

## Scaling Biotech Innovations for Global Impact



**Remembering Dr Bhan:  
The man who changed the landscape  
of Biotech Sector**



**birac**  
*Ignite Innovate Incubate*

Biotechnology Industry Research Assistance Council  
(A Government of India Enterprise)



March **2020**

No. 1 | Vol. 7

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## Leader's Message



**Dr. Renu Swarup**  
Secretary DBT  
& Chairperson BIRAC



**डॉ. रेणु स्वरूप**  
**DR. RENU SWARUP**

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### Message

Biotechnology has profound impact in the fields of health, nutrition, agriculture and others. In the past century, technological progression has galloped at staggering rates, with new innovations, developments, and breakthroughs making way for affordable solutions for common human problems. The biotech innovations industry is one of the major industries to follow through this decade. These innovations have key to solving challenges in healthcare, food and energy-security; both at global and national level. BIRAC has focussed on fostering innovation and research for affordable product development.

The foundation laid by BIRAC during its 8-year journey so far has provided the Biotech industry a platform to leverage the entrepreneurial surge and investor appetite. BIRAC has strived to foster innovation and entrepreneurship, promote affordable innovation in key social sectors, empowered start-ups & small and medium enterprises. BIRAC has contributed towards capacity enhancement and diffusion of innovation via its many partnership programmes. BIRAC is not only committed to promote innovations and enable their commercialization but also to ensure global competitiveness of Indian enterprises.

As we move forward it is imperative that we now focus on the sustainability and scale up of these innovators and enterprises and also continue to provide an enabling ecosystem to ensure that we can create a national and global impact.

On the 8th Foundation Day of BIRAC, I take this opportunity on my personal behalf and on behalf of the entire Biotech community to pay tribute to our Founder Chairman BIRAC and Former secretary, DBT Dr. M.K. Bhan. It was his vision to create this wonderful platform and I am confident that we all will continue take forward his dream of India becoming a Global Innovation Hub

Lets us all strive to draw on our collective experiences, learn from our mistakes and co-create a future that meaningfully brings in biotech innovation as solutions to our common problems in our daily lives. I am confident that DBT and BIRAC would continue to strengthen and energize the innovation ecosystem in the country.

(Renu Swarup)  
Secretary, DBT & Chairperson, BIRAC

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## **Chief Editor's Take**



**Dr. Mohd. Aslam**  
Advisor DBT  
& MD BIRAC

Innovation in science & technology are integral to the long-term growth and dynamism of any nation. Biotechnology has revolutionized and transformed the areas of innovation, whether it is science, technology, health, medicine and any other sectors. Over a few decades, techniques have improved rapidly; yielding extraordinary new products and processes. India is at the threshold of a decade of innovation and Indian biotechnology is capable of providing solutions to the myriad challenges we face as a country, whether in terms of health, food, growth or national safety. The solutions that India would offer would be important both nationally and globally. Entrepreneurs and innovators are driving the next wave of innovation by creating affordable products addressing the needs of the largest section of society.

The role of innovation hubs that amalgamate entrepreneurship, industry, capital and research have never been more essential. Undoubtedly, innovation is essential to economic growth. Biotechnology serves mankind in helping to move towards a biotechnology-led economy, transforming as many lives as possible, creating opportunities and promising development for all.

The mandate of BIRAC is to nurture and empower the biotech innovation ecosystem and transform all elements of the nascent biotechnology industry systems. In the last eight years, BIRAC has played a pivotal role in promoting the culture of innovation in the field of biotechnology through various programs and initiatives.

BIRAC supported innovations have come a long way in resolving problems in the sector of agribusiness to health care and pharmaceuticals to energy and computing. The vibrant ecosystem that BIRAC has offered to the innovators has been very helpful in addressing major societal problems. Biotechnology's role is crucial for the Indian knowledge economy to grow as it is a chief contributory sector to the ambitious goal of 5 Trillion USD economy. In this scenario, BIRAC assumes a greater role in order to achieve the said target. With DBT's constant endurance and support, BIRAC will fuel these innovations to create a global impact.

I also take a moment to remember Dr M. K. Bhan, whom we lost this 26th January 2020. Dr. Maharaj Kishan Bhan was a pioneer in biomedical science, a thorough leader in the field of science and technology. I will always remember him as an inspiring philosopher and a visionary. I also had an opportunity to work under his guidance in Department of Biotechnology which I will cherish for the lifetime. Dr. Bhan left behind him an unmatched legacy in the public health domain. We at BIRAC will continue to work on Dr. Bhan's principles and will make all efforts to fulfil his vision.

Dr. Mohd. Aslam  
Advisor DBT & MD BIRAC

## BIRAC Remembers Dr. Bhan

Medical Community in India recently lost one of its pioneers Dr Maharaj Kishan Bhan, the eminent paediatrician and clinical scientist who contributed significantly to science and healthcare in India. He passed away on 26<sup>th</sup> January 2020 at the age of 72 after succumbing to a prolonged illness.

Born in 1947 in Srinagar, Dr Bhan received his M.B.B.S. Degree from the Armed Forces Medical College, Pune and M.D. Degree from Post Graduate Institute of Medical Education and Research, Chandigarh. Following stints at these institutions, he went on to conduct extensive research for his post-doc at the All India Institute of Medical Sciences (AIIMS) studying child nutrition to further robust public health outcomes.

Dr Bhan's career spanned a spectrum of different activities and roles in a highly successful manner that only a few people could have donned. Beginning as a trained paediatrician, to becoming an academic clinician at AIIMS, to further progressing to become Secretary in Department of Biotechnology, his perseverance made him successful in each of his assignments.

It was in 1985 when Dr Bhan began his endeavour towards developing the Rotavac.

In India, Diarrhoea is one of the leading causes of death in children under five years of age. However, through this vaccination, millions of kids have been benefited. A three-dose vaccination course of Rotavac vaccine costs just Rs 180 which is easily accessible as well as affordable.

Dr. Bhan was the man behind the Rotavirus Vaccine, the first indigenously developed rotavirus vaccine which drastically lowered the cost of vaccination for diarrhoea. Dr Bhan brought together government organisations, non-profit organizations, international organisations as well as private sector players to develop this life-saving vaccine. From the Department of Biotechnology to the Bill & Melinda Gates Foundation to the National Institutes of Health to Research Council of Norway and Industry partner Bharat Biotech, the formulation of the Rotavac witnessed an institutional collaboration that is rarely seen around the world. It was the first vaccine that is made in India from scratch. It was licensed for use in India in 2014, and is one of four WHO-approved oral vaccines for the disease.

In recognition of his exemplary research, Dr. Bhan was awarded the prestigious Shanti Swarup Bhatnagar Prize for Science & Technology in 1990.

As Secretary of the DBT from 2005 to 2012, he established new institutions like the Translational Health Science and Technology Institute in Faridabad, which conducts extensive research into vaccines, infectious diseases and drug development. He was

instrumental in enabling industry-academia collaboration in the field. Further, he developed BIRAC (Biotechnology Industry Research Assistance Council), a Public Sector Enterprise bringing industry and academia together on one platform to strengthen the innovation ecosystem across the country.

Among other contributions, he played a key role in bringing international funding by establishing partnerships with the US-based Bill & Melinda Gates Foundation and the UK-based Wellcome Trust. The Wellcome Trust/DBT India Alliance — a public charity that funds research in health and biomedical sciences in India was only made possible because of Dr Bhan's efforts.

He was awarded the coveted Padma Bhushan, in 2013 for outstanding contributions to governance and civil service.

As great leader, he transformed the landscape of biotechnology in our country — from enabling industry-academia collaboration to developing new institutional governance models to the vaccine and creating partnerships. One such successful partnership between the DBT and Bill & Melinda Gates Foundation led to the start of the Grand Challenges India (GCI). GCI was launched with the aim of directing funding, research and encouraging innovation to address some of the greatest public health and development challenges that India faces today.

Despite his achievements, it was his warmth that stood out for his colleagues. He was a teacher at heart who motivated the younger generation to come forward and take up new innovative ideas. His constant advice was to move out of the comfort zone and take the risk.

