

birac

e3

Ignite • Innovate • Incubate



Scaling Bio-entrepreneurship



birac

Ignite Innovate Incubate

Biotechnology Industry Research Assistance Council

(A Government of India Enterprise)



March 2016

No. 1 | Vol. 3

chief editor's take



Scaling Entrepreneurship requires specific focus on key components of finances, mentorship and enabling services. BIRAC has made concerted efforts to focus on these. Over the last four years BIRAC has created a vibrant startup culture as well as helped many SMEs to grow, especially through our flagship programmes such as BIG (for early stage funding), BIS (Bioincubator Support), SBIRI and BIPP (to scale nationally important and highly innovative projects). Our aim to build a US \$100 billion Indian bioeconomy would need scale up of many biotech startups and SMEs to develop innovative and affordable products not only for India, but also for the world, which will be crucial for a successful 'Make in India' programme. BIRAC along with the BIG and SPARSH partners, is working towards providing focused mentorship and other support to over 200 Startups to help them successfully scale BIRAC's effort in fuelling the pipeline starting from the beginning of the ladder at the student innovation level, going up focussing on enabling and empowering the graduate and post graduate students, then entrepreneurs and Startups, finally moving to SMEs and other Biotech Companies. We also believe that our young entrepreneurs should learn from each other and alumni of our entrepreneurs would provide the correct network strength for future growth. We seek continued support from all our stakeholders to scale up not only our Startups but also BIRAC's activities. ■

Renu Swarup
Senior Adviser/Scientist 'H', DBT, GoI. & Managing Director, BIRAC

leader



Over the last four years, BIRAC has had a sustained focus on building the biotechnology ecosystem in the country. The tools deployed by BIRAC are a mixture of funding support, incubation, IP support and many more tangible and intangible ones such as networks and mentorship. In the last few years, along with our partners, we have been able to build a foundation for startups, especially through programmes such as the Biotechnology Ignition Grant (BIG). We intend to help catalyse a conducive environment so that startups and small and medium enterprises (SMEs) are able to grow and scale. Many in our biotech industry have scaled and continue to deliver extremely high quality products at affordable prices. Examples are the vaccine-, seed-, and biosimilars- industries.

We have also built partnerships with organisations such as WISH (Wadhvani Initiative for Sustainable Healthcare) Foundation that intend to amplify the interface of BIRAC innovations with State healthcare systems thus creating possibilities for impact through market creation.

Precise understanding and navigation of the regulatory system is also crucial for companies to scale. BIRAC conducts regulatory workshops for biotech startups and SMEs to help them understand regulatory requirements and processes in India as well as in other geographies.

Scaling bio-entrepreneurship presents challenges that are different from other sectors. Some of these relate to early stages of the startup. The distinctiveness continues to late stage validation, clinical trials, field trials, maintaining quality through large production-operations, last mile delivery, and exploring new markets etc. A key challenge, then is to retain the ability to have a culture of innovation even while the organisation is growing.

Aspects of scaling also pertain to understanding trends in global markets as well as create platforms where serendipitous possibilities for partnerships increase. Our partnerships with UKTI and Tekes aim to make Indian innovators and their counterparts in their respective countries connect and explore collaborative opportunities.

Mentorship is critical for success through these challenges. BIRAC, working with its partners, connects each entrepreneur to a network of mentors who provide expert strategic guidance for growth. Our BIG and SPARSH (Social Innovation Programme for Products Affordable & Relevant to Societal Health) partners help us deliver this crucial aspect of mentorship.

We implicitly recognise that exponential scaling of several bio-enterprises will lead to rapid growth of the overall industry, which is a must if we are to achieve our stated goal to be a US \$100 billion bioeconomy by 2025. We also understand that successful scale-up of innovative bio-enterprises would bring immense societal benefits and that scaling of bio-enterprises involves a cohesive 360° strategy. BIRAC is aware of this and continually strives to understand the current and future needs of bio-enterprises. ■

BIRAC has devised programmes that address other aspects of scale. Programmes such as Biotechnology Industry Partnership Programme (BIPP), which work through a dual contribution mode, aim at late stage validation and scale up during product development, thus helping in transitioning industries to scale up product development and increases the chance of eventual commercialization.

Prof. K. VijayRaghavan
Secretary, DBT, GoI & Chairman, BIRAC

in this issue

03	leader		14	reports	Bio-Entrepreneurship, Grant Writing and Intellectual Property Management
04	cover story		15		Current Regulations on Medical Devices & in vitro Diagnostic Kits
06	through the prism		16		Membrane Separations: Theory and Techniques in Bioprocessing
09	NovaLead Pharma		17		Bioinformatics techniques in Genome and Proteome analysis
11	feature		18		Building a Biotech Enterprise Ecosystem

Editorial Committee
Satya Prakash Dash
 Head, Strategy Partnerships & Entrepreneurship Development
Ankur Gupta
 Sr. Manager, Business Development

Design, Production and Circulation
 creativEdge
 AFE Consultants Private Limited
 Aravali House, 431/D-22, Chhatarpur Hills New Delhi-110074
 Email: ce@aravali.foundation.in

Anthem BioSciences

Creating a Global Impact



Ajay Bharadwaj
Chief Executive
Officer



Ganes Sambasivam
Chief Scientific
Officer



Ravindra KC
Chief Operating
Officer

How did you decide to go into entrepreneurship? What were the trigger points for founding of Anthem? What gap in the market was Anthem trying to bridge?

Ajay Bharadwaj, Ganes Sambasivam and Ravindra KC (AB, GS, RKC) : After decades in a corporate environment, we had learnt a lot of 'what not to do' and also how it could be done better. Too many years in a job, you get taken for granted and a lot of your creative spirit is stifled. To see if our ideas had wind under their sails, we thought it was best to step out on our own. From being delivery centric and employee focused, older organizations often migrate to being customer acquisition centric and numbers focused. Our attempt at being entrepreneurs was to correct that.

