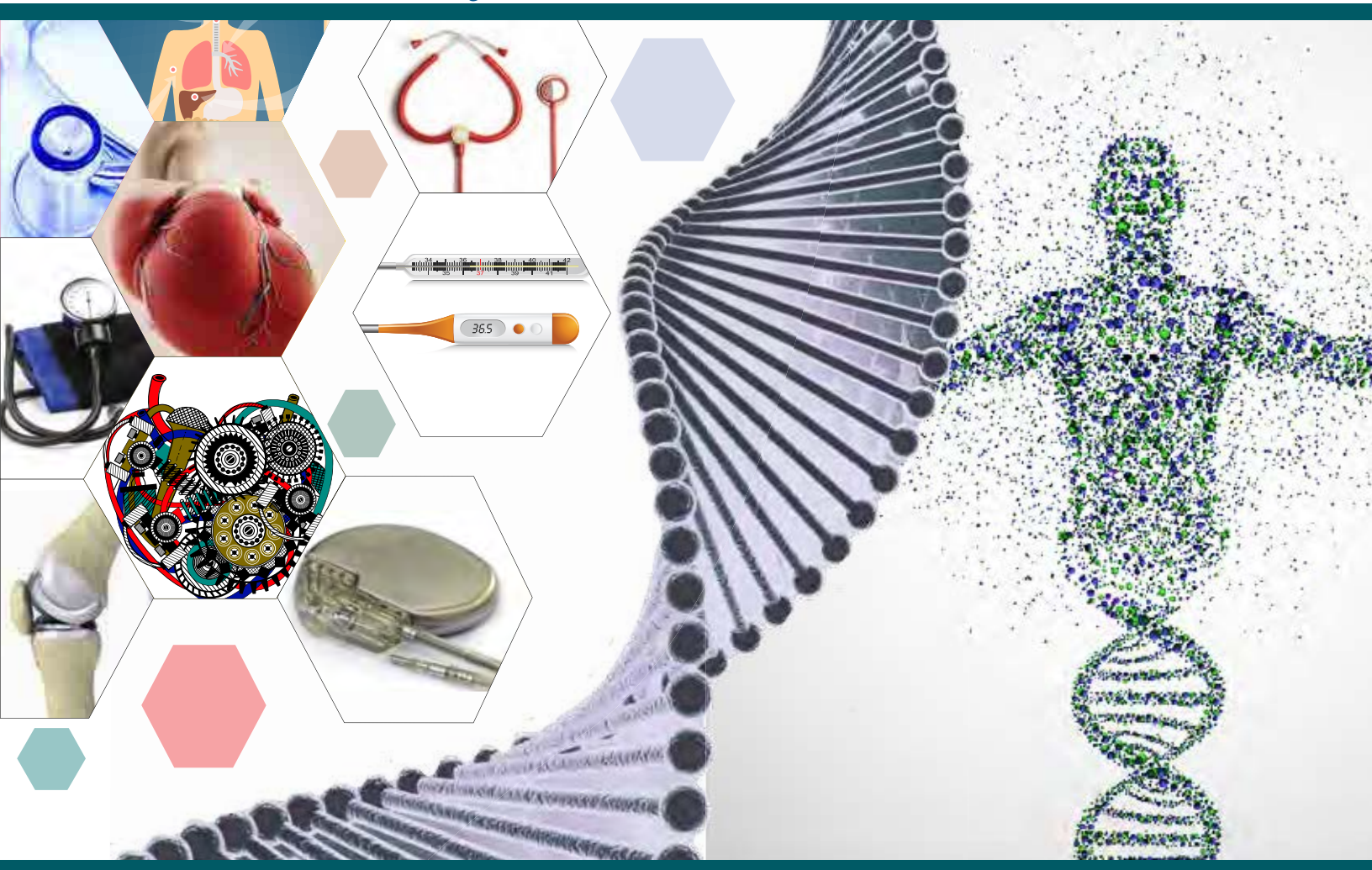
birac i3

Ignite • Innovate • Incubate



Promoting MedTech Innovations

Quality, Affordability and Accessibility

birac
Ignite Innovate Incubate
Biotechnology Industry Research Assistance Council
(A Government of India Enterprise)

June 2015

No. 2 | Vol. 2

chief editor's take

It is with great pleasure we present before you the 6th edition of the BIRAC Newsletter. Through BIRAC we have made an attempt to present before you the latest updates on the Biotech Innovation Ecosystem for the latest Innovation Research, to new financing opportunities and other Ecosystem Drivers and Enablers such as Infrastructure, access to research resources, Network and new collaboration opportunities. Each newsletter focuses on a special theme of relevance.

In this issue of BIRAC, we focus on the Medtech sector. Medtech is an important component of the Indian biotech-healthcare ecosystem and in the last 5 years we have noticed increasing interest in young start-ups to ideate for product development in this domain.

Product development in Medtech sector involves unique challenges that require access to engineering tools and prototyping facilities. BIRAC is aware of the needs of the medtech community and we have put together a comprehensive set of mechanisms to de-risk product development in medtech, be it through early stage funding or medtech focused incubators as well as focused partnerships on Medical Electronics with Deity and TB Diagnostics with USAID and IKP. Many of our early stage funding especially under the Social Innovation Immersion Programme (SIIP) also attracts multidisciplinary teams that ideate to bring medtech products to bridge gaps that they identify. Through our late stage funding programme – BIPP, we have also supported many medtech product's development be it hand-held devices or other high end instruments that aid in oncology.