Dr Bhan was truly an example who believed in celebrating every moment in life and being good to everyone around.

BIRAC lost a friend, a mentor, a teacher and a visionary early this year. Dr. M K Bhan was many things to many people and organisations, but to us in BIRAC, he was our founding father.

While his loss leaves a void among us, it is our moral imperative to find inspiration in the life, work and dedication of this exemplary person, to continue the work that he started and to achieve the potential he always said that we should, in the service of the nation.

Of his legacies, and there are many, we in BIRAC felt that we were entrusted with a task that, at the time, no other institution was charged with. This was to nurture the fledgling biotechnology capability of a country with a billion dreams and as many needs. This is a responsibility that we continue to hold dear.

An incorrigible visionary, Dr. Bhan always pushed everyone to think big and beyond the usual. Even in meetings and gatherings where Sir spoke, we always learnt something new each time. Sir always worked





Memories with Dr.Bhan

5 years ahead of where we were at the time, he always encouraged planning for tomorrow.

From the discovery of the rotavirus strain that would go on to become the first made in India vaccine which save thousands of children every year, to the establishment of several institutes during his time as Secretary DBT, to creating and nurturing partnerships both nationally and internationally, Dr. Bhan's professional career stood testament to his belief that one should work for the benefit of the country.

It was a privilege to know and work with Dr. Bhan, for many of us in BIRAC who had the chance to.

As his family put it, his life is to be celebrated. And for us in BIRAC there is no better celebration of his life and legacy than to continue working to achieve the vision he had for a healthy and prosperous India.

Thank you Sir, for everything. We will miss you.

- From the BIRAC Family

## BioAsia 2020

BioAsia 2020 was held during 17<sup>th</sup> to 19<sup>th</sup> Feb 2020 at HICC, Hyderabad, India. The 17<sup>th</sup> edition of the event with the theme of 'Today for Tomorrow' was inaugurated by KT Rama Rao, Minister for Industries and commerce & IT, Government of Telangana. BioAsia is the annual flagship event of Government of Telangana and has become one of Asia's largest Life Sciences and Biotechnology convention. The 3 days event saw the presence of stalwarts from Life Sciences, Biotechnology, Pharma and Healthcare industries in India and abroad and focused on how innovations and technological disruptions are re-shaping the global life sciences sector. Over 2,000 delegates from Industry, Government, Scientist Community, Academia and Start-ups representing 37 countries participated in the global bio-business event.

The event hosted eminent global leaders from the life sciences industry including Mr. Vas Narasimhan, CEO, Novartis, Dr Carl H June, CAR-T Pioneer, Dr Peter Piot, London School of Hygiene and Tropical Medicine and Co-Discoverer of Ebola, Mr Dilip Shanghvi, Chairman, Sun Pharma, Ms Kiran Mazumdar Shaw, CMD, Biocon, Mr Ajay Piramal, Chairman, Piramal Group, Mr Satish Reddy, Chairman, Dr Reddy's Laboratories, among others.

Dr Manish Diwan, Dr Hafsa Ahmad and Mr Amit Kumar from BIRAC participated in this event. The exhibition was inaugurated on day 1 of the event. BIRAC stall received a high response from start-ups, students, academicians and researchers showing great interest to know about the various schemes and activities of BIRAC. Young start-ups and researchers exhibited enthusiasm to know about our new initiatives, incubators, time of various calls and possibilities of collaborations in different capacities. The exhibition also had representation from many BIRAC supported incubators and start-ups.

BIRAC sponsored panel discussion on Collaborative R&D: Unlocking the potential of public and private partnerships was held on Day 2 of the event. Dr. Ajit Shetty, Corporate VP Global Operations, J&J USA (Retd.), Chairman Emeritus, Janssen Pharmaceutica, Belgium & Chairman, International Advisory Board, BioAsia moderated this session and the panel included Mr. Ajit Rangnekar; Director General, Research & Innovation Circle of Hyderabad, Dr. Subodh Deshmukh; Global Head of Product Development, Sandoz, Mr Krishna Kanumuri; CEO & Managing Director, Sai Life Sciences Ltd., Mr Jonathan Hunt; CEO Syngene International, Dr. Srinivas S Rao; Global Head, Translational In Vivo Models Global Research Platform, Sanofi, USA, Dr. Omkaram Nalamasu; Chief Technology Officer, Applied Materials & President, Applied Ventures, USA; Dr. Margrit Leuthold; Deputy Program Director, 'Future Health Technologies' Program, Singapore ETH Zurich Centre. The session converged upon establishing various ways and mechanisms to develop programs based on public-private partnerships for solving global health problems.

BIRAC co-sponsored the start-up stage awards that concluded on day 3 of the event. Mr. KT Rama Rao; Hon'ble Minister for Industries and Commerce, Government of Telangana graced the award ceremony. The top 5 awardees receiving this prestigious award were Heamac Healthcare Pvt. Ltd., Callzy, Flexmotiv, Lycan 3D, Oncosimis Biotech Pvt. Ltd.



Glances from BioAsia 2020



## 3<sup>rd</sup> Emerging North East 2020

The Associated Chambers of Commerce and Industry of India recently organized “Emerging North East” event. The 3<sup>rd</sup> edition was held from 27<sup>th</sup> February to 29<sup>th</sup> February 2020 at Maniram Dewan Trade Centre, Guwahati. The three day exhibition brought a large number of national and international stake-holders from the industry, institutions, Government and the development sectors to showcase their programs and schemes, products, technologies and services; along with focus on opportunities and the way forward.

The event comprised series of discussions, technical sessions and business meetings with focus on leveraging agri and food processing potential, role of industry and institutions in exploring the opportunities and leveraging the overall development of the north-eastern region.

The Governor of Assam, Jagdish Mukhi inaugurated the event. Other dignitaries from Ministry of Industry & Commerce, Food processing industry, Ministry of Micro, Small & Medium Enterprises (MSME) were also present at the event.

BIRAC supported as well as participated in the event and familiarized the audience about various programs/schemes/ongoing calls. Ginny Bansal, Consultant (Communications) represented BIRAC.

The closing day of the 3<sup>rd</sup> Emerging North East event focused on building capacity of tribal entrepreneurs through training in personality development, negotiation skills, marketing and branding.

The event was supported by Ministry of food processing and industries, Department of Tourism and Department of Skill Development.



Glimpses from 3<sup>rd</sup> Emerging North East event 2020



## Project Vigyan Samachar Workshop

India is excelling in science and technology, and a lot of Indian scientists have made their mark globally. Every day, newsworthy achievements of science & technology are generated by different departments and various organizations of the Ministry of Science & Technology and Earth Sciences. However, a lot of developments in the sector of science and technology generally go unpublished in various media.

In order to bridge this gap, Vigyan Prasar (VP) organised the inaugural workshop called “Project Vigyan Samachar workshop” – an initiative to streamline and hasten the process of science communication and increase the visibility of science and technology news in different media. VP an autonomous organization of DST has been entrusted with the responsibility to coordinate news stories received from Department of Science and Technology (DST), Department of Scientific and Industrial Research (DSIR), Department of Biotechnology (DBT) and Ministry of Earth Sciences (MoES) and other associated institutions for all four media sources – print media, electronic media, various digital platforms and social media.

The workshop was organised at Prithvi Bhawan, Lodhi Road on 14<sup>th</sup> January 2020.

Professor Ashutosh Sharma, Secretary, Department of Science and Technology, Dr. Renu Swarup, Secretary, Department of Biotechnology, Dr. Shekhar Mande, Secretary DSIR and Director General, CSIR and Dr. M Rajeevan, Secretary MoES graced the occasion.



Glances from Project Vigyan Samachar Workshop

Science Communication nodal officers from all autonomous institutions of the different departments as well as several science journalists and scientists, participated in the workshop. Dr. Hafsa Ahmad and Ginny Bansal, Consultant (Communications) from BIRAC attended the workshop. Participants were divided into teams representing their respective departments and a closed door interaction was held to arrive at the possible mechanisms of taking this forward. Representatives from various media agencies were also present.