How were the initial days of Anthem? What hurdles did you face and how did you overcome it?

(AB, GS, RKC) : We were nervous and unsure of the direction our venture would take. There is a bewildering range of activities which have to be accomplished, and often we were overwhelmed by the effort. Finance, HR, manufacturing, quality control, statutory compliance, research.... IT and endless list of things, all equally important that have to be tackled simultaneously.

Additionally, we had to arrange finance, place of business, research team, business partners etc. We quickly set up a core team for different verticals, negotiated purchase of land (always a risky proposition) and convinced a bank to fund our project.

How did you nucleate a team for Anthem? How important is team for a successful venture? Do you

think it is better to have a couple of co-founders rather than a single founder company?

(AB, GS, RKC) : In our experience multiple founders, with different skills and great personal chemistry are a big plus. When starting a new venture many activities kick-in simultaneously. So a team is very helpful. There is no sure shot formula but our experience dictates more than one founder is better. However, if one can have assured business / support from an established venture / mentor then it provides the elbow room to make mistakes which every entrepreneur must endure.

Was funding an issue for Anthem? How did you strategize to access funding? What should startups keep in mind when they are seeking growth funds? Do you think the landscape of venture funds has changed in the country?

(AB, GS, RKC) : Funding was a big challenge. We could bring in an initial investment but our aim was to start with a certain scale and that needed funds. We ran the whole gamut of options, VCs, angel investors, backers who wanted majority stake etc. One thing we discovered was that our strong resume helped. Our track record of establishing India's first biotech company gave us credibility. Once we had done the rounds of various interested parties we settled on the debt route. SBI came forward to fund us. The equity we saved by not going to VCs could now be shared with other colleagues to create broader ownership in the company.

Of course the VC funding landscape has undergone a tectonic shift over the last 10 years. India is the flavour of the month, the only bright spot in the otherwise gloomy global outlook. While the sun shines, our entrepreneurs should make the most of it.

How important is it for startups to have mentors? How does one choose a mentor?

(AB, GS, RKC) : Entrepreneurs are wide eyed visionaries. Young entrepreneurs lack experience and can benefit tremendously from a mentor. Mentors can point them in the right direction business wise, help avoid obvious pitfalls, and provide much needed business contacts. But finding a mentor who fits ones needs is no easy task. Mentor also needs to have time to coach and chaperone but the best mentors are successful people themselves and therefore quite busy.

What were your strategies to scale Anthem? How did it happen? Which networks did you tap into? What

are the barriers for scale? How do you maintain quality when an enterprise scales?

(AB, GS, RKC) : Barriers to scaling up are funds, human capital and customers to absorb your expanded capacity. Before scaling up one has to invest in people and systems which will ensure quality. The top management has to be committed to quality and everyone in the company has to be on board with that philosophy. We started at a fairly decent scale, a strategy not recommended for everyone. In our case it worked because we had special domain knowledge. We had a network of vendors, financial advisers, customers and agents which was extremely fortunate and handy.

Where do you see Anthem in the next 5-7 years?

(AB, GS, RKC) : In the next 5-7 years, Anthem will be a globally recognized player in the biotech area. We intend to build a new annual revenue base of USD 130 - 150 million. The company would be strongly associated with biotech activities, as a provider of services and products. We want to be a 'go to' vendor of choice for services and products for both nutritional and life sciences based companies.

What are your perspective about the growth of biotech in India? How can India leverage its potential to become a manufacturing and R&D hub? How do you see the evolution of CRAMS in India?

(AB, GS, RKC) : Indian biotech has a long way to go. Our main attraction is our large internal market. This is a compelling reason to have manufacturing and R&D here. The CRAMS market has the potential to grow provided the Government Policies and the Regulatory processes are streamlined for speedy evaluation and approvals of such projects.

What are your thoughts on startup culture in India especially life science/biotech startup culture. How do you think the ecosystem would evolve?

(AB, GS, RKC) : Unlike IT services, biotech is still in its infancy. BIRAC has played the role of anchoring this activity but as companies step out of its shadow, they will need a different, bold vision. The ecosystem will need nurturing and timely regulatory approvals from the government.

Any advice to would be entrepreneurs?

(AB, GS, RKC) : Be prepared and hang on! It's going to be an exhilarating but rough ride. ■

GPS Renewables

Fast Off The Block



Mainak Chakraborty
CEO
GPS Renewables

Mainak Chakraborty is the Director and CEO of GPS Renewables, which he had co-founded with Sreekrishna Sankar. Mainak completed his MBA from IIM Bangalore and his engineering from NIT, Calicut. Recently, he was named as one of the top Indian innovators under the age of 35 by the MIT Technology Review. Mainak focuses on the large projects division for GPS Renewables.

How did you decide to go into entrepreneurship? What were the trigger points for founding GPS? What gap in the market was GPS trying to bridge?

Mainak Chakraborty (MC): The key trigger for entrepreneurship in my case was the adrenalin rush I experienced while working in other product startups, prior to starting up on my own. The advantage of being in a city like Bangalore is that you are surrounded by startups, and startup stories, which makes that urge to take the plunge even stronger. A big inspiration for me in particular was Mr. Sam Pitroda. My ex-boss had been a part of the initial core team of C-DOT, that Mr. Pitroda had handpicked to build arguably India's greatest tech product so far. The C-DOT stories, coming from a person who was an integral part of it, were important to me. It gave me the belief that it is possible to build world-class tech products in India, and that our country needs many more similar technology-for-good success stories.

When my co-founder, Sreekrishna Sankar and I started off, we didn't have any business idea as such. We didn't have any eureka moments. We just knew that we wanted to do something around the concept of technology-for-good. For zeroing in on the exact business idea, we started scouting for problems that we face today - problems that are huge, have a huge social and environmental impact, and most importantly have a role for technology to play. Being in Bangalore, one of the first problems that came to our minds was waste, and as we dug deeper, one thing led to other, eventually forming the basis of what we are doing today.