BIRAC's endeavour is to foster and facilitate an optimal ecosystem for medtech in the country such that we are able to alleviate the healthcare challenges of the country and beyond.■

Renu Swarup
Managing Director, BIRAC &
Senior Adviser/Scientist 'H', DBT, Govt. of India

in this issue

Design, Production and Circulation
AFE Consultants Private Limited
Aravali House, 431/D-22, Chhatarpur Hills
New Delhi-110074
India

Medical Devices & Diagnostics Sector

Seizing the Opportunity

The economic growth of a nation is closely intertwined with the health of the nation. Medical Technologies (Medtech) play an important role in keeping any society healthy through rapid detection and prognosis of diseases especially aiding clinicians in accurate diagnoses and rapid point-of-care decision making. India faces healthcare challenges both in infectious and chronic diseases, for instance on one hand India has a quarter of worlds' TB patients while on the other it is a global hotspot for diabetes. To surmount these challenges we need to build high quality and affordable solutions.

More than 70% of medical devices and diagnostics in India are imported, highlighting the opportunity to create an indigenous medtech industry built upon innovative R&D. BIRAC is focused on fostering and making India an innovative product nation especially in healthcare. In the last few years we have seen an effervescence of biotech start-ups including those in the medical technologies (medtech). BIRAC's BIG and DBT's Stanford India Biodesign have played an important role in seeding many of these medtech start-ups. Many of the medtech start-ups have now transitioned into receiving follow on funding for manufacturing scale.

Innovation in medtech industry needs interdisciplinary expertise especially in the fields of hardware (including embedded systems), software, engineering design, biology and chemistry. The needs of medtech start-ups & SMEs are not only funding but importantly access to engineering laboratories (or tinkering labs) that provide tools such as 3D printers, microfluidic etchers for prototyping and clinical feedback.

BIRAC has focused on building an ecosystem for medtech in the country. Our funding, as mentioned before, has spurred several medtech start-ups and we have created focused medtech incubator at IIT Madras Research Park. We have also launched a focused call on medical electronics in partnership with DeitY (Department of Electronics & Information Technologies), Ministry of Communications & IT, Government of India. The collaborative initiative will provide further impetus to the medtech industry in the country.

Our future strategy to strengthen medtech in the country would involve strengthening existing programmes and providing mentorship and access to technologies to medtech startups & SMEs. Further we will seek partnership with national and global agencies in this field.■

Prof. K. VijayRaghavan
Chairman, BIRAC & Secretary, DBT, Govt. of India

3rd BIRAC FOUNDATION DAY

Focused on Make in India

In March 2015, **BIRAC** complete 3 years of its journey towards enabling and empowering the Biotech Innovation Ecosystem with the mandate to foster and promote innovation research in biotech industries specially start-ups and SMEs. To celebrate its eventful journey as an institution **BIRAC** organized a two day technical programme from 19 – 20 March 2015 at New Delhi to mark the occasion.

BIRAC completed three years of its journey towards creating and empowering the Biotech Innovation Ecosystem to serve its mandate to foster and promote innovation research in biotech sector, especially startups and SMEs. Since its set up three years ago, BIRAC's effort has been to not only enhance the innovation research capacities within the biotech industry, but also to encourage young entrepreneurs to take their new innovation ideas forward and meet challenge that the country faces in developing products that are affordable without compromising on quality parameters. BIRAC is already supporting more than 140 entrepreneurs, 270 companies (including startups) and 15 incubators. They constitute an important part of the Innovation ecosystem of the country.

To celebrate its eventful journey thus far, and also to mark the occasion of its 3rd Foundation Day, BIRAC organized a two-day technical program on 19-20 March at New Delhi. The event started with a video message from the Hon'ble Union Minister of Science & Technology & Earth Sciences, Dr Harsh Vardhan. In his address, Dr. Harsh Vardhan congratulated BIRAC for the role it has played in spurring and strengthening the entrepreneurial ecosystem within the Biotech landscape of the country. He highlighted the increasing number of success stories in the country's biotech sector as well as increased budgetary provisions for scientific innovations in the form of ATAL Innovation Mission (AIM) and Self Employment and Talent Utilization (SETU). He expressed optimism that Indian biotech industry shall achieve its target within the framed timelines.

Shri Y.S. Chowdary, Hon'ble Minister of State for Science & Technology & Earth Sciences, was the Chief Guest for the 3rd Foundation Day and inaugurated the event. In his address, Sh. Chowdary announced the launch of the equity based "**BIRAC AcE Fund**" for Accelerating Entrepreneurs. The Equity Fund is aimed at addressing the funding needs of growing entrepreneurs in the field of Biotechnology. It shall be operated by BIRAC with Incubators and Business Accelerators as its partners. Sh. Chowdary also emphasized that S&T ministry is in talks with the Reserve Bank of India, Ministry of Finance and Ministry of Small and Medium Enterprises to declare biotechnology as a priority sector to boost lending and spending in the sector by the Government as well as private investors. He also highlighted the budgetary provisions for the biotech sector aimed at encouraging self-employment and start-ups as well as the plans to set up a helpdesk for stakeholders and entrepreneurs wishing to know more about these programs.

A documentary movie on the role, activities and impact of BIRAC on the innovation ecosystem was screened for the audience. Prof. K. VijayRaghavan, Secretary, DBT & Chairman, BIRAC, gave the Keynote Address and highlighted the roadmap of BIRAC for further catalysing the Indian biotech ecosystem. Dr. Renu Swarup, Senior Adviser, DBT & MD, BIRAC, while welcoming the gathering recounted BIRAC's journey since its inception and also highlighted various achievements of BIRAC till date in fostering the innovation ecosystem. Sh Y.S. Chowdary, Prof. K. VijayRaghavan and Dr. Renu Swarup also launched the BIRAC Brochure for the year 2015.