## Grant Writing Workshops

To apprise the potential applicants about various funding schemes of BIRAC and on writing effective grant proposals, BIRAC is organizing a series of Grant Writing Workshops. Two of these were organized in the month of February, 2020, the first in association with IKP-Eden, Bangalore and the second with ASPIRE-BioNEST, University of Hyderabad. These workshops were attended by about 200 participants from academia, Industry and Start-ups. Active participation was also seen from other Incubator Managers so that they could guide the incubated companies on the funding options available with BIRAC. The third workshop in this series is scheduled to be held at Society for Innovation and Entrepreneurship, IIT-Bombay in March, 2020.



Glimpses of the Workshop at University of Hyderabad



Participants of Grant Writing Workshop held at IKP Eden



## Third Edition of DBT –BIRAC Leadership Dialogue Series

Department of Biotechnology (DBT) and Biotechnology Industry Research Assistance Council (BIRAC) have been making tremendous efforts in order to promote biomedical research, translational research education and entrepreneurship development. DBT and BIRAC initiated “Leadership Dialogue Series” – a platform to bring together leaders from various domains across the world to share their experiences.

This series will be helping the scientific community and students to learn from the vast experiences of the stalwarts in various fields and start a dialogue to take the country to develop into a strong and stable bio-economy. The format of this series is interactive.

The first edition of the Leadership Series was held on 18<sup>th</sup> July 2019 in partnership with Indian Institute of Science, Bengaluru. The first lecture in the series was delivered by Bharat Ratna Professor C.N.R Rao on “Climbing the limitless ladder of excellence”.

The second lecture in the Leadership Dialogue Series was delivered by Dr. Trevor Mundel, President, Global Health, Bill & Melinda Gates Foundation on “Innovating for Impact: How India can lead in helping solve some of the world’s toughest health challenges”. The event was held on 29<sup>th</sup> July 2019 at J L Auditorium, All India Institute of Medical Sciences, New Delhi.

Recently, the third lecture in the series was delivered by Dr. Eric Green, Director, National Human Genome Research Institute on 8<sup>th</sup> January 2020 on topic titled “From the Human Genome Project to Precision Medicine: A Journey to Advance Human Health” at National Institute of Immunology, New Delhi. Genomics is an emerging medical discipline that involves using genomic information about an individual as part of their clinical care and other implications of that clinical use. Dr Green elaborated upon the first three decades of genomics and the new realities and opportunities. Human genome was sequenced for the first time by the Human Genome Project, where the cost of sequencing a human genome could be reduced by nearly ~1 million folds. This genome project lead to profound advances in understanding how the human genome functions which has paved the way in unraveling the genomic bases of human diseases. He further emphasized that cancer genomics, pharmacogenomics, rare genetic disease diagnostics and prenatal genomic testing are currently important areas of genomic research.



Glimpses from DBT – BIRAC Leadership Dialogue Series at NII, New Delhi

Dr. Dr. A. K. Panda, Director, National Institute of Immunology gave the welcome address and Dr. RenuSwarup, Secretary, Department of Biotechnology and Chairperson BIRAC gave an introduction about the distinguished speaker and an overview about the Leadership Dialogue Series. More than 300 people including representative from different institutes, students, academicians and scientific community were a part of this interactive event. The lecture was followed by Q & A session with active participation from the audience with keen interest to know about the genomic medicines. The Leadership Dialogue Series will be held in various part of the country to benefit the scientific community at large.



## Award Ceremony for BIRAC-Social Alpha Quest for Assistive Technologies supported by Mphasis

The 'BIRAC-Social Alpha Quest for Assistive Technologies—supported by Mphasis' was launched in June 2019, New Delhi to support and scale Assistive Technologies (AT) from Start-ups under a strategic Public-Private Partnership. Large numbers of applications 100+ were received. The winners were chosen based on their; business model, technological innovation, product-market fit, focuses on affordability and accessibility and socio-economic impact by expert jury members.

The winning solutions included assistive technologies in speech and hearing impairment, locomotor disability, visual impairment and intellectual disability for children and adults. The top 14 Indian startups selected as the winners were given certificates during the Award Ceremony held on 23<sup>rd</sup> Jan 2020 at Taj Gateway hotel, Bangalore. The list of the awardees: Trestle Labs Pvt. Ltd., Kidaura Innovations Pvt. Ltd., Thinkerbell Labs Pvt. Ltd., Demosthenes Technologies Pvt. Ltd., Tactopus Learning Solutions Pvt. Ltd., Flexmotiv Technologies Pvt. Ltd., BeAble Health Pvt. Ltd., Truce Consulting Services Pvt. Ltd., Indent Designs Pvt. Ltd., Brajma Intelligent Systems Pvt. Ltd., Innaumation Medical Devices Pvt. Ltd., Raised Lines Foundation, SM Learning Skills Academy for Special Needs Pvt. Ltd. and Inceptor Technologies Pvt. Ltd.

The winners were awarded grant prize up to INR 50 lakh each meant for completion of the clinical trial, improvement in design-for-manufacturability and fulfilment of work orders. Additionally, they were enrolled in a 3-month accelerator programme, 'Social Alpha Accelerator for Inclusive Solutions'.

The winners received appreciation for recognizing the need of assistive technologies and providing solutions that would enhance equal participation and dignity for people with disabilities in all the areas of society. The speakers at the Award Ceremony included, Mr.



Partners from BIRAC, Social Alpha & Mphasis at the Award Ceremony of BIRAC-Social Alpha Quest for Assistive Technologies Supported by Mphasis



Dr. Manish Diwan, Head SPED, BIRAC Addressing the Audience at the Award Ceremony

Manoj Kumar, CEO and Co-founder, Social Alpha, and Head of Innovation and Entrepreneurship, Tata Trusts, Ms. Deepa Nagraj, Global Head-Sparkle Innovation Ecosystem & Mphasis Corporate Communication, Mphasis and Dr. Manish Diwan, Head-Strategy Partnership & Entrepreneurship Development, BIRAC.



Cohort of 14 Awardees of BIRAC-Social Alpha Quest for Assistive Technologies Supported by Mphasis

## BIRAC TiE Entrepreneurship Awareness Workshops

BIRAC in collaboration with TiE-Delhi NCR organised 4 Entrepreneurship Conclaves in various cities in India including Jalandhar, Kolkata, Kerala and Delhi. The initiative aimed to spread awareness about Bio-Entrepreneurship across the country. The conclaves brought together several successful startup entrepreneurs to share their stories and experiences with students and young entrepreneurs. The young minds were also made aware of BIRAC's role in bolstering the Indian start-up culture as well as exploring avenues for a smoother transition from a university environment to the real world. The speakers addressed various important factors in the start-

up creation process – from ideation to venture creation and funding – and an introduction to legal compliances for start-ups, among other things, during the sessions. Approx 300 Students and young entrepreneurs from various educational institutions benefitted from discussions on pertinent topics, interesting case studies and introduction to various aspects of entrepreneurship. With the Entrepreneurship Conclaves planned across cities, BIRAC provided a knowledge-sharing platform to young students and entrepreneurs to be inspired and empowered, by listening to and learning from the experiences of the masters in the entrepreneurial domain.



BIRAC TiE Entrepreneurship Awareness Workshops

## Workshop on Grant Writing, Intellectual Property & Technology Management in Life Sciences

BIRAC organized a two day workshop on “Grant Writing, Intellectual Property & Technology Management in Life Sciences” in association with BITS, Goa on 14<sup>th</sup> & 15<sup>th</sup> February, 2020. The program was designed for the Start-ups, Academia and SMEs to aware them on writing an effective grant proposal, important aspects on Intellectual Property, Technology Transfer and Commercialization process and regulatory requirements related with the biotech innovations.

The workshop was well represented by about 50 participants from academic institutes, medical colleges, start-ups and aspiring entrepreneurs engaged in life science sector. The first day of the workshop covered the topics such as key elements for writing a effective grant proposal, role and importance of IP for Start-ups, Patentable subject matters in India, Patent searches and an overview of Technology Transfer & Commercialization. Last day of the workshop was focused on the regulatory compliances associated with medical

device & diagnostics and also with the utilization of the National Biodiversity resources for research and commercialization purposes.