We at GPS believe that the reason why we have a waste problem today is because biogas hasn't worked the way it should have. Had biogas been effective, a big chunk of the problem could have been taken care of. There have been many legacy technology problems with biogas, such as huge space footprint (making them inviable in urban areas due to lack of space), huge water footprint, low efficiency and efficacy (due to which the industrial/hospitality and banking sectors never championed biogas). More than 25% of any city's waste across the world, comes from its bulk waste generators. A compact and reliable captive biogas plant for such institutions can make business sense, and also solve a big problem for our cities. This is a gap yet to be tapped in an organized way across the world. That is what GPS is trying to address through the BioUrja, its first product.

How were the initial days of GPS? What hurdles did you face and how did you overcome it?

MC : The gestation period for product startups is high, more so in the biosciences space. Our initial days were no different. To make things tougher, given that there had been many failures in the biogas space in the past, raising funding at an early stage was very difficult and expensive. So, until we were selling our product, there was very limited money. We were very lucky that we got a big break in the form of the Biotech Ignition Grant. We had to be very judicious about every paisa spent. Our research efforts still continue and we knew that to do the kind of things we wish to do, it would take many years. Hence the plan from the beginning was to get a minimum viable product out as soon

as possible so that it could sustain the firm. And that strategy has worked well for us. We have been profitable from year one of commercialization. The only equity funding that we have raised so far is Rs. 25 lakhs, and that was back in 2012. This strategy has given us the liberty to pursue our technology vision without being forced to scaleup prematurely.

There were other hurdles too, all of which were a manifestation of the lack of money. For instance, getting the right people to work for us or collaborating with the right research institutions was a big challenge. We overcame that by applying for and winning various national and international awards. This gave much more weight, prestige, respect to what we were doing/trying to achieve. This also brought us great interns not just from India but from other countries too.

How did GPS seek early stage funding? How did you strategize to access funding? What should startups keep in mind when they are seeking growth funds? Do you think the landscape of venture funds has changed in the country?

MC : By the time we started scouting for our seed fund, we had already put in substantial savings of our own into the prototype. I had opted out of placements from IIM Bangalore. We knew that the team and the idea was good. So, we were confident that raising seed money wouldn't be an issue. Given that, instead of carpet bombing all existing seed funds at that stage, we tried to figure out who could be the right investor for us. We were looking for a fund, which would not only give us the money but also mentorship. We were looking for a mentor who had built products before and would be willing to spend time on our firm, ideate and debate with us during the product development phase, rather than just write a cheque. When we added these additional requirements, we weren't left with too many options back in 2011/12, and thus zeroed in on Venture Factory (then i2india Ventures). Their CEO, and now our Chairman, Deepam Mishra, had been a part of three tech startups in the US. He had been at Stanford Research International, and was looking for startups who were trying to solve problems through technology like ours.

The venture funding scenario has definitely changed for sectors such as e/m-commerce, cab aggregators, food tech, etc, but not for biotech/biosciences space. There are very few funds who appreciate technology and are okay with the kind of gestation periods that characterise such sectors. On the other hand, the so called patient capital funds are too BoP focused. There are still hardly any funds in India who are ready to back firms that want

to build billion dollar success stories, but at a slower pace than their e-commerce counterparts.

Who were your early mentors and advisors? How important is it for a startup to have mentors? How does one choose a mentor?

MC : From our experience, we can vouch for the fact that mentors can play a very important role in a startups's story, especially so, when the team has limited business experience. There are so many potential mistakes that one can make due to the lack of experience, many of which can be very expensive. This could vary from boring (for a tech entrepreneur) tax related implications to structuring of one's first term sheet with an investor. Our first set of mentors/advisors were Deepam (mentioned previously), V. Subramanian (Ex-Secretary, MNRE), Pratima Ram (Ex-CEO, India Infoline & Ex-Country Head, SBI, US), some of our professors who had taught us, such as Prof Kumar (NSRCEL, IIMB's business incubation cell), etc. We had sought for mentors/advisors keeping in mind the kind of technology/business areas where we needed guidance. So, while Deepam, being an ex-products guy, guides on the product development front, Mrs. Pratima Ram, guides on the finance front, and so on.

How is GPS thinking to scale? You have gone into Bangladesh and USA? How did it happen? Which networks did you tap into? What are the barriers for scale? How do you maintain quality when an enterprise scales?

MC : We have slow but big internationalization plans. Our dream is to take our solution to all cities which have a waste problem. And that covers more or less all cities across the world! The internationalization so far has happened through word of mouth, people reaching out to us directly via google/seeing our awards, etc. It has been completely organic with us having spent zero rupees on marketing. For instance, we recently closed a project for one of the fastest growing chocolate firms in Japan over Skype! A lot of this has been happening because many of our international awards and mentions have generated great leads for us, and have lent that credibility which often affects startups like us in India. What affects us a lot in the international market is the perception that Indians don't/can't make world class products.

As far as maintaining quality while scaling up is concerned, we have been doing that by scaling up gradually, step-by-step. It is very tempting to raise big money when all of your friends around are doing so. We have resisted the temptation so far.



Where do you see GPS in the next 5 years?

MC : Our aim is to be world's first truly global and largest bioenergy firm. We have been able to achieve many milestones and showcased them on the technology front. A lot more has to be demonstrated on the business front. And that's what the next 3-4 years are going to be about.

As of today, we have 50 tons of waste (across India and Bangladesh) under our management and we are extracting more energy from it than anybody else in the world. We are generating more than 12 lakh kgs of clean LPG equivalent every year, and in the process mitigating over 20,000 tons of GHGs per year. We are expanding to the US this month and Malaysia in the next quarter. But these numbers are small compared to the potential. By 2021, our aim is to look 100 times the numbers we are doing currently.