During the inaugural session, three BIRAC supported innovators (Achira Labs, Pandorum Technologies and Navya Biologicals) showcased their success stories and journey to entrepreneurship. The event was designed in the form of panel discussions focused on issues pertinent to making biotechnology one of the key drivers of the 'Make in India' program. The theme for the foundation day - "**Accelerating Innovations: India the Next**

Biotech Global Hub", clearly focused on the importance of innovations in Make in India initiative of the Government of India.

The first panel discussion in the evening themed, "**India the next Global Biotech Hub: The status of our readiness?**" witnessed the participation of eminent speakers from the field of Biotechnology. The panel was moderated by Sh. Utkarsh Palnitkar, Partner, KPMG and the panelists were:

- Prof. K. VijayRaghavan, Secretary, DBT & Chairman, BIRAC
- Dr. M. K. Bhan, Former Secretary DBT & Founder Chairman BIRAC
- Prof. G. Padmanaban, INSA Senior Scientist & Senior Science & Innovation Adviser, BIRAC
- Sh. Amitabh Kant, Secretary, Department of Industrial Policy & Promotion
- Dr. V. M. Katoch, Former Director General, ICMR
- Dr. Kiran Mazumdar-Shaw, Chairman and Managing Director, Biocon
- Dr. Krishna M. Ella, Chairman and Managing Director, Bharat Biotech
- Sh. Pramod Chaudhari, Executive Chairman, Praj Industries

The panel deliberated on the policy changes and inherent modalities that would hasten the process of making India a destination of choice in the global biotech landscape. The scope of discussion was diversified over various issues including size and scale of biotech industry, financing landscape for biotech start-ups & SMEs, risk taking capabilities of Indian innovators & entrepreneurs, risk aversive approach of investors, tax benefits and government initiatives to promote lending in the sector, and creation of a motivating entrepreneurial ecosystem at the university level in the country. The panel discussion kicked-off the technical programme and provided momentum for the discussions scheduled for Day 2 (20th March 2015).

The second day started with a thematic presentation - '**Enabling Vibrant Biotech Hubs in India'** by Bain and Company, aimed at highlighting the role of critical components of the biotech ecosystem required for making India a choice destination for biotech industry. The pointers include mentoring, career flexibility, cross-sector networks, infrastructure and government policies.

Following session was a Plenary Talk on '**Make in India': A Perspective on the Biotech Sector: The opportunities, The enablers, and The Challenges'** by Dr. Kiran Mazumdar-Shaw. In her talk, Dr. Shaw highlighted the importance of a strong connect between academia and industry to realize the commercial potential of biotech leads. She also urged biotech industries to go to capital market and get them listed which would increase the investors confidence in the industry as a whole. Dr. Shaw mentioned that business cells should be created at academic institutes to ensure that the right mix of science and business is created at the right time for a successful venture.

Among the other themes for discussion were topics like -India a Bio-manufacturing Hub: Bridging the Paradigm for Quality and Affordability; and Leveraging Partnerships to Make in India: Collaborating with national and international partners for enhanced competency.

The second day panel deliberations witnessed involving discussions from various stakeholders present amongst the audience.

For detailed report, please visit: http://www.birac.nic.in/webcontent/3_Foundation_day_Report.pdf ■

Medtech Sector : **A Sea of Opportunities**

Nandakumar. S
Chief Executive Officer
Perfint Healthcare Pvt. Ltd.

As technology and innovation opens new possibilities of enhancing the longevity and quality of human life, medical devices sector has emerged as a new frontier where scientific R&D and business come together to serve unmet needs. biraC3 spoke to Nandakumar. S about India's vantage point in the medtech sector and his own experience as a tech-entrepreneur.

What dynamic changes have you noticed in the national and global medtech space, in terms of technology & business models?

Nandakumar. S (NS) : Across the world healthcare systems are coming under severe pressure - both capital investment and operating budgets are being cut. The bar on quality is increasingly being raised. Hospitals are fighting for the same set of patients. These trends have direct implications for the medtech industry. Technologies that do not directly impact clinical outcomes or revenue generation or operating costs are finding it difficult to be adopted by physicians.

Integration of data from multiple devices to enable decision making at the bedside or in the procedure room is increasingly the norm. User experience is becoming even more important as physicians are faced with new devices every day. Precision medicine, healthcare IT, technologies that enable minimally invasive procedures, technologies that enable home care, therapy enabling devices like robotics and navigation, procedure specific workflow solutions, disease specific imaging are all seeing robust investor interest. The bigger players are showing interest in big data for healthcare.

There is also growing recognition of the fact that technologies that address challenges of low resource markets like South Asia or Africa or Latin America could well be relevant for advanced markets.

Investment in high value capital equipment is a challenge but we also see robust growth in surgical robots and multi-million dollar imaging and therapy equipment. While disposable intense technologies that allow pay-per-use are critical, several healthcare systems are concerned about the high cost of such disposables and potential unethical practices. Emerging markets are being led by public investment in medical technologies with or without private partnership in such investment.

What are the opportunities and challenges for medtech in India? How can this sector contribute to the Make in India programme?