Workshop on Grant Writing, Intellectual Property & Technology Management in Life Sciences



## **BIRAC's IP Law Clinic organized at KIIT-Bhubaneswar on 8<sup>th</sup> February, 2020**

BIRAC conducted IP Law Clinic at KIIT-Bhubaneswar on 8<sup>th</sup> February, 2020 where BIRAC supported grantees had one to one interaction with the BIRAC IP & Technology Management team on IP & Technology Management related matters. The clinic was organized to provide a strategic advisory on IP filing process and to provide a solution based approach on complex IP & Technology Transfer matters. The team also explained about the financial-aid available under BIRAC-PATH scheme for its grantees to provide the support for Patenting and Technology Transfer emerging out from the BIRAC supported projects. The IP Law Clinic was well attended by around 13 BIG grantees.



BIRAC's IP Law Clinic organized at KIIT-Bhubaneswar

## **BIRAC Awards**

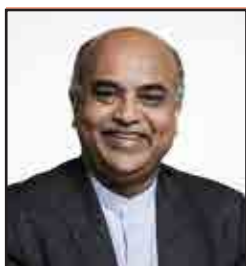
BIRAC received "IPR Leadership Award" for excellent contribution in the field of Patents during the event organized by Social Talks with Niti Aayog on 1<sup>st</sup> February, 2020. BIRAC IP & Technology team Dr. Shirshendu Mukherjee and Dr. Vinita Jindal also received the "IPR Leadership Award" for excellent contribution in the field of Patents.



Glimpses from the Award Ceremony



## Updates



Dr. Shirshendu Mukherjee



Dr Vinita Jindal

**BIRAC is privileged to have 2 RTTP 's**

**Heartiest Congratulations to Dr Shirshendu Mukherjee  
and Dr Vinita Jindal for being recognized as Registered  
Technology Transfer Professionals by ATTP**



***Congratulations***

**11 Professionals supported by National Biopharma Mission  
and mentored by Sathguru Management Consultants are  
recognized as Registered Technology Transfer  
Professionals (RTTP) by ATTP**



## HR & Admin Activities

### New year 2020

On the occasion of New Year 2020 Dr. Renu Swarup, Secretary DBT & Chairperson BIRAC and Dr. Mohd. Aslam, Advisor (Scientist 'G') DBT & MD BIRAC addressed employees.

Glimpses of 2019 were presented during the event and employees experienced a sense of nostalgia as they reflected on the events that took place in the past 12 months.

Employees of BIRAC also actively participated in the event by singing group and individual songs.

A wave of joy swept past the office as it was great goodbye to the passing year and a welcome to 2020 with a great zeal and fervour.



Glimpses from New Year Celebrations

### Training and Development

In-house training on Communication and Effective Presentation Skills has been organised on 14<sup>th</sup> February 2020 from All India Management Association (AIMA) for BIRAC employees.

The training included hands-on exercises and practical activities which helped employees to communicate confidently and competently to all types of audiences.



Glimpses from training programme on communication & effective presentation skills





Biotechnology Industry  
Research Assistance  
Council (BIRAC)  
(A Govt. of India  
Enterprise)

## BIOTECH INNOVATION IGNITION SCHOOL (BIIS)



BIRAC's SITARE  
Partner:  
Society for Research  
and Initiatives for  
Sustainable  
Technologies and  
Institutions (SRISTI).

**About BIIS :** Biotech Innovation Ignition School (BIIS) is to provide an exposure and orientation for entrepreneurial journey through hands-on-technical training, interactive sessions with experts, access to bioincubation centre etc. This to promote grass root innovations and nurture ideas with societal impact, pioneered by undergraduate students. The BIIS will try to develop solutions for grassroots applications for human, animals, and agricultural applications including herbal technologies, medical devices and microbial application.

**Eligibility:** Students pursuing Bachelors program in any discipline can apply, preferably from Tier II/Tier III cities and aspirational districts within India.

Up to 50 Students each are selected for fully funded residential BIIS workshops  
Top 10 Students from each BIIS workshop are awarded SITARE-Appreciation Grant Award



Upcoming  
BIIS:

Details of BIIS workshops	Apply Before
15 <sup>th</sup> March – 5 <sup>th</sup> April, 2020	25 <sup>th</sup> February, 2020
1 <sup>st</sup> – 22 <sup>nd</sup> June, 2020	30 <sup>th</sup> April, 2020
5 <sup>th</sup> - 26 <sup>th</sup> October, 2020	31 <sup>st</sup> July, 2020
3 <sup>rd</sup> - 24 <sup>th</sup> December, 2020	30 <sup>th</sup> September, 2020

INR 1 LAKH  
GRANT  
AWARD

**Venue:** Gandhinagar, Gujarat

**Apply online only under "SITARE" at BIRAC website ([www.birac.nic.in](http://www.birac.nic.in))**

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## GRAND CHALLENGES INDIA

### Lecture by Dr. Steven Buchsbaum

Dr. Steven Buchsbaum, Deputy Director, Discovery and Translational Sciences, Bill and Melinda Gates Foundation leads the Grand Challenges family of programmes and other experiments in sourcing innovation and development of the discovery ecosystem.

Prior to joining the foundation in 2005, he served as the founding director in the Homeland Security Advanced Research Projects Agency of the Department of Homeland Security in the United States of America. During his tenure in the Department of Defence, he was instrumental in building research programs related to the nation's security.

After leading DARPA and HSARPA initiatives, Dr Buchsbaum joined Gates Foundation to lead the Grand Challenges family of programs right from its nascent stage. Grand Challenges targets the areas of greatest unmet needs and seek novel and target-oriented potential needs that help in reaching a solution to address those unmet needs.

On his recent visit to India, Grand Challenges India organised a lecture at India Habitat Centre on 22<sup>nd</sup> Jan 2020. Dr. Steven delivered a lecture on "Reflections from: DARPA to HSARPA to Grand Challenges". In his presentation, he gave an overview of innovations and DARPA and HSARPA models for organisations to source the right innovations for making a difference. He also spoke about the process for defining challenges, building collaborations and managing and measuring progress. He also described the parameters for measuring the performance of the funded innovations. The lecture was followed by Q & A session with active participation from the audiences.



Glances from Dr. Steven's Lecture

Dr. Renu Swarup, Secretary, Department of Biotechnology and Chairperson BIRAC graced the occasion. She congratulated Dr. Buchsbaum for his contribution to the foundation. Grand Challenges India team and representatives from BIRAC were present at the event.

A meet and greet event was organised later in the evening to cherish the glorious partnership of Department of Biotechnology and Gates Foundation. The event saw the participation from India country office of Gates Foundation and other key stakeholders.

### Second Scientific Advisory Committee

Second Scientific Advisory Committee Meeting to review the program progress of 'Food-based nutritional security for malnourished rural households through capacity building and establishment of Nutri-gardens' being implemented by MS Swaminathan Research Foundation (MSSRF), Chennai

The Second Scientific Advisory Committee Meeting for the project on 'Food-based nutritional security for malnourished rural households through capacity building and establishment of Nutri-gardens' program being implemented by the MS Swaminathan Research Foundation a specialized initiative under the Grand Challenges India program was held on 7<sup>th</sup> February 2020 at BIRAC Office.

The meeting was chaired by Dr. S. P. Ghosh and was attended by the Scientific Advisory Committee (SAC) members, Dr. G. N. Hariharan,

Executive Director, and Principal Investigator from MSSRF, representatives from Krishi Vigyan Kendras (KVKs) from the four zones involved in the program and State Agriculture Universities. Dr. Shirshendu Mukherjee, Mission-Director, GCI and Ms. Arshi Mehboob, Manager (Programmes), hosted the meeting.

The goal of the meeting was to understand the project activities more closely and through detailed interactions between stakeholders, mentors and the grantee, the project team will benefit from insights and feedback and accordingly plan future activities for effective implementation of the program to achieve the desired results. The meeting introduced the KVK Coordinators to SAC members which resulted in deeper conversations about the ground activities' challenges and issues.

The meeting commenced with Dr. Ghosh's address on the importance to address not only protein and calorie deficiencies but that micronutrient deficiencies and to widen the varietal diversity in our diets.

