-president, life sciences practice, Ernst and Young

From 2005, the growth of the pharma industry has been tapering. Last year, the F-DA approved 25 products, majority of which were biologics. The prediction is that around 40 to 50 percent of products in the future will be biologics and today, a lot of work on them is taking place.

Collaborations needed

Panelists strongly recommended more industry-academia collaborations in India. A time would come when the Big Pharma would just be involved in phase III and marketing of products, said the panelists. This is where India has an opportunity because the country is home to a rich pool of skilled talent.

Mr Rajiv Pillai mentioned, Ã¢â?¬Å?A lot depends on the way drugs are positioned to the investor community. There are ways and models to align a product pipeline which would appeal to the investor community.Ã¢â?¬?

Session V:

Strategies to Strengthen Drug Pipeline

Panelists

Bangalore: Mr Ajay Bharadwaj, founder, Anthem Biosciences; Dr Ram K H, managing director, SMO Clinical Research; Dr Surinder Kher, CEO-Asia, Ecron Acvunova (moderator); and Mr Mohan Pandey, head, operations and project management, Biocon BMS R&D Center, Bristol-Myers Squibb India

Mumbai: Dr Bharat Doshi, independent clinical research consultant; Dr Arun Bhatt, president, ClinInvent; Mr Apurva Shah, co-founder and group managing director, Veeda Clinical Research; Dr Supriya Desai, associate director, medical affairs and safety management, Diagnosearch; Mr Rajendra Talele, vice-president, Clinical Operations Ã¢â?¬â?? Asia and Europe, Siro Clinpharm; and Mr Sujay Shetty, partner-pharmaceuticals and life sciences, PricewaterhouseCoopers (moderator).

Mr Ajay Bharadwaj**Mr Ajay Bharadwaj,** founder,
Anthem Biosciences

With India and China strengthening their patent laws, there is explosive growth of CROs in these countries.

Understanding the needs of the potential client, creating value for clients, maintaining deadlines and keeping egos out of conversation are prime factors that would help create a successful venture.

The CRO landscape for the next five years will include integrated medicinal chemistry and supporting biology, enabling novel technologies, and the CROs will eventually mature into contract innovation services for survival.

Dr Ram K H**Dr Ram K H,** managing director,
SMO Clinical Research

With an increase in preferred suppliers and with partnerships becoming stronger, joint ventures and real strategic partnerships have increased. Multinational companies have started their ventures and have slowly stratified into different sectors, like data management, with strategic alliances. With our abundant skills and English-speaking ability, we can expect more business opportunities.

Mr Mohan Pandey**Mr Mohan Pandey,** head, operations and project management,
Biocon BMS R&D Center, Bristol-Myers Squibb India

Pharma, along with other industries, will face some challenges, but the point is how we fight this challenge. Countries that have spent more than two percent of GDP in R&D are most prosperous. Innovation will create prosperity, and it is time for innovation to globalize itself. Export-derived income for pharma has been increasing steadily, and R&D outside home-base has increased. Perhaps because of this, the pharmaceutical industry has been able to maintain superior returns compared to others. It is also globalizing, partnering and outsourcing and this has helped pharma companies to maintain good returns on investment.

(The views expressed by Mr Mohan Pandey are his personal views. He attended the event in his personal capacity and was not representing the views of Bristol-Myers Squibb)

Dr Surinder Kher**Dr Surinder Kher,** CEO-Asia,
Ecron Acvunova

There have been public-private partnerships in the last five-to-seven years, especially with the Department of Biotechnology, in creating centers of excellence. The industry has to be forthright and come forward with its innovation and ideas. Although there are job cuts happening in the pharmaceutical industry, there is also outsourcing that is countering this action. The concept of research has to change significantly and that has already started happening. Over a period of time, this domain will change and we are looking forward to it.

Dr Arun Bhatt**Dr Arun Bhatt,** president,
ClinInvent

There are three challenges for India: site, infrastructure and ethics committee support. We need to have a strong pharmacovigilance. This apart, I feel that we have challenges in the form of three 'R's - recession (which has been sorted), regulatory structures and, lastly, publicity by reporters.

Mr Apurva Shah**Mr Apurva Shah,** co-founder and group managing director,
Veeda Clinical Research

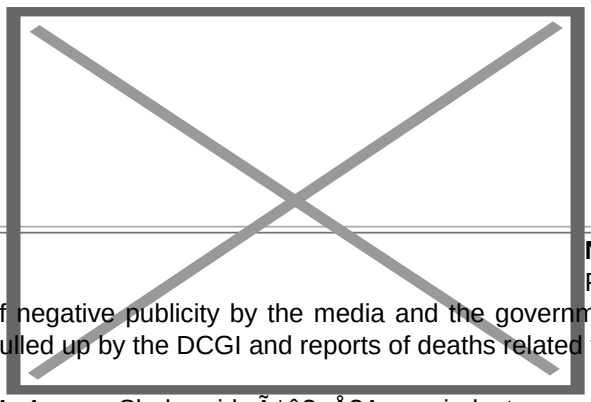
India is on the right path of drug discovery but there needs to be adequate government support in terms of conducive policies and regulatory framework. Indian scientists have a zeal and passion that is different from others. Government policies have killed research in drug discovery in India. The opportunity is in conducting niche clinical trials.

[image_library_tag 922/44922, height="200" width="300" alt="Mr Rajendra Talele," align="left",default]**Mr Rajendra Talele,** vice-president, clinical operations Ã¢â?¬â?? Asia and Europe,
Siro Clinpharm

India has a huge talent pool and I feel the opportunities lie in support services required for clinical trials, like medical writing, statistics and data analysis.

Dr Supriya Desai**Dr Supriya Desai,** associate director, medical affairs and safety management,
Diagnosearch

There are opportunities in medical writing for defining protocols, benchmarks and standards for India. There is a dearth of medical writers in the country and we need to train more people. India is losing out on development of new treatments, IP knowledge, new drugs because early phase clinical trials are not allowed in the country. Also, the regulators needed to be trained and that they needed to realize the companies' loss of face due to delay in approvals for trials.



Mr Bharat Doshi,
independent clinical research consultant

The present scenario in India poses some good opportunities for India but the challenges are many. Regulations are a challenge and there needs to be improvisation of the type of trials. I see a lot of opportunities in conducting trials for niche therapeutic areas.

Negative publicity for CRO industry

Panelists were of the view that the CRO industry has become the target of negative publicity by the media and the government. This was in the light of pharmaceutical and CRO companies being pulled up by the DCGI and reports of deaths related to clinical trial appearing in the media.

Mr Apurva Shah said, Ã¢â?¬Å?As an industry, we are not doing anything. Association on Clinical Research Organizations (ACRO) is in talks with the government to put things into perspective.Ã¢â?¬?

Prev | Next

Concluded
Nayantara Som in Mumbai and
Romi R in Bangalore