NS : Opportunities - The Medtech space is expected to grow at a CAGR of 15% over the next few years to hit USD 150B by 2017. The sheer size of India's population, growing at both ends – ageing citizens and younger group, with slow but steady increase in disposable income translates to higher spend on healthcare. NRHM, NUHM, Healthcare for all, Universal health insurance, states led health insurance like in TN, AP and Karnataka, PE led investment in healthcare services are all opportunities for players in the medtech space. Primary care is still a big focus for the public investment. That said, huge amounts of money is also being invested in setting up all the new AIIMS, upgradation of teaching hospitals under the PMSSY etc. NCDs are also getting a lion's share of the investment : CVD, Cancer, Diabetes etc.

So for medtech companies there is growing opportunity on both ends of the spectrum : basic devices that are needed for every bed and every PHC that's added or upgraded to those that are needed in super specialty care centers. In our space of cancer care, the National Cancer Control program envisages upgradation of infrastructure at about 70 cancer care centers apart from National Cancer Institute's. These would call for addition of top end imaging equipment to linear accelerators or surgical rooms etc.

Several Indian companies are present in the primary care end, surgical tools and devices, but we have little presence in the serious

technology space. The challenge is the scale of capital needed for R&D and the long gestation period before investments convert into revenue. Without a significant market opportunity, players weren't keen on investing. But when the opportunity presents itself like it is today, there isn't a mature well developed medtech industry to capitalize on it. So it's largely an imports game today. That said, for the next several decades this growth will sustain and hence there is a big opportunity for Indian players. Today, there are hundreds of start-ups that are looking at developing technologies from here and that's the way to go. Key would be the eco-system for these players to sustain and grow. India doesn't have the eco-system that US or EU or Japan or Israel has for medtech. Not too late yet, but needs a mission-mode focus.

Make in India shouldn't be reduced to Manufacture in India. If its simply manufacture in India then the giant global players will again have a field day. Manufacturing in India would at best be a part of the larger game where unique solutions that are relevant for the diseases and the healthcare eco system (affordability, availability of trained physicians, constraints of physical access, low awareness) in India and India like societies would have to be created, i.e designed, developed, tested, regulated, made and continuously improvised in India. We are then talking of India being a leader for markets such as ours. After all, more than half of the world population would be an immediate market for such products and technologies. Thus making in India needs to address all these factors. We will be a winner if we can rope in the world's best medtech players to collaborate with us in this attempt.

What was the trigger for your entrepreneurial journey? & What early partnerships you forged for taking your product to the market?

NS : Our trigger was our urge to get back into Healthcare space after a brief stint by each of the founders outside of the Healthcare industry. All the founders of Perfint have had worked at GE Healthcare before exploring opportunities outside of the healthcare industry. Our hearts were in medtech and we got together to found Perfint Healthcare in '05 as a R&D services firm. In '08 we became a product company focused on therapy enabling devices for Image Guided Minimally Invasive Cancer Care and Paincare.

Our partnership has always been with our customers with whom we co-created technological solutions to improve quality of life of those fighting cancer and pain. Our global clinical advisory panel constantly assists us in validating ideas, specifications and early prototypes, in clinical evaluation and conducting studies to substantiate our claims. When we started our product journey we worked with a panel of Radiologists led by Dr. Roy Santosham from Chennai. Credit goes to them for helping us conceptualise the first solution : A robotic navigation technology for needle biopsies in the lung and liver, which we launched in '09. We have been fortunate enough to further expand our advisory panel to include some of the best physicians from around the world, probably a first for an Indian medtech player. That has brought in a global perspective and new thoughts to the table. With the help of our advisors we have expanded into Tumor Ablation and interventional paincare.

Our advisors have always reminded us that customers like their patients more than technology and hence any solution will have to keep patients at the core. That's been a very powerful guiding principle in our product design. Top institutions around the world use our products today. About 7000 procedures have been performed around the world using our products We are today amongst the leading navigation technology players in the oncology space. Several peer-reviewed papers around the effectiveness of our solutions have been published and presented in top scientific journals and scientific events around the world. We have been awarded 4 patents by the US Patent office and have more in the pipeline. More products are in the pipeline too. We were recently awarded the 2nd most innovative healthcare company in the world by the Fast Co magazine.

Another important yet silent partner has been the Government of India. In our early days, we leveraged the STEP and TBI promoted by DST. As we grew we were able to find support from DBT through its various soft financing programs.

Of course we couldn't have been here without capital and we partnered with investors who have given us more than just capital. They have been there through the highs and lows and have guided us effectively at all stages.

How did Perfint strategise to receive FDA approval of your product? How was the process? How do you create market adoption?

NS : We had no prior experience with obtaining a USFDA clearance. So we probably did or didn't do several things because of which it took longer than what we would have liked to obtain the USFDA clearance. But I would encourage every Indian medtech player to go through the experience. It's very enriching. Learning from our experience, these are critical elements for successful USFDA clearance :

a. Thinking about the regulatory pathway to obtain an USFDA clearance very early in the design process. To some extent you design for regulatory clearance.
b. Will your product be cleared on equivalence to existing predicates or on extensive clinical evidence, which makes a world of a difference to your commercialization efforts and chances of success.

c. If predicates exist then it's critical to establish substantial equivalence to the predicate and why any technological difference wouldn't add new risk that cannot be ordinarily verified.
d. Clarity on the intended use and indications for use and marketing claims are all important elements of USFDA regulatory clearance – your brochure shouldn't make unsubstantiated claims.
e. Design control processes that are in line with USFDA guidelines not only help you with quicker clearance but will also discipline your development efforts. Important to maintain a design history file along with risks retirement strategy at all times makes submission easier.
f. Establishing a very robust verification and validation process including clinical trials or studies or post market data as appropriate – to demonstrate product claims, effectiveness and safety.
g. Sterility, bio-compatibility, ease of use, packing & packaging, labels and labelling need to be considered during product design as they impact the clearance process.
h. A well designed and rigorously implemented Quality Management system including Good Manufacturing process is critical.