The MSSRF project team shared the highlights of efforts by MSSRF on Food and Nutrition Security for the last 3 decades and presented the detailed introduction of the project activities and implementation strategy for all four state sites and plan of action on this program.

Dr. V. K. Singh, IARI, SAC member, highlighted the nutrition value of ICAR released improved varieties of millets with high nutrition content in Samai and the culm of which can be used as fodder and its inclusion in the garden. He opined that the focus shall be given to millets as Millet Mission has introduced millets in the public distribution system.

Dr. Srivalli Krishnan, Senior Program Officer, Agriculture Development at the Bill & Melinda Gates Foundation, India Country Office stressed on the development of baseline data of nutrition status of focused districts, develop project implementation plan and framework based on the baseline with measurable indicators and plans for mid-term evaluation and course corrections through capacity building.

Dr. Shirshendu Mukherjee stressed that technical recommendations from the SAC members shall be documented and adhered to while submitting the next report.

Ms. Arshi Mehboob opined to integrate nutrition module to farmers in the local language which will be disseminated through Community Health Fighters (CHWs). Post-harvest value addition shall be included in the practices of packages. Advocacy materials to be prepared/ printed for the use of Master Trainers and project beneficiaries.

The meeting saw an in-depth discussion of the implementation plan for all four sites. The grantee team and the KVK coordinators got clarity on the project's implementation scope, expected outcome deliverables and thereof. The meeting set the collaboration hygiene across sites for a uniform implementation plan, cross-learning between sites, self-monitoring, and capacity building for monitoring, and scaling up to facilitate on-ground implementation.



Dr. G. N. Hariharan, Executive Director and Principal Investigator presenting the progress made in last one year to the SAC members

## Grand Challenges India's tribute to Prof. M K Bhan (1947-2020)

Prof. M K Bhan was the Chair of the Scientific Advisory Committee of Grand Challenges India and this partnership of the DBT and Bill & Melinda Gates Foundation, was one that he had brought in and nurtured and brought it to where it is today.

Several programmes that GCI runs today, were begun with Prof. Bhan's vision, the All Children Thriving (ACT), Knowledge Integration and Translational Platform (KnIT), the ki for maternal and child health program among many others.

In many ways, Sir as he was fondly called, guided and mentored not just the design and review of programs, but also the young GCI team as well. Some of our fondest memories as a team, are discussing programs and new ideas with Sir, in BIRAC or in his office. We would often joke that after a meeting with Sir, we would have to go through the pages of notes the meeting would generate, and each time we did, we would find a new idea that Sir would have casually mentioned.

GCI, along with BIRAC lost a mentor, a guide and friend. And for us, the greatest tribute to this visionary, would be to work tirelessly to realise his and our dream for the nation.



# MAKE IN INDIA



## DPIIT-CII National Consultation Forum for Make in India 2.0

### “Towards \$1 Trillion Manufacturing Economy by Stimulating Growth & Investments”

DPIIT recognized fourteen champion sectors to give a renewed focus to Manufacturing and Make in India 2.0, among which biotechnology is one of the key sectors which has high potential for growth and contribution in making India a \$5 Trillion economy by 2025.

DPIIT along with CII organised a Pre-Forum Consultation meeting for Make in India 2.0 on 15<sup>th</sup> January, 2020 at India Habitat Centre. Make in India Facilitation Cell at BIRAC organized a consultative meet with 40+ representative stakeholders on 14<sup>th</sup> January, 2020. The discussions included representatives from Biotech industries (Vaccines, Biosimilars, Emerging therapies, Bio-Services, Medical Devices, Diagnostics, Agritech) to discuss the sectoral recommendations, policy interventions, tax incentives, infrastructure & regulatory interventions required for creating a firm roadmap for India to become \$150 Bn Bio-economy by 2024-25. These recommendations were submitted to the Pre-forum meeting organised by DPIIT-CII on 15<sup>th</sup> January, 2020.

The Pre-forum meeting, held on 15<sup>th</sup> January 2020, focused on sectoral roadmaps for Make in India 2.0. The Sectoral Sessions were designed as small thematic working group roundtables with selected stakeholders including policy makers, senior corporate leaders and research institutions, regulators and others from the sector. Biotechnology session was moderated by Dr. Rajesh Jain, Chairman, CII National Committee on Biotechnology & MD, Panacea Biotech Ltd. BIRAC was represented by Dr. Manish Diwan, Head-SPED; Dr. Kavita

Singh, Mission Director-National Biopharma Mission; Dr. Bhuvnesh Shrivastava, Manager-Make in India Cell and Dr. Varsha Sirohi, Officer-Make in India Cell. Mr. Alok Kumar, Advisor, NITI Aayog chaired the session. Dr. Kalaivani Ganesan, Scientist-E, DBT along with a CDSCO official were also present. Discussions involved various inputs on specific issues restricting manufacturing growth in Biotech sector, key imperatives to boost global competitiveness and suggestions for incentive packages for Make in India 2.0.

Following the pre-forum discussion, a Report-Back Policy session to Shri Piyush Goyal, Hon'ble Minister of Railways and Commerce, was held to review the sectoral roadmaps for Make in India 2.0. Mr. Amitabh Kant, CEO NITI Aayog; Dr. Guruprasad Mohapatra, Secretary, DPIIT also graced the occasion. Dr. Renu Swarup, Secretary DBT, Make in India team from BIRAC attended the forum.



Glimpses of DPIIT-CII National Consultation Forum for Make in India 2.0





## State Biotech Cohort Meeting with DST Rajasthan

Rajasthan's 1<sup>st</sup> Biotech Cohort Meet was organised on 10<sup>th</sup> January 2020 at Birla Institute of Scientific Research, Jaipur, Rajasthan to promote Biotech innovation ecosystem and sensitize the stakeholders for developing Biotech sector in the country. The meeting was chaired by Ms. Mugdha Sinha, Secretary DST, GoR. Meeting was attended by VCs, Deans and representatives from Universities /Institutions of the State, such as, University of Rajasthan, Banasthali Vidyapith University, Central University of Rajasthan, SKR Agricultural University, Jaipur National University, SKN Agriculture University, Manipal University, Amity University, B. Lal Institute of Biotechnology, SGV University, IIS university, Startup Oasis Rajasthan and others. Dr. Manish Diwan, Head-SPED, BIRAC; Dr. Varsha Sirohi, Officer-Research Analysis & Facilitation, Make in India Cell, BIRAC and Dr. Manoj Modi, Scientist-E, DBT India also joined the meeting.

Secretary S&T in her address spoke about various DST initiatives which will strengthen biotech ecosystem in the State of Rajasthan. She also highlighted the Industry-Academia interface program launched by DST-Rajasthan that will assist inter-collaboration between industry and academia, providing the opportunity to the people to work in either of the location for a period of six months.

Dr. Manish Diwan provided a comprehensive information about BIRAC and its different funding opportunities for startup, entrepreneurs, incubation centres and small-scale biotech industries. Dr. Manoj Modi spoke about mission, goals and objectives of the DBT to make

India globally competitive in the Biotechnology sector. He emphasized on DBT's focus to create a vibrant research ecosystem and to support the cutting-edge research.

The stakeholders presented the major biotechnology thrust research areas, ongoing researches, existing infrastructure facilities, scholarships for the students, collaborations, publications, patents, copyrights, designs, challenges faced in their institutes/universities.

Dr. Renu Swarup, Secretary DBT, MoST, Gol joined the meeting post lunch and sensitized the stakeholders about the efforts and initiatives taken up by DBT and BIRAC across the country to enable the developing Biotech sector. She emphasized that BIRAC will further collaborate with the State of Rajasthan to promote the Biotech innovation ecosystem. She suggested to involve Rajasthan in the Biotech North Cluster meetings and the State of Rajasthan can work closely with BIRAC.