What are your thoughts on startup culture in India especially life science/biotech startup culture. How do you think the ecosystem would evolve?

MC : The best thing to have happened to the life sciences/biotech space is BIRAC. In our case, when that research money was needed the most, we got the first cheque in 4-5 months from the call for proposals. I think that is unheard of even in a global context. The kind of leaders and mentors that BIRAC has, are the best one could have hoped for. And that reflects in the kind of ideas that are coming out of the BIG kitty. This

also reflects in the enthusiasm of all the startups whenever a BIRAC meet is organized. This wasn't the case even when we at GPS were starting off. Having said that, the one gap that still exists is that of post-BIG funding. While BIG has been a great kickstarter, most of BIRAC related startups like us need more patient capital. Not because of our focus on the BoP. Many of us aren't focused on BoP. But we still need patient capital because building great companies in these spaces takes time. We don't need further grants, but we do need it from investors who understand and value technology. Such funds/investors still hardly exist in India. This is the one big gap that is still there. Today, we have the talent pool, we have the BIG grants to kickstart great potential ideas, we have the BIG partners to nurture these ideas and provide them all the necessary infrastructure support. The only actor missing in the story are the right post-BIG funds - to evolve this great ecosystem into one that can churn out billion dollar success stories.

Any advice to would be entrepreneurs?

MC : Two pointers from our story so far:

1. Apply for international business competitions. There are many of them, and lend a lot of credibility that can be leveraged for various things such as sales, collaborations, hiring, PR, etc.
2. Choose the right mentors - not based on their "brand" value, but based on your needs and how much time they can spare for you, based on how excited are they by your idea. ■

NovaLead Pharma

Striking Impactful Notes



Supreet Deshpande
Managing Director
NovaLead Pharma

Supreet Deshpande is the visionary behind NovaLead. With an international career of over 23 years in various senior strategic positions in large companies like Mahindra & Mahindra Ltd. and Bajaj Auto Ltd., Supreet is a business development person at heart. Developing new markets, designing and implementing business strategies and leading market linked product strategies are some of the key areas of his contribution. With business development experience in multiple geographies like the USA, Europe, Latin America, Africa and Asia, Supreet brings with him significant learning for building an efficient and result oriented organization. In 2011, Supreet received prestigious BioSpectrum Asia Entrepreneur of the Year 2011 Award. This year, under Supreet's leadership, NovaLead received DBT-BIRAC Best Innovator Award in Healthcare.

How did you decide to go into entrepreneurship? What were the trigger points for founding of VLife/Novalead? What gap in the market was VLife/Novalead trying to bridge?

Supreet Deshpande (SD): Drug discovery is one of the most inefficient processes where only 1 out of 10000 compounds studied become a drug. It takes 12-15 years for a drug to reach market and costs over \$ 2 billion, as per latest Tuft's University report. Majority of this expense is towards cost of failures. So, earlier the molecule fails, the better it is both in terms of cost and time. VLife / Novalead was created to develop simulation technology by which molecules could be designed, studied and failed even before going to the lab thus saving both cost and time in drug discovery.

How were the initial days of VLife/Novalead? What hurdles did you face and how did you overcome them?

SD : When VLife started, the idea of simulation technologies for drug discovery was very new in India. New ideas always find resistance due to their novelty and absence of prior successful example. We too faced such resistance. But our conviction in the idea and persistence in developing a prototype

helped us to gradually convince people about the usefulness of the technology. And by using that technology in-house and developing a potent drug development pipeline, people started taking notice. Now, VLife technology and Novalead's research programme is generating a lot of interest in the industry.

How did you nucleate a team for VLife / Novalead? How important is team for a successful venture? Do you think it is better to have a couple of co-founders rather than a single founder company?

SD : An entrepreneur is only as good as his team. Therefore, having people in your team better than yourself is the key for success. So it is very important to have a knowledgeable team which shares your vision. Every startup has its share of turbulent times and it is then, that the value of your team becomes critical. These times have to be patiently dealt with and it is possible only when there is complete commitment of the entire team. As regards co-founders, it is always good to have them. That allows sharing of responsibilities for better focus. Yet, I believe one of them has to be the more equal than the rest and sometimes, decisive action is needed and someone has to take responsibility for it. Consultation amongst all, yes, but decision still remains to be taken by someone.

through the prism

How did you strategize to access funding? What should startups keep in mind when they are seeking growth funds? Do you think the landscape of venture funds has changed in the country?

SD : The landscape of funds in India has improved but fund raising still remains a process which is not very well defined. There is no one ideal approach to raise funds. However, conviction in business idea, clear road map to revenues, committed knowledgeable team and a detailed business plan are essential components of any fund raising effort.

How important is for a startup to have mentors? How does one choose a mentor?

SD : For a startup, a mentor is very helpful as a first time entrepreneur has several dark spots and may not know how to handle challenges that come from time to time. A mentor who has successful experience in turning an idea into a business would be very helpful. In scientific field like ours, scientific mentors are very helpful and needed. Brainstorming with them helps in robust design of experiments as well as identifying technology gaps.

What were your strategies to scale VLife/Novalead? How did it happen? Which networks did you tap into? What are the barriers for scale? How do you maintain quality and a culture of innovation when an enterprise scales?

SD : Availability of funds is one of the biggest barriers for scale up in a discovery based company like Novalead. Every molecule to be developed requires significant investments and when one has a promising pipeline as of Novalead, the funding required is that many times over. This barrier can be crossed once at least one compound has shown human proof of concept as we have done with Galnobax. As a strategic commitment, we stayed away from services business. This has helped single minded focus on discovery research and commitment to develop IP for future licensing.

Where do you see VLife/Novalead in the next 5-7 years?