Designing products that meet these guidelines ultimately benefit the patient. Being cleared by the USFDA builds credibility in the eyes of the physician. We enjoyed working with the USFDA. I personally would hope that all Indian medtech players voluntarily subject themselves to USFDA clearance even if they don't intend to sell in the US.

Market Adoption

Our adoption strategy revolves around connecting with Key Opinion Leaders (KOLs) in the oncology space and getting their inputs right from the product design stage. In the initial stages of product launch, we have also installed our products free of cost in several leading hospitals allowing them to perform various clinical studies and publish so awareness is created. Along-side we have benefited from their feedback. Product design is not a one time effort and there is always an opportunity to make your product better. And as product gets better, adoption gets better. Making sure that customers utilise the product is as important as selling to the customer. Our application specialists conduct in-depth training to ensure that the end-user understands the full potential of the product. Further we periodically hold extended training sessions for doctors and technicians on upgrades, new features, new procedures and techniques that we gather from users around the world – best practice sharing.

How can public procurement in India help in giving a push to R&D especially in the medtech sector?

NS : In India, the government is the largest provider of healthcare services as a large portion of the population cannot afford private healthcare. It's therefore only appropriate for the government to become the largest customer for medical technology and public procurement should prioritise purchase of Made in India goods. However, it is also important that the public procurement policy is well orchestrated, transparent and centered around relevant key diseases. Merely buying what is used in the West may not lead to innovation or R&D here. Working with the industry to create products in India for India and similar other countries would catalyse R&D in India.

Grants from the center to states for procurement of **"Created in India"** products would be a big boost. There are several countries that provide preference to patented domestic technologies for public procurement.

In India, public procurement of proprietary technologies (those that may not have a direct competition) is discouraged. That's a big dampener. On one hand we cannot ask for innovation and on the other hand we cannot penalize the players for developing unique technologies. We have seen several cases where tenders take years to conclude because there is a single bidder. Hospitals and patients are the losers in the process. It may be worth while to develop procedures that safeguard public interest without restricting innovative technologies from being procured.

What would be your advice to young entrepreneurs in India especially in the medtech sector.

NS : My advice for entrepreneurs would be to develop solutions that address the unique challenges of India and India like markets.

- Build a strong advisory panel. Work closely with your customers during the development process.
- Just low cost wouldn't do. Products will need to be comparable with the best in the world. Do not compromise on design control, reliability, clinical trials, regulatory clearances, aesthetics, usability.
- Medtech needs deep pocket and patience. Raise much more capital than what you believe is adequate. Revenues take much longer to come than you thought – do not panic. Customers ask for clinical data that will support your claims, which in turn ought to address customer challenges or critical needs. If you are raising capital from investors, you must plan for their returns or exit. Not always can you go for an IPO. So you need to think of who will buy your company and why and that should be part of your product strategy.

India needs innovators. India is a great place to Create Solutions that can scale globally. Go for it. All the best. ■

Hannover Messe 2015

"Make in India" Strides Forward

Hannover Messe 2015, organized from 13-17 April 2015, was ceremoniously opened by German Chancellor Angela Merkel together with Hon'ble Prime Minister of India, Shri Narendra Modi. The fair, where India was given the coveted "Partner Country Status", had "Make In India"-theme splashed all over, which was visible all over the fair ground and the city of Hannover. More than 300 Indian companies participated in the fair as exhibitors. Department of Biotechnology and BIRAC booth at the Hannover Messe 2015 saw many visitors from across the globe.■

BIOtech Japan 2015

Looking East

BIRAC participated as a part of Indian delegation at the BIOtech Japan 2015, held from 13-15 May at Tokyo, Japan. The platform provided an opportunity to showcase India's strengths and capabilities in the biotechnology sector. The focus of the participation was to promote international trade co-operation, and networking of the Indian organizations with the counterparts from Japan and other countries.■

BIO International Convention 2015

At the world stage

The 2015 BIO International Convention was held on 15-18 June at Philadelphia, USA. The convention was a platform for an aggregation of scientists, researchers, academicians, universities, start-ups, entrepreneurs, SMEs, industries, cities and countries from across the globe, to network, share and exchange the info-knowledge in the biotechnology arena. BIRAC had put up a booth at the convention and also participated in the discussions and sessions focused on showcasing the capabilities and capacity of India as a biotech nation.■

Health as the Bottom Line

Identifying promising innovation ideas and nurturing them to a fruitful conclusion lies at the heart of BIRAC's mandate. Here we showcase a few of the many successes, in the medtech sector, achieved by innovators across the country in collaboration with BIRAC.

Padmaseetha Technologies Pvt. Ltd.