During her visit to the State of Rajasthan, Secretary DBT also visited Banasthali Vidyapith University on 11<sup>th</sup> January, 2020. Dr. Swarup was invited to deliver the Prof. Sushila Vyas Memorial Lecture, which is held every year in the memory of Sushila ji. "It was such a great pleasure to meet the bright energetic girls at Banasthali Vidyapith, the largest residential women's university focussing on key principles of education for overall development" said Dr. Swarup. She also stressed on the nurturing & promoting women led entrepreneurial ventures to achieve USD 150billion Bioeconomy.



Glimpses of the State Biotech Cohort Meeting, Jaipur



Visit to Banasthali Vidyapith





## GLOBAL COMPETITIVENESS OF INDIA

#1

Ease of  
Doing Business  
Ranking in  
South Asia

#1

Supplier of DPT, BCG and  
measles vaccines globally

#2nd

Highest number of USFDA approved  
manufacturing plants outside the US

#3%

Share in the Global Biotechnology Industry

#3rd

Largest biotech destination in Asia Pacific Region

#52nd

Rank in Global Innovation Index



MAKE IN INDIA FACILITATION CELL FOR  
BIOTECHNOLOGY AT BIRAC



## NATIONAL BIOPHARMA MISSION

### Hands-on Training Programme on Medical Device Prototyping IIT Kanpur 13<sup>th</sup>-17<sup>th</sup> January, 2020

A five-day training program on medical device prototyping was organized at IIT-Kanpur under the National Biopharma Mission. Experts and faculty from IIT-Kanpur deliberated at length on the various aspects of medical devices. Topics covered included design thinking, creativity and innovation, product evolution, EMI and EMC testing, flexible electronics, rapid manufacturing, simulation, prototyping techniques, and analytics, successful entrepreneurship, doctors' viewpoint in using devices, understanding the patients' needs, ethics committee approval, IPR and laws for medical devices, computer aided manufacturing and design practical, electronics and programming in medical devices, writing a BIG grant, do's and don'ts, strategy, operations, and outreach,

financial concerns in entrepreneurship, taxes and litigation in incubation. Around 30 candidates were trained including 14 female candidates.

Faculty included: Dr. J Ramkumar, Dr. M. Jalil Akhtar, Dr. Siddhartha Panda, Dr. Amandeep Singh, Mr. Ravi Pandey, Mr. Abhishek Verma, Mr. Siddhant Sri and Mr. Anubhav Misra, from IIT Kanpur, Dr. Sandip Patil, Dr. Rohini Dutta, Ms. Aditi Kumar, Mr. Rahul Patel, Mr. Yogi Srivastava, Mr. Aishwarya Vaish, from SIIC, IIT Kanpur. Dr. Krishna Kant Dakonia, Medical Practitioner from Kanpur and Dr. Jagbinder Singh, Medical Practitioner from Bhathinda.



Hands-on Training Programme on Medical Device Prototyping held at IIT Kanpur during 13<sup>th</sup> -17<sup>th</sup> January, 2020

### Hands-on Training Programme on Downstream Bioprocess Development KIIT-Technology Business Incubator, Bhubaneswar 20<sup>th</sup>-24<sup>th</sup> January, 2020

A five-day training program on downstream bioprocess development was organized at KIIT-Technology Business Incubator, Bhubaneswar under the National Biopharma Mission. Experts in the field delivered lectures on various aspects of bioprocess development. Around 25 candidates were trained including 12 female candidates.

Lectures: Molecule to Marker, introduction to chromatography, size exclusion chromatography, ion exchange chromatography, hydrophobic interaction chromatography, affinity chromatography, process optimization, unicorn, column packing basis and DoE. *Restriction enzymes & biotechnology revolution*: relation between science and technology, major discoveries in the field of biotechnology, Introduction to restriction enzymes and function of restriction modification system, revolution in biotechnology and recombinant DNA technology using restriction enzymes, techniques involved in purification of restriction enzymes. *Membrane Protein Purification for drug targets*: introduction to membrane proteins & how it interacts with drugs, different pathways involved in the process, different membrane protein purification strategies, problems and

complications in membrane protein purification, troubleshooting. *Strategies for purification*: introduction to Integral proteins and their significance in cellular processes, brief idea on different protein purification techniques, frequent complications & challenges in protein purification, possible approaches to solve these complications. *Optimization of Monoclonal Antibody purification process using chromatographic techniques*: different approaches towards production and purification of monoclonal antibodies, case studies of few batch purification processes of Monoclonal antibodies.

*Practicals*: Ion Exchange (Linear and step) chromatography, Hydrophobic interaction chromatography (linear and step), Unicorn programing and small-scale column packing DoE demo.

*Faculty included*: Dr.C. Sivapathaseakaran and Mr. Bhargav Prasad; Fast Trak lab, Life science division, Wipro GE healthcare, Bangalore; Dr. D.N. Rao, Professor, IISc Bangalore, Dr. A. Arulandu, Group Leader, ICGEB, New Delhi; Dr. Neel S Bhavesh, Group Leader, ICGEB, New Delhi; Dr. Abir Banerjee, Deputy General Manager, Enzene Biosciences Ltd, Pune.





Hands-on Training Programme on Downstream Bioprocess Development held at KIIT-Technology Business Incubator, Bhubaneswar during 20<sup>th</sup>-24<sup>th</sup> January, 2020

## Lecture Series on Good Clinical Practice Clinical Development Services Agency, Faridabad 28<sup>th</sup>-29<sup>th</sup> January, 2020

A 2-day programme to create awareness and understanding of Good Clinical Practice (GCP) to enable compliance with the current guidelines and regulatory requirements was organized at Clinical Development Services Agency, Faridabad during 28<sup>th</sup>-29<sup>th</sup> Jan 2020. National and international experts in the field deliberated upon various aspects pertaining to GCP. Dr. Sucheta Banerjee Kurundkar, Director Training, CDSA, THSTI gave an overview of GCP. Dr. Rubina Bose, Deputy Drugs Controller (India), CDSCO West Zone discussed the salient features of New Drugs and Clinical Trials (NDCT) Rules. Prof. Y. K. Gupta (Moderator) Principal Adviser (Projects), THSTI; Former Dean (Academics), AIIMS, New Delhi, deliberated upon the need to know GCP and Indian regulations and took queries related to NDCT Rules, 2019. Shri. A. B. Ramteke, Former Joint Drugs Controller (India), CDSCO-HQ; Consultant, Regulatory Affairs, CDSA, THSTI along with Prof. Y. K. Gupta (moderator) and Dr. Rubina Bose, addressed queries related to NDCT Rules, 2019. Dr. Nandini K. Kumar, Former Deputy Director General Sr. Grade, ICMR; Vice-President FERCI; Adjunct Faculty, CDSA, THSTI, deliberated upon ethical considerations. Ms. Shubhra Bansal, Director Clinical Portfolio Management, CDSA, THSTI, discussed the roles and responsibilities: Sponsor, institution, and monitor. Dr. Temsunaro R. Chandola, Senior Research Scientist, Centre for Health Research & Development, Society for Applied Studies, New Delhi, discussed the roles and responsibilities of an investigator. Dr. V. Koneti Rao, Staff Clinician, National Institutes of Health (NIH), Bethesda, United States of America (USA), discussed the challenges of collaborative clinical trials: IRB operations & implementing GCP in letter and spirit. Ms. Joy Beeler, Clinical Trials Project Manager, Leidos Biomedical Research, Inc., Regulatory Compliance and Human Subjects Protection Program, USA, discussed ICH GCP E6 (R2) hot topics including Quality management over view and Risk-based monitoring. Ms. Vandana Chawla, Training Manager, CDSA, THSTI discussed case studies and conducted exercises for the participants. Prof. Shinjini Bhatnagar, Dean, Clinical Research; Professor & Head, Paediatric Biology Centre, THSTI, DBT addressed the gathering to formally close the training programme. About 63 participants were trained in this programme including 28 female participants.