SD : I see Novalead to be one of the global leaders in the field of drug repositioning and as an essential partner for innovative pharmaceutical companies for building a more efficient research programmes by relooking at their shelved compounds and identifying all probable indication areas for their developmental candidates ab-initio. By doing so, they can both salvage some sunk cost in failed research and also plan out more commercially viable product life cycle strategies for each of their candidates in development.



What is your perspective about the growth of biotech in India? How can India leverage its potential to become an R&D as well as manufacturing hub? How do you see the landscape of drug discovery in India evolve?

SD : One of the most important inputs needed for India to become a research hub is to improve quality of scientific education in Indian universities. These universities must produce industry ready students rather than theoretical experts. If this is acted upon, there is no stopping for India to become global research hub in the field of biotech / pharma. As far as manufacturing is concerned, India is already a significant player and continuing to build efficiencies and quality will ensure India grows its already leadership position in manufacturing.

What are your thoughts on startup culture in India especially life science/biotech startup culture? How do you think the ecosystem would evolve?

SD : Success breeds success. We need some successful examples soon in the life sciences field. That will be a big motivation for the young entrepreneurs as well as funding agencies to pursue and support innovative ideas. Evolution is a gradual process but can be hastened by some shining successful examples. India is getting ready to have some in near future.

Any advice to would-be entrepreneurs?

SD : I am no one to give advice because every business idea and conditions in which it has to be nurtured is different. However whatever be the difference, two things remains constant for a successful venture - Conviction and Persistence. ■



Grand Challenges in Global Health

Making a Difference

Started in 2003 by the Bill & Melinda Gates Foundation, the Grand Challenges in Global Health initiative seeks to promote and nurture innovation and research to solve various health problems plaguing the globe.

Grand Challenges is a family of grant initiatives focused on developing new tools that can drastically improve public health across the globe. Since its inception, Grand Challenges has galvanized new approaches that could one day impact millions of lives.

Challenges cover all kinds of health and development priorities: from vaccines, to point-of-care diagnostics, to the next generation of condoms, to more efficient agricultural practices.



Since its launch in 2003, new partners have adopted the Grand Challenges model to advance their work.

- **Grand Challenges Canada (GCC):** GCC funds innovators in low-and middle-income countries and Canada who work on “bold ideas with big impact.” In 2015, the Government of Canada renewed funding to GCC for a large-scale initiative aimed at developing and testing new innovations supporting maternal, newborn and child health in developing countries.
- **US Agency for International Development (USAID):** Since 2011, USAID has played a critical role in expanding Grand Challenges to address a range of global health and development issues. Most recently, USAID launched “Fighting Ebola: A Grand Challenge for Development” to help health care workers on the front lines provide better care and stop the spread of Ebola.
- **Grand Challenges Brazil:** In 2013, the Gates Foundation, the Brazilian Ministry of Health and the Brazil National Council of Technological and Scientific Development launched a Grand Challenge titled “Reducing the Burden

of Preterm Birth,” the first country-specific Grand Challenges initiative. Building on its success, the “All Children Thriving Grand Challenge” was launched in 2014 to focus on measurement tools and new combinations of approaches to ensure all children become healthy adults.

- **Grand Challenges India:** Grand Challenges India (GCI) was launched in 2013, jointly by Department of Biotechnology and the Bill & Melinda Gates Foundation. The aim of this initiative is to foster Indian innovation and research to develop affordable and sustainable solutions that improve the health and well-being of the Indian population. Till date, three grant programmes have been launched – *Achieving Healthy Growth through Agriculture and Nutrition*; *Reinvent the Toilet Challenge* and *All Children Thriving*.
- **Grand Challenges South Africa:** In 2014, at the 10th Grand Challenges meeting in Seattle, the Gates Foundation and the Department of Science & Technology of the Republic of South Africa launched the first Grand Challenges South Africa Request for Proposals under “All Children Thriving.”

Few ongoing projects in India

Designing on farm participatory models of integrated Farming system for enhancement of house hold diet diversity and livelihood of women small holder farmers

Annamalai University
Tamil Nadu

The integrated farming system in place in Cuddalore aims to enhance diet diversity, nutritional and health status of wetland women farmers, through integrated farming of rice, fish and poultry; and integrated goat, millet / vegetable and apiculture farming system.



Integrated farming system in Cuddalore, Tamil Nadu



Women small-holder farmers benefiting from the pilot in Cuddalore, Tamil Nadu

Ensuring year-wise nutritional food security to Indian Women through Community level implementation of Domestic Solar Conduction Dryer

Science for Society

The project aims to introduce a Solar Conduction Dryer (SCD), electricity free solar powered food dehydrator that reduces moisture content in agri-animal produce so that

women farmers and rural women can preserve seasonal produce up to 1 year without using any chemicals and earn additional income through sale of dehydrated products.



Calendar to monitor dietary consumption



Solar Conduction Dryer

Field testing of off-grid, self-sustained, modular, electronic toilet for slums, with solar energy for Indian weather and integrated with mixed waste processing unit, with water, energy/ fertilizer recovery

Eram Scientific Solutions Pvt. Ltd.
Kerala



Field testing of a solar power modular electronic toilet

Reducing zinc malnutrition in rural women and children through agronomic bio-fortification of food crops

Amity University
New Delhi

The grantee project involved improving the zinc nutritional status of food crops through soil and foliar application of zinc rich fertilizer. The project has created awareness among

farmers about the use of zinc fertilizers in low zinc soils to get better yields and also enhance zinc content in crops.



Soil application of rice crop at Manjhawali, Faridabad district



Foliar application of rice crops at Manjhawali, Faridabad district

Workshop

Bio-Entrepreneurship, Grant Writing and Intellectual Property Management

18-19 February 2016 | BITS, Pilani, Goa Campus

BIRAC organized a two-day workshop on “Bio-entrepreneurship, grant writing and intellectual property management” in association with BITS, Pilani, Goa Campus.