For an Affordable, Anytime Dialysis

W. Gowrishankar

For the several lakhs of End Stage Renal Failure (ESRF) patients in our country, and millions world over, dialysis treatment is the only mechanism for survival. Hemodialysis treatment is cumbersome, and needs to be done twice a week. Patients are literally chained to their hospital beds for dialysis, severely affecting their lifestyle, career and occupation.

mobile Continuous Ambulatory Peritoneal Dialysis (mCAPD) becomes vital not only for patients' survival but also of their dependants, as their work/career is left undisturbed by the treatment, wherein the patients can carry out dialysis on their own anytime/anywhere, even on their workplaces automatically without any inconvenience or intervention. Thus retaining their livelihoods in spite of the crippling nature of the disease, they can continue to support their families/dependants as usual, which itself is a boon to this suffering community and is bound to lift their moral and spirits in a very big way.

mCAPD will surely raise the survival rate among the children and elderly who suffer from ESRF, who need dialysis to survive in multiple ways. Firstly, as their veins may be too small, hemodialysis is not possible and thus in many cases, the children have to go to CAPD. mCAPD allows the children to carry out dialysis even in their schools, without any hindrance to their school activities. mCAPD is a boon to such children, which allows them to continue a normal childhood growth, inspite of the crippling disease.

mCAPD offers a simple and affordable solution for the BoP population in remote and rural areas, by allowing them to carry out dialysis at their place, avoiding the time and cost of travel and associated expenses in going to hospitals at far away places, just for their dialysis treatment, twice a week.

An intelligent embedded controller with miniaturized peristatic pump, carries CAPD dialysis at the prescribed time and duration automatically without any intervention from the patients, who are free to carry on their work/study or occupation. mCAPD worn in the form of a belt, and the CAPD fluid bag carried in a convenient bag is all that is required to undergo CAPD dialysis.

Any abnormal event is automatically tracked and the patient is alerted, so that corrective action can be taken. There are intelligent sensors which initiate, control and monitor the flow of CAPD fluid into and out of the body (fill and flush operations), the output fluid volume, color which is an indication of the quality of dialysis and patients health, warming the CAPD fluid to comfortable level before fill operation, logging all the events and sending it to a patient monitoring system online. Both patients and doctors can be alerted via SMS if any alarming situation is encountered in the patient's condition during dialysis, which is not available in the existing alternate systems.

An intuitive app, mCAPD, running on any smartphone, can be used to control all operations of the mCAPD. It is a convenient and effective alternate to Auto Cycler

Machines, where CAPD is carried at night when the patients sleep, while being extremely affordable as compared to existing solutions.

An intelligent patient monitoring system, networking renal patients, nephrologists for the benefit of the community is being planned. Research is being carried out to measure urea/ creatinine clearance from the dialysis output, which will go a long way in maintaining patients health, and is not available in existing solutions.

Bio-compatible CAPD fluid, which can reduce the stress and increase the efficiency and longevity of the CAPD process is being researched.

CFPD, Continuous Flow Peritoneal Dialysis, where a small amount of CAPD fluid is pumped out at regular intervals, recycled after cleansing using a sorbent technology is being looked at, which makes the mCAPD extremely cost effective and increase comfort levels of patients.

BIRAC has offered space to ideate, upon a firm foundation of network, with an enchanting voice of support to the seed of my idea by kindling my passion of fire and offering rays of hope to enable the world reap the fruits of dedication and hard work.

In short BIRAC has been to my idea what mother nature is to life, i.e, create and nurture an ecosystem for many thoughts to manifest.

mCAPD will just not be there, without BIRAC, in every way. ■

Innovator Lab Consultants India Pvt. Ltd.

Mechanical Heart Valve Fixation System

Sujay Shad

When a surgeon affixes a mechanical valve into a patient's heart, the space available for the valve is limited. There are occasions when a larger more active patient gets a rather small heart valve due to this anomaly. Small patients, especially small children, often are subjected to repeated heart surgeries so as to progressively implant bigger size valves to allow the heart as well as the patient to grow.

We theorised that we could obtain an increase in the area of blood flow through the heart valve orifice by removing its suturing ring. This is the fabric ring that surgeons use to pass sutures to fix a metal body to the heart annulus. As the area of blood flow through especially the aortic valve increases, so the resistance decreases. Resistance to blood flow increases the afterload or mechanical stress on the heart. Mechanical stress is one of the prime triggers for development of left ventricular hypertrophy and its associated adverse cardiac outcomes. With our modification, we aim to increase the effective orifice area of a heart valve, such that more blood can flow through with much reduced resistance to flow.

Chief deliverables from this development are:

- Improved effective orifice area for improved hemodynamic function
- Other benefits could be
  - Possibility of reduced infective complications
  - Reduced risk of paraprosthetic leaks.
  - Stable fixation; speedier healing.
  - Reduced suturing time.
- Probable and not implausible benefits
  - Reduced need for anticoagulation
  - Simpler manufacturing process

During the course of this study we have realised that not much is known about blood flow characteristics within the ventricle or the ventriculo-aortic junction. This needs more study and research.

Acceptance of this project by BIRAC provided us with a review by a body of experts and reassurance that the scientific principle is sound. BIRAC also guided us to craft the business model, something we would need to work more over the next year. ■

Indian Institute of Technology, Guwahati

A Stitch in Time

Utpal Bora

Silk based sutures are one of the most widely used implants in surgery for wound closure due to their mechanical and chemical properties. This has been the case even long before the biomimetic potential of silk was better understood. Although silk protein is produced from over 2500 insect species, the commercially available silk sutures are fabricated from a single domesticated species- Bombyx mori. A large number of wild silks are yet to be explored and evaluated for use as potential suture materials. A considerable knowledge gap exists that hinders processing of wild silkworm fibers into sutures. We have focused on developing the technology for fabricating sutures from Muga (Antherea assama), an indigenous silk variety prominently associated with Assam.