Lecture series on Good Clinical Practice held at CDSA, Faridabad during 28<sup>th</sup>-29<sup>th</sup> January, 2020

## **Lecture Series on Good Clinical Laboratory Practice Clinical Development Services Agency, Faridabad 30<sup>th</sup>-31<sup>st</sup> January, 2020**

A training programme on Good Clinical Laboratory Practice (GCLP) was organized at CDSA, THSTI, Faridabad on 30<sup>th</sup>-31<sup>st</sup> January, 2020 with the support from National Biopharma Mission. Good Clinical Laboratory Practice (GCLP) is a set of standards that provide guidance on implementing Good Laboratory Practice (GLP) and Good Clinical Practice (GCP) principles to the analysis of samples from a clinical trial. By combining the GLP and GCP sets of guidelines, GCLP ensures the reliability, quality, consistency, and integrity of the clinical trial data generated by laboratories. Compliance with this standard provides assurance that the data and reported results are credible and accurate and that the rights, safety, and confidentiality of trial subjects are protected. Dr. Sucheta Banerjee Kurundkar, Director Training, CDSA, THSTI; NABL and NABH Assessor deliberated upon various aspects of Laboratory Quality Management System (LQMS): GLP,

GCLP, and GCP and their scope and benefits. She further discusses demystifying Good Clinical Laboratory Practice (GCLP): GCLP Principles; various GCLP Guidelines. Document control, SOP Ethical considerations were also discussed in detail and several group/Individual exercises and role-play and case studies were conducted. Dr Kurundkar also took lectures on data management, laboratory Information and management system (LIMS). Ms. Meenakshi Bakshi, Director-Quality & Projects, Dr. Dangs Lab, New Delhi discussed in detail quality control including IQC, EQAS and method validation. Further role-play and case studies were also discussed. Ms. Vandana Chawla, Training Manager, CDSA, THSTI conducted the GCLP quiz and various other group/Individual exercises. About 57 participants were trained in this programme including 29 female participants.



Lecture series on Good Clinical Laboratory Practice held at CDSA, Faridabad during 30<sup>th</sup>-31<sup>st</sup> January, 2020



## Hands-on Training on Biopharmaceutical Product Development ICT, Mumbai 3<sup>rd</sup>-7<sup>th</sup> February, 2020

A five days training on Biopharmaceutical Product Development was organized under the aegis of National Biopharma Mission at Institute of Chemical Technology, Mumbai during 3<sup>rd</sup> to 7<sup>th</sup> Feb 2020. National and international experts from industry, regulatory bodies and academia deliberated upon various aspects of development of biopharmaceuticals. A total of 98 participants were trained in this programme including 43 female participants. Major topics covered in the module: trends and changing landscape for biologics, product and process development of biosimilar/biologics: overview and considerations, 5 essential elements for biosimilar development, manufacturing biosimilar: challenges and opportunities, downstream processing for biologics, critical quality attributes in biologics, importance of “critical quality attributes” in development of therapeutic proteins, critical quality attributes for a therapeutic biologic, identification and characterization of critical quality attributes in biologics: biophysics to the rescue, biosimilar/biotherapeutic protein and peptide characterization by mass spectrometry, current trends in cell line development for production of affordable recombinant proteins, basics of cell line development for biosimilar, bioassay design and development, medium design and fed batch culture, automated process for clone selection, transfection: A delivery service for macromolecules, virus clearance in DSP, affinity chromatography, multimodal chromatography, basics of data analysis and interpretation of N-Glycan Analysis and Peptide mapping data obtained by LCMS, strategic applications of ion-mobility mass spectrometry for the characterization of biopharmaceuticals, protein metrics Byoshost cell protein workflow for comprehensive characterization of host cell proteins in

biopharmaceutical products, controlling N-glycosylation in the manufacture of biosimilars, characterization of proteins- a biophysical approach, understanding the protein structure, stability and biomolecular interactions, understanding the thermodynamic properties of macromolecules using differential scanning calorimeter (DSC), data analysis of analytical ultracentrifugation, nuclear magnetic resonance in biologics, higher order structure (HOS) characterization of biologics, characterization of proteins- a biophysical approach, design of experiments, impact and need of data analytics across lifecycle of biopharmaceuticals, cell culture profiling and protein characterization on Q-ToF LCMS, basics of Isothermal titration calorimetry (ITC) and differential scanning calorimetry, innovative technologies for the generation of next generation biotherapeutics, CBER guidance on standards, data integrity & ethics in biopharmaceutical product development.

Faculty: Dr. Narendra Chirmule, Symphony Tech Biologics, Pune; Dr. Dhananjay Patankar, Syngene, Bangalore; Dr. Sanjeev Gupta, IPCA, Mumbai; Dr. Sandeep Majumdar, Intas Pharma, Ahmedabad; Dr. Prateek Gupta, Intas Pharma, Ahmedabad; Mr. Sachin Joshi, PharmNXT biotech, Mumbai; Dr. Shardul Salunkhe, Intas Pharma, Ahmedabad; Dr. Saranya Ganapathy, IPCA, Mumbai; Dr. Shubrata Khedkar, USP, Mumbai; Dr. Mugdha Gadgil, NCL, Pune; Dr. M.S. Ravindran, Perkin Elmer, Bangalore; Dr. Radhika Kotwal, USV, Mumbai; Dr. Rahul Bhambure, NCL, Pune; Dr. Rahul Fadnis, Syngene, Bangalore; Dr. Jyoti Iyer, Biocon, Bangalore; Dr. Venkata R Yeturu, Lupin, Pune; Dr. Amarnath Chatterjee, Wockhardt, Aurangabad



Hands-on Training on Biopharmaceutical Product Development held at ICT, Mumbai during 3<sup>rd</sup>-7<sup>th</sup> February, 2020



## Acute Febrile Illness Surveillance Discussion under the Clinical Trial Field Capacity Strengthening of National Biopharma Mission, BIRAC Office, 10<sup>th</sup> February, 2020

A meeting was held on 10<sup>th</sup> February 2020 at BIRAC Office for discussion on Fever Investigation Algorithm for carrying out Acute Febrile Illness Surveillance at different geographical locations in the country.

NBM's focus is to strengthen product development capabilities in vaccines, biotherapeutics and medical devices to a level that will be globally competitive over the next decade. One of the key areas for NBM is to strengthen clinical trial capabilities, that is vital for providing evidence-based insights to characterize the disease and populations at risk, assess safety and efficacy of products through conduct of regulatory compliant clinical trials. The current portfolio of vaccines being supported under the mission are in different phases of development. In this portfolio there are vaccine candidates for Dengue and Chikungunya also which will need to undergo clinical development soon. In addition, few other vaccine companies are working towards development of Dengue and Chikungunya vaccine candidates. All these vaccine candidates will need to undergo population-based Phase II/III clinical trials for testing efficacy.

Such Phase II/III clinical trial of Dengue and Chikungunya vaccine candidates' studies require GCP compliant field sites with information

on seroprevalence and incidence of Dengue and Chikungunya. Additionally, the sites should also have background information on disease epidemiology (information on disease incidence, age, gender variability, disease transmission indices, etc.) and some background knowledge on other causative agents of fever.

To support the Vaccine Clinical Development, National Biopharma Mission is providing Grant-in Aid to applicants spread out across different regions who will be studying the disease epidemiology and also ensuring GCP compliant systems and processes. These sites will be carrying out Acute Febrile Illness surveillance regarding which a meeting was held with the relevant experts to discuss the type and sequence of investigations to be followed in a harmonized manner across all sites. Dr. NK Arora, Executive Director, INCLEN Trust International chaired the meeting. Clinicians from AIIMS, Maulana Azad Medical College, and Officials from National Centre for Disease Control, Delhi along with BIRAC officials, participated in the discussions. Dr Naveen Gupta, Joint Director & Head, Zoonosis Division, NCDC and Dr. Sanket Kulkarni, Deputy Director, NCDC also informed the committee on NCDC efforts towards arboviral diseases in the country.