Attended by around 70 participants including representatives from academic institutes such as Goa University; Alliance University, Goa; BITS Pilani, Goa; and Industries such as Cipla, Lab India, Vergo Pharmaceuticals, Unichem and aspiring entrepreneurs and research scholars who are engaged in the biotech activities, the Workshop was inaugurated by Dr. Jose Manuel Noronha, Chairman, Goa State Pollution Control Board (GSPCB). Other distinguished guests at the inaugural session were Dr. K. Raman, Former Director, BITS Pilani, Goa Campus; Dr. Sunil Bhand, Dean, Sponsored Research & Consulting Division; Dr. Satya Prakash Dash, Head, SPED, BIRAC; Prof. Srikanth Mutnuri and Dr. Sumit Biswas, BITS Pilani, Goa Campus.

Welcoming the participants, Dr. K. Raman highlighted the activities of BITS Pilani aimed at Entrepreneurship Development and strong associations BITS Pilani has forged with industrial sector and how these links encourage BITS faculty to take on

entrepreneurial challenges. Delivering the inaugural address the Chief Guest, Dr. Jose Manuel Noronha brought the audience upto speed about the initiatives of GSPCB with hotels and restaurants in solid waste treatment and management. He requested the students, scientists and industries to come up with new ideas on treating the sewage and other waste generated by hotels and restaurants.

The first day of the workshop focussed on disseminating information about the various entrepreneurship development initiatives of BIRAC and its funding programmes. An important section dedicated to the key elements of Grant Writing was taken up by Dr. Shirshendu Mukherjee, Wellcome Trust, to explain to the participants, the nuances of writing a proposal.

The last session of the day was on experience sharing by BIRAC BIG grantee, Mr. Deepak Raj K., Df3D.

The theme for deliberations on the second day of the workshop was Securing & Exploiting Intellectual Property Rights In Biotech Sector. At the end, Dr. Vinita Jindal presented a summary of the deliberations and also sought participants feedback on the content and structure of the workshop. ■



BIRAC-CDSA Regulatory Workshop Series

Current Regulations on Medical Devices & *in vitro* Diagnostic Kits

24 February 2016 | Central Drugs Standard Control Organization, Chennai

BIRAC in collaboration with Clinical Development Services Agency (CDSA) organised a workshop on ‘Current Regulations on Medical Devices and *in vitro* Diagnostic kits’ on February 24, 2016 at Central Drugs Standard Control Organization (CDSCO), Shastri Bhawan, Chennai.

The objective of the workshop was to provide direct, relevant and valuable information on medical devices and *in vitro* diagnostic (IVD) kits including its regulations in India. It focused on sharing the updates on regulatory developments (discussion on the salient features of the Draft Bill) and guidance documents, review and approval process, step-wise development process including regulatory and scientific requirements, pre-clinical and clinical needs specifically in the area of medical devices.

Attended by 62 participants from various organisations comprising of 12 faculty members (including 4 Senior Regulators from CDSCO, 2 Present and 2 Former Regulators), the workshop gave an opportunity to the participants to clarify doubts through networking and interaction with senior regulators to seek answers to various unresolved queries on both medical devices as well as *in vitro* diagnostic kits.

Delivering the *Keynote Address*, Dr. Eswara Reddy, Joint Drugs Controller (India), CDSCO, New Delhi discussed about the

Medical Device Draft Bill and current regulatory scenario in India related to the regulation of medical device and IVD kits. Following this, Dr. S. Manivannan, Deputy Drugs Controller (India), CDSCO, South Zone, Chennai gave an overview of the Central Drugs Standard Control Organization (CDSCO) including its structure with respect to medical devices while also covering aspects related to the regulation for import, manufacture and sale of medical devices.

Dr. R. K. Sharma, Scientist – III & Head of Immunodiagnostic Kit Laboratory, National Institute of Biologicals (NIB), Ministry of Health & Family Welfare, NOIDA, spoke on the regulations for IVD kits and explained the role of NIB in testing. Design and Development of Medical Devices was discussed by Dr. Mohanasankar Sivaprakasam (Associate Professor of Electrical Engineering & Director of Healthcare Technology Innovation Centre, IIT Madras). Shri. Muraleedharan CV, Scientist/Engineer G, Biomedical Technology Wing, Sree Chitra Tirunal Institute for Medical Sciences & Technology, Trivandrum spoke on Biocompatibility where he addressed the safety assessment studies related to medical devices. The session on clinical investigational plan (clinical development) of medical device was addressed by Dr. Chetan Mittal, Consultant, Philips



Healthcare who explained the steps necessary to be taken prior to embarking upon clinical studies involving a medical device. In the session devoted to Medical Device Standards, Sh. Kalyan Varma, Vice President, TUV Rheinland (India), Bangalore spoke about CE Certifications and various steps involved in seeking compliance to ISO 13485.

A panel discussion on the regulatory process focusing on the Drugs and Cosmetics ACT, Medical Device & Patient Safety

Bill and probabilities of developing Indian CE marking system was moderated by Dr. G. Bhuvaneshwar, Former Director, Innovation & Education, Trivitron Healthcare, Chennai. All faculty members participated in the discussion.

All participants were given a handbook on *Regulatory Guidelines for Medical Devices and in vitro Diagnostic kits* (in DVD). All the presentations were uploaded at CDSA website and the web link was shared with all the participants. ■

Hands on Training

Membrane Separations: Theory and Techniques in Bioprocessing

25-27 February 2016 | Venture Center, Pune

BIRAC organized a three-day hands on training workshop on “Membrane Separations – Theory and Techniques in Bioprocessing” in association with Venture Center, Pune.

20 participants from 11 different enterprises attended the workshop which had Dr. Sanjay Nene, Dr. Ulhas Khaul, Dr. Sushmuna Shukla and Dr. KSMS Raghav Rao associated with it as Expert Faculty.