Our focus is to develop standardized reeling and degumming protocol for Muga silk for eventually braiding and swaging them into needles of appropriate size to make a complete surgical suture. There is a significant scope of innovations at every step of the journey - from a cocoon to a suture - including packaging that is safe and friendly to the surgeons.

We have developed various working prototypes. The technological knowledge gained from the process can be utilized to fabricate a diverse range of composite sutures comprising of fibers from different wild silks. Based on extensive animal studies the prototype has to be fine tuned to comply with international standards before embarking on human clinical trials.

Besides the financial support that was critical to give concrete shape to our ideas, , BIRAC, through its various programs, has helped us with the intricacies that a bio-innovator and a bio-entrepreneur has to master. This has helped not only in pushing the project, but also overcome our own insularities of the academic world and focus on developing actual bench side products.

BIRAC encouraged me to form a start up with excellent people like Suradip Das, B.B. Borthakur and Pragya Sharma who have made critical contributions to the process of developing this product. On a lighter side, in an effort to cut down their costs, organizers of BIRAC's conferences have often made me share hotel rooms with fellow scientists who were, till then, strangers. My interaction with them made me realize that they were a wonderful combination of intelligent innovators and dreamers. Some of them are now very close friends. I can bet these new friends of mine are the hope and future of this country.

Unilumen Photonics

Pulsed fibre lasers for prostrate surgery

Anil Prabhakar

Prostrate reduction has traditionally relied on invasive surgery. More recently, hospitals offer transurethral resection of the prostate (TURP) using microwave thermal ablation. Laser-TURP further reduces post-operative discomfort. However, the primary lasers being used in India are infra-red at a wavelength of 1 micron. A green laser, at a wavelength of 532nm, has the added advantage of selective tissue ablation of the gland. However, these lasers are not available in India. The alternative of 2 micron infra-red lasers is not considered because of the high cost of the disposable catheter.

The traditional solid state Nd:YAG lasers have an active gain medium that is limited in its ability to dissipate thermal energy. A Yb-doped fibre laser is built with the same gain volume, but a much larger surface area as the gain volume is embedded within a silica fibre. Both Nd:YAG and Yb-doped fibre lasers operate at a wavelength of 1064nm. However, the fibre lasers offer better stability, control, and easier optical pulse-energy customization. By frequency doubling a 1064nm Yb-doped laser, we achieve a 532nm green fibre laser capable of photo-ablating tissue. We have the added advantage of being able to use the same catheters that are currently used for Laser-TURP.

Fibre lasers and amplifiers are a platform technology useful in many surgical applications, including ophthalmology, dentistry and dermatology. They also find use in microscopy, optofluidic lab-on-chip, and in bio-imaging applications. We are developing fibre lasers at different wavelengths, customized to each application. In addition we will provide an alternative to more expensive, imported, femtosecond lasers.

BIRAC's support has been critical to jump-starting Indian innovation in surgical lasers. BIRAC's partner organizations such as C-CAMP have provided us with mentorship, and introduced us to the larger biomedical and bioengineering community. BIRAC's support for the Ignite program, at Cambridge, has helped us understand the different phases of entrepreneurship, and try to build successful business models, while catering to the needs of Indian society. ■

R&D and Entrepreneurship

Stimulating med-tech in India

Mohanasankar Sivaprakasam
Head, Healthcare Technology Innovation Centre (HTIC)
Indian Institute of Technology, Madras

At over Rs. 30,000 crore market in India with 80% of them served by imports, the opportunities for domestic med-tech production in the country are plenty. With growing healthcare market, increasing insurance penetration, rising incomes, increased health awareness and more elective medical procedures, med-tech market is expected to grow more than 15% annually. Today's domestic med-tech industry is largely focused on consumables, disposables, and low complexity devices with very little play in high value and complex products. This is reflected in the industry distribution with more than 50% of domestic med-tech companies having annual turnover of less than Rs. 10 crore.

One of the primary challenges of med-tech is its inherent element of complexity and sensitivity since it deals with human lives and as a result, the long winded pathway from concept to market. Unlike other high technology markets where the number of product categories has remained tractable with increasing volume and ensuing consolidation and standardization, med-tech market, on the other hand continues to grow more diverse, complex and fragmented. Current estimates indicate that med-tech products fall into over 50 clinical specialties and few thousand product categories. Further, due to the small or medium volume (100s to 1000s annually for equipment) and long product life cycles (typically 5-7 years in Indian settings), industry continues to face pressure to introduce new products in order to be relevant and competitive in this market.

The diversity of products in med-tech segment ranging from plastic vials to surgical instruments to ECG machines to bone implants to MRI machines necessitates specialization and focus in order to build a quality product. Indeed, this also leads to most companies focusing only on one or few products. This limits the capability of even successful industry to expand and grow further, after the initial market capture is completed thus resorting to imports for market expansion. This requires a robust R&D pipeline to be competitive in the market. Today's industry is limited in R&D capabilities, a major impediment for developing new products. On the other hand, IITs, CSIR labs, and other R&D institutes have developed R&D capabilities over the years but have limited translation capabilities such as engineering for manufacturing, validation for standards etc. A strong linkage between these two with the goal of developing products is one of the crucial missing pieces in creating an effective med-tech R&D ecosystem. Public funding mechanisms encouraging, and in some cases mandating, such joint R&D arrangements for funding proposals are indeed in the right direction.