Acute Febrile Illness Surveillance Discussion under the Clinical Trial Field Capacity Strengthening of National Biopharma Mission held at BIRAC Office on 10<sup>th</sup> February, 2020

## Lecture Series on Good Clinical Practice Venture Center, NCL Innovation Park, Pune 11<sup>th</sup>-12<sup>th</sup> February, 2020

A 2-day programme to create awareness and understanding of Good Clinical Practice (GCP) to enable compliance with the current guidelines and regulatory requirements was organized at Venture Center, NCL Innovation Park, Pune during 11<sup>th</sup>-12<sup>th</sup> Feb 2020. National and international experts in the field deliberated upon various aspects pertaining to GCP. Dr. Sucheta Banerjee Kurundkar, Director Training, CDSA, THSTI gave the overview of GCP, record keeping and data handling. Dr. Nandini K. Kumar, Former Deputy Director General Sr. Grade, ICMR; Vice President FERCI; Adjunct Faculty, CDSA, THSTI discussed the ethical considerations. Dr. Sudha Basnet, Professor, Dept. of Child Health, Institute of Medicine, Tribhuvan University, Kathmandu, Nepal deliberated upon roles and responsibilities of an Investigator while roles and responsibilities of sponsor were discussed by Ms. Ruteja Joglekar, Senior-Manager, Clinical Operations & Start-up management, Covance; ISCR Representative. Dr. Cristina E. Torres, FERCAP Coordinator, Forum for Ethical Review Committees in Asia & Western Pacific, Thailand; Adjunct Professor,

National Institutes of Health, University of Philippines, Manila, Philippines talked about the current challenges in clinical trials/research: GCP implementation. This topic was further deliberated upon by Ms. Abhidnya V. Desai, IRB Administrator, Tata Memorial Hospital, Mumbai.

Dr. Monika Bahl, Director Clinical Portfolio Management, CDSA, THSTI discussed the clinical trial documents while Dr. Rubina Bose, Deputy Drugs Controller (India), CDSCO West Zone discussed the salient features of New Drugs and Clinical Trials (NDCT) Rules, 2019. Shri. A. B. Ramteke, Former Joint Drugs Controller (India), CDSCO HQ; Consultant, Regulatory Affairs, CDSA, THSTI moderated a panel discussion with all the other speakers on board to address queries related to NDCT Rules, 2019. Ms. Vandana Chawla, Training Manager, CDSA, THSTI conducted role-play and case studies and quiz along with other individual/group exercises. Feedback from participants was also taken. 60 candidates participated in this training including 29 female candidates.



Lecture Series on Good Clinical Practice held at Venture Center, NCL Innovation Park, Pune during 11<sup>th</sup>-12<sup>th</sup> February, 2020

## Hands-on Training on Operation and Testing of Medical Devices Central Scientific Instruments Organization, Regional Center, Delhi 24<sup>th</sup>-28<sup>th</sup> February, 2020

A five days training programme on testing of medical devices was organized at CSIR-CSIO, Regional Center, New Delhi with support from the National Biopharma Mission.

Ms. Shashi Moitra, CSIR-CSIO introduced the participants to the subject, further deliberating upon test and measuring instruments, principle, operation and testing of ECG machine, electrosurgical unit, infusion device. She further conducted hand on projects on testing & calibration of infusion device & electrosurgical unit, testing & calibration of multipara monitor & defibrillator. Sh. D. Bansal, CSIR-

CSIO deliberated upon electrical safety and the safety aspects in biomedical instruments as per IEC 60601 guidelines besides giving a brief introduction to medical devices. Dr. Sanjeev Kumar CSIR-CSIO discussed the principle, operation, testing of defibrillator. Other experts also deliberated upon principle, operation, testing of pulse oximeter, multipara monitor, and infusion device besides discussing, hands-on safety, calibration & traceability. 25 participants were trained in this training including 07 female participants.



Hands-on Training on Operation and Testing of Medical Devices held at Central Scientific Instruments Organization, Regional Center, Delhi during 24<sup>th</sup>-28<sup>th</sup> February, 2020



## Invites proposals

**for development, validation  
& pre-commercialization  
of products/technologies  
in the areas of**

Healthcare

Energy & Environment

Agriculture & Secondary Agriculture

Veterinary Sciences & Aquaculture

under

### Promoting Academic Research Conversion to Enterprise (PACE)

**Supports academia through:**

**i. Academic Innovation Research (AIR):**

For development of products/  
technologies (up to proof-of-  
concept)

**ii. Contract Research Scheme (CRS):**

For validation of products/  
technologies towards  
commercialization

### "i4" (Intensifying the Impact of Industrial Innovation)

**Supports industry through:**

**i. Small Business Innovation Research  
Initiative (SBIRI):**

For development and initial validation  
of new products/technologies

**ii. Biotechnology Industry Partnership  
Programme (BIPP):**

For validation, demonstration and  
pre-commercialization of products/  
technologies

### Eligibility

**PACE:** Academic institute, University, NGO or Research Foundation, registered/accredited by a government body can apply either alone, or in partnership with academia or industry (while involvement of industry is optional for AIR scheme, it is mandatory to have an industrial partner for CRS).

**i4:** Single or consortia of Indian Company (ies) (registered under the Indian Companies Act, 2013) or Limited Liability Partnership (incorporated under the Limited Liability Partnership Act, 2008) with/ without an academic partner.

For Online application and Scheme details logon  
to BIRAC website ([www.birac.nic.in](http://www.birac.nic.in))

Apply before:  
**31<sup>st</sup> March, 2020 (5.30 pm)**

For queries, please contact: GM and Head - Investment, BIRAC | Email: [investment.birac@gov.in](mailto:investment.birac@gov.in)



**Launches**

## **i4** Intensifying the Impact of Industrial Innovation

to support high risk biotechnological product/technology development by strengthening R&D capabilities of start-ups/ companies/ LLPs

The Programme would be operated through two schemes



### **Small Business Innovation Research Initiative (SBIRI)**

#### **Scope**

- Supports development and initial validation of new products and technologies
- The end point of the proposed study should be TRL6 or below

#### **Funding**

- 100% Grant from BIRAC to primary + collaborating company (if any) upto Rs. 50 Lakhs
- For projects more than Rs 50 Lakhs, BIRAC grant would be Rs. 50 Lakhs + 50% of the cost exceeding Rs 50 Lakhs

### **Biotechnology Industry Partnership Programme (BIPP)**

#### **Scope**

- Supports validation, demonstration and pre-commercialization of products and technologies
- The end point of the proposed study should be TRL7 or above

#### **Funding**

- Irrespective of the amount, BIRAC contribution to the total project cost will not exceed 50%

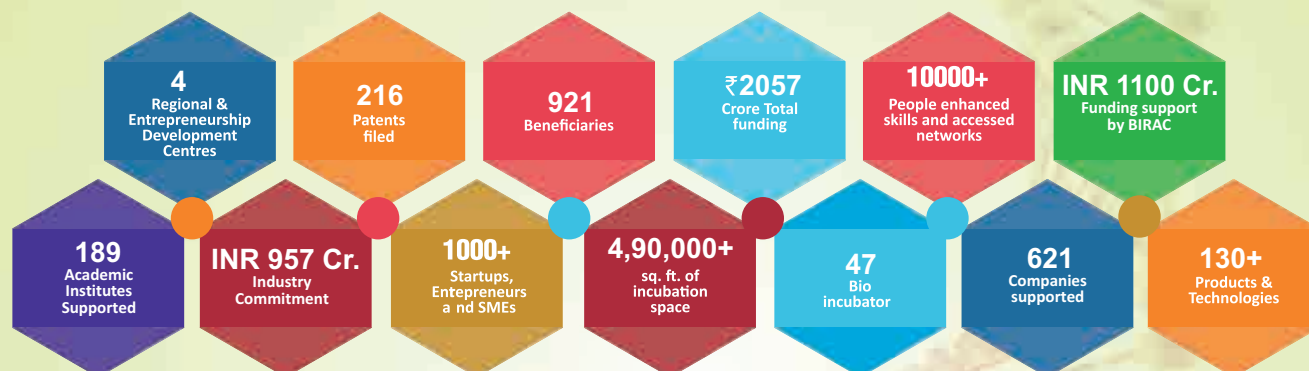
### **Common Features**

- No ceiling with regard to overall project cost
- The entire cost to the collaborating academic institution (if any), would be borne by BIRAC
- Single or consortia of Indian Company (ies) (registered under the Indian Companies Act, 2013) or Limited Liability Partnership (incorporated under the Limited Liability Partnership Act, 2008) with/without an academic partner are eligible to apply
- Royalty would be admissible as per BIRAC guidelines