The primary aim of the workshop was to cover the fundamental principles and techniques used in experimental and process membrane separations in the area of bioprocess and product recovery. The workshop focussed on basic principles underlying membrane separation processes, theory of microfiltration, ultrafiltration, nanofiltration and reverse osmosis, gas filtration/separation and pervaporation and their application

in bioprocesses, food processing and beverages. Handouts for conducting the experiments and data analysis were provided as and when each group went for the actual experimentation. A visit to an industrial membrane manufacturing facility, Uniflux was also a part of the programme.

The experimental set-up involved preparation of flat sheet membrane and their clean water flux, passage/ rejection of standard compounds, osmotic membrane distillation and forward osmosis for treatment of fruit juices, recovery of aroma and other volatile products. Demonstration of microfiltration, ultrafiltration and nanofiltration for application in different bioprocesses was also conducted.

The participants appreciated the content and timing of the workshop especially the visit to Uniflux. ■



Workshop

Bioinformatics techniques in Genome and Proteome analysis

16-17 February 2016 | International Centre for Genetic Engineering and Biotechnology, New Delhi

International Centre for Genetic Engineering and Biotechnology (ICGEB) organized a DBT Sponsored two-day workshop on Bioinformatics techniques in Genome and Proteome analysis. It was attended by 16 researchers from different academic institutes & 4 grantees from BIRAC.

The first day of the workshop focussed on concepts of Proteomics & Systems Biology. The second day was dedicated to NGS analysis using “SanGenix”, a software developed

by Persistent Systems Pvt. Ltd. with financial support from BIRAC. Representatives from Persistent Systems explained the trainees about the phenomena of variant identification, variant annotation and visualization in yeast genome, RNA Sequence analysis and CHIPSeq. The participants were also informed as to how chromatin IP sequencing application allows researchers to expand the scale of their studies to identify binding sites across the entire genome including human genome. The participants found “SanGenix” to be very user-friendly & productive. ■

Short Term Training

Application of Marker Assisted Selection and Transgenic Development for Crop Improvement

18-20 February 2016 | ICAR-National Research Centre on Plant Biotechnology, New Delhi

In the recent past use of Marker Assisted breeding and transgenic approaches have resulted in development of several improved varieties that have benefited the resource poor farmers of India in a significant way. Therefore, use of such newer technologies aiming at product development needs to be encouraged. However, there are some considerations while applying such new technologies in science-led agriculture. Also, there is a need to sensitize all stakeholders about the technological aspects and achievements of biotechnology in crop improvement.

To take this forward, BIRAC and ICAR-National Research Centre on Plant Biotechnology, New Delhi organised a short term training course on “Application of Marker Assisted Selection and transgenic development for Crop Improvement”. 22 participants, (11 from industry and 11 from academia), attended the workshop. The experimental setups were also planned in the workshop, to give a practical experience of the protocols to the attendees. This included PCR amplification with SSR and ISSR markers and gel electrophoresis of the amplicons



to show polymorphism and selection in a population, Gene amplification; Cloning into binary vector; Confirmation using PCR; Agrobacterium mediated transformation, Confirmation of transgenic events using PCR and Southern and Northern blot analysis; bioassay. Faculties with the likes of Dr. T.R Sharma, Dr. AK Singh, Dr. S.R Bhatt, Dr. Firoz Husain amongst others spoke of their own experience of product development in crop biotechnology.

The participants felt that the workshop was well balanced in terms of theoretical content as well as practical setup and requested BIRAC to conduct more of such workshops. ■

Bio-incubator@iitk

Building a Biotech Enterprise Ecosystem

4 March 2016 | SIDBI Innovation and Incubation Center, Kanpur

The Bio incubator at SIDBI Innovation and Incubation Center (SIIC), Indian Institute of Technology - Kanpur (Bio-incubator@iitk) was inaugurated on 4th March, 2016 by Dr. Renu Swarup, MD BIRAC in the presence of Prof. Indranil Manna, the Director of IIT Kanpur and other BIRAC representatives including Dr. Satya Dash and Mr. Rajneesh Kumar. Established by BIRAC, under the BIS (Bio-Incubator Support Scheme), Bio-incubator@iitk will give a leg up to budding entrepreneurs working in areas of biotechnology, biopharma and biomedical devices. Given the location of bio-incubator at IIT-Kanpur, one amongst India's most prestigious technology institutions, the incubatee companies will not only have access to world class incubation facilities but also to the infrastructure and faculty expertise at IIT Kanpur.

The Bio-incubator@iitk has state-of-the-art facilities for molecular biology, biochemistry, cell biology and tissue engineering, including many different kinds of fermenters for large scale protein production for pharmaceutical purposes. At present there are nine companies incubated at Bio-incubator@iitk. Some of the current incubatee companies have availed funding under BIRAC schemes and are involved in the domains of drug discovery and smart material development for the

purpose of implantation. To support commercialization ready implant fabrication, the incubator has a high-end class 10000 Clean room, which is unique in the incubation space.

At the inaugural function, Prof. Amitabha Bandyopadhyay, faculty in-charge of Bio-incubator@iitk appreciated and welcomed the support of BIRAC. He also underlined the critical role of the Bio-incubator in enabling incubated companies to make use of the labs, equipment and other facilities, thereby saving precious capital and cutting down operating expenses on research and product development.

Dr. Dash commenting on industry-academia partnerships, emphasized on the importance of having incubators within academic campuses, particularly in the bio domain that is highly capital intensive. Not only it facilitates innovation but is also in line with the national agenda of facilitating affordable health care for all, he added. Prof. S. Ganesh, Head of Department of Biological Sciences and Bioengineering, IIT Kanpur, gave an overview of biosciences related research activities at IIT Kanpur. Following this, participating IIT-K faculty members introduced their research domains and possible translational angles to their work, to the gathering.