Another dimension that has been missing in the Indian med-tech arena is healthy number of startup companies targeting specific problems through solutions based on innovation and R&D. This is starting to change with startups emerging in this genre. Two companies that standout are Perfint Healthcare and Forus Healthcare, in interventional oncology and ophthalmology space respectively. Started over five years ago, both have now developed world class products that have reached the market in India and overseas. Their success illustrates the possibilities and challenges of med-tech startups in India. Several startups have emerged in the past few years with some of them having global offices and connectivity even at an early stage, for R&D and market development. This is a highly encouraging trend and needs to be supported and sustained. Nurturing this startup ecosystem will be a key driver for advancing domestic med-tech industry.

Succeeding as a med-tech startup requires a holistic view and understanding of the larger healthcare market, of which med-tech is a part of (around 5%), clinical practice of the product,

> Med-tech market continues to grow more diverse, complex and fragmented. The diversity of products necessitates specialization and focus in order to build a quality product. Indeed, this also leads to most companies focusing only on one or few products.

market dynamics for the product category and underpinning policy aspects governing regulation, manufacturing and commerce of the product. On the product development front, the pathway of R&D, product engineering, clinical validation, regulatory compliance, manufacturing, market development, and distribution need to be chalked out. To support this, one needs access to physical, intellectual, financial resources, and networks comprising of R&D entities, technical and medical institutions, government agencies, public and private funding sources, regulatory bodies, manufacturing services. Developing these capacities in the country over time is critical for making med-tech startups successful.

While R&D and entrepreneurship address the supply side, the demand side of med-tech in terms of health systems adoption of domestic med-tech products and governing policies remain unaddressed. Lack of a regulatory framework for medical devices, currently regulated under the framework for drugs, is a huge unaddressed gap. Without standards for safety and quality, indigenous innovation and manufacturing cannot flourish and compete, leaving room for high cost imports and poor quality spurious products. Lack of adoption of indigenous innovations by public health systems that provide healthcare to majority of population is a major disincentive for startups and established companies to develop devices for primary and secondary care, which are highly fertile areas for affordable med-tech innovation.

The need to build and strengthen capabilities discussed above is reflected in the discussions and recommendations of the med-tech community. This is naturally expected of a nascent domestic industry attempting to grow and scale. While we gradually build these capabilities in the country to develop a strong med-tech ecosystem, in the short term, we need to be innovative and opportunistic to generate successes in order to attract more resources and policy attention.

What is clear is that there is opportunity for indigenously developed, R&D and innovation driven, affordable products for serving needs of resource constrained healthcare markets like India. In particular, affordable devices for early detection, low cost hospital equipment that are rugged and require little maintenance, systems for conducting medical procedures that overcome skill barriers and shortage of medical personnel, out-of-hospital monitoring and care, are untapped med-tech opportunities that would benefit Indian healthcare and can reach globally where healthcare costs are rising alarmingly. The journey in pharmaceuticals and vaccines over three decades that has led to industry's success in both domestic market and exports should serve med-tech aspirations of the country, both as inspiration and reminder for the need to build capacities on the R&D, regulatory, manufacturing and commercial front. ■

Call for Proposals

Biotechnology Ignition Grant (BIG)

BIRAC invites proposals from

- Biotechnology start-ups/entrepreneurs having a registered company incorporated on/after 1st July 2012.

Or

- Academicians, Scientists, Researchers, PhD, Medical degree holders, Biomedical Engg. Graduates, incubating in a technology business, who have innovative technology idea with considerable potential for impact/commercialization.

Scope and Support

- BIG supports high level innovation in the Biotechnology sector. BIG does not support basic research projects.
- BIG scheme supports only up-to Proof-of-Concept stage.
- Grant-in-Aid up-to Rs. 50 lakh.
- Grant periods of 18 months.
- Mentoring support and project monitoring by BIG Partners.

How to Apply

Only online submission of proposal is allowed under BIG scheme. Register on BIRAC website under "BIG User" for submission of proposal. User registrations are open round the clock. Prior recipient of BIG grant are not eligible. For further details on the scheme, eligibility criteria, FAQs and registration log on to www.birac.nic.in

Proposals Submission Starts : **1st July, 2015**

Proposals Submission Closes (midnight of) : **14th Aug., 2015**

Small Business Innovation Research Initiative (SBIRI)

Supports discovery, proof-of-concept and early stage innovations in companies for development of biotechnological products and processes with high societal relevance

- Create opportunities for starting new technology-based or knowledge-based business by science entrepreneurs
- Strengthen and encourage smaller business to increase their R&D capabilities and capacity

Biotechnology Industry Partnership Programme (BIPP)

An Advanced Technology Scheme for high risk, transformational technology/process development from proof-of-concept to validation leading to high value product commercialization.

Who can Apply

A single or consortia of Indian company(ies) registered under "The Indian Companies Act 2013" with minimum 51% Indian ownership, and DSIR recognized in-house R&D unit, are eligible to apply either alone, or in collaboration with a partner from another Company/Institute/University

How to Apply

Proposals for both the schemes are required to be submitted online only. For scheme details and submission of proposal, please log on to BIRAC website www.birac.nic.in

Last date for Submission of Proposals : **31st July, 2015**

FORTHCOMING CALL FOR PROPOSALS

Contract Research Scheme : **01 August 2015**

SPARSH : **15 August 2015**

For Details: Visit - http://birac.nic.in/

For further information please contact:
Biotechnology Industry Research Assistance Council (BIRAC)
1st Floor, MTNL Building, 9, CGO Complex, Lodhi Road, New Delhi - 110 003
E-mail: BIRAC.dbt@nic.in | Web: www.BIRAC.nic.in