Highlighting the strategic importance of the bio-incubator in the R&D ecosystem of IIT Kanpur, Professor Amalendu Chandra, Dean, Research & Development, IIT Kanpur said "IIT Kanpur is keen on expanding the available infrastructure to further reduce the up front cost for the current and future incubatee companies".

The plenary talk by Chief Guest, Dr. Renu Swarup, MD, BIRAC & Senior Adviser, DBT on "Fostering a bio-innovation culture to build a globally excellent Indian Bioeconomy" was very

enlightening and motivating for the potential entrepreneurs and PhD students present in the gathering. The evening ended with the tour of Motwani Accelerator and Bio-incubator@iitk.

The event was attended by several participants from the industry including Dr. Ruchi Sood, (Daiichi Sankyo), Dr. Ganesh Sambasivam (Anthem BioSciences), Dr. Arjun Surya (Curadev), Amardeep Udeshi (Cipla) and Dr. Ajith Kamath (Pfizer), which added value to the event. ■



Biotechnology Industry Research Assistance Council

(A Govt. of India Enterprise)

Invites proposals

For Supporting

Affordable Biopharmaceutical Development

(Identifying novel tools/technologies and Process optimization)

Small Business Innovation Research Initiative (SBIRI)

&

Biotechnology Industry Partnership Programme (BIPP)

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

- Identification and validation of novel bioprocesses for biopharmaceuticals at lab scale (5.0 L)
- Innovative R&D solutions for upstream and downstream process optimization

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/Organization.

(Companies in the process of obtaining DSIR recognition may also apply; however, their funding would be subject to getting DSIR recognition).

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 products for commercialization

- Pilot scale validation of novel processes
- Demonstration of novel engineering processes for existing technologies

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 the BIRAC website (www.birac.nic.in).

Last date for Submission of Proposals:

31st March, 2016



BIOTECHNOLOGY INDUSTRY RESEARCH ASSISTANCE COUNCIL

Empowering and Enabling the Biotech Innovation Ecosystem for Affordable Product Development

BIRAC is a 'Not-for-Profit Company' set up by Dept. of Biotechnology, Govt. of India as its interface agency to serve emerging biotech industries. BIRAC is guided by an independent Board of Directors comprising of senior professionals, academicians, policy makers and industrialists. BIRAC operates a variety of schemes to serve various dimensions of its mandate.

BIG

Biotechnology Ignition Grant (BIG) is available to scientist entrepreneurs from research institutes, academia and startups. It is designed to stimulate commercialization of research discoveries by providing very early stage grants to help bridge the gap between discovery and invention. The BIG Innovators receive mentoring and networking help from five BIG Partners (C-CAMP Bangalore, IKP Hyderabad, FITT IIT Delhi, NCL Venture Center Pune and KIIT-TBI Bhubaneswar).

SBIRI

Small Business Innovation Research Initiative (SBIRI) is the first of its kind, early stage, innovation focussed PPP initiative to support incremental R&D in the area of Biotechnology to facilitate innovation and risk taking by SMEs. SBIRI support is in the form of a mix of soft loans and grants.

BIPP

Biotechnology Industry Partnership Programme (BIPP) seeks to provide support for early to late stage high risk biotech R&D by industry and/or accelerate commercialization of new indigenous technologies.

CRS

Contract Research and Services (CRS) scheme supports academic institutes across the country to take forward research leads through a validation and translation cycle by the industry. Funding is in the form of grant given to both the academic as well as the industrial partner. While the industry performs its role as a validation partner and engages on a contractual basis, the IP rights reside solely with the academic partner.

SPARSH

SPARSH combines social innovation and biotechnology for the well-being of the society by helping identify and support cutting edge innovations towards affordable product development with potentially significant social impact. SPARSH provides support in the form of impact funding and fellowships.

BIS

In order to foster techno entrepreneurship in biotechnology, BIRAC has initiated a scheme for Strengthening and Up-gradation of the existing Bio-incubators and also to establish New World Class Bio-incubators. These Bio-incubators will provide the incubation space and other required services to startup companies for their initial growth.

UIC

The University Innovation Cluster Initiative (UIC) focuses on Universities, where conducive environment for biotechnology collaboration and innovation thereof exists and where all stakeholders including industry can be brought together in synergy with each other. UIC initiative seeks to create an entrepreneurial culture in the Universities and help students to take their novel ideas to proof of concept.

DBT-BMGF

BIRAC manages the DBT-Bill and Melinda Gates Foundation project to support collaborative scientific and technological research to alleviate some of the world's most critical global health and development issues.

IIPME

BIRAC collaborated with Department of Electronics and Information Technology (DeitY), Ministry of Communications & IT, Government of India, to launch an Industry Innovation Programme for Medical Electronics. The first call under the partnership was launched in May 2015, focusing on – *Imaging & navigation, technologies for chronic diseases, convergence of medical devices and bioinformatics, and increasing the outreach through medical electronics.*

GC-TB Control

BIRAC collaborated with USAID to fund a joint programme on TB Diagnostics which is managed by IKP Knowledge Park, Hyderabad. The programme call is planned to aim at supporting new diagnostics for TB. The call was launched on December 1, 2015 focusing on the theme - *Innovative Solutions from India to improve TB Detection, Case Notifications and Treatment Outcomes for Adapting in Developing Countries in Africa and South Asia and Scaling up in India*

FORTHCOMING CALL FOR PROPOSALS

Biotechnology Ignition Grant (BIG) | 01 July 2016

For further information please contact:

Biotechnology Industry Research Assistance Council (BIRAC)

1st Floor, MTNL Building, 9, CGO Complex, Lodhi Road, New Delhi-110003, INDIA

Tel: + 91-11-24389600 / Fax: + 91-11-24389611

E-mail: BIRAC.dbt@nic.in | Web: www.BIRAC.nic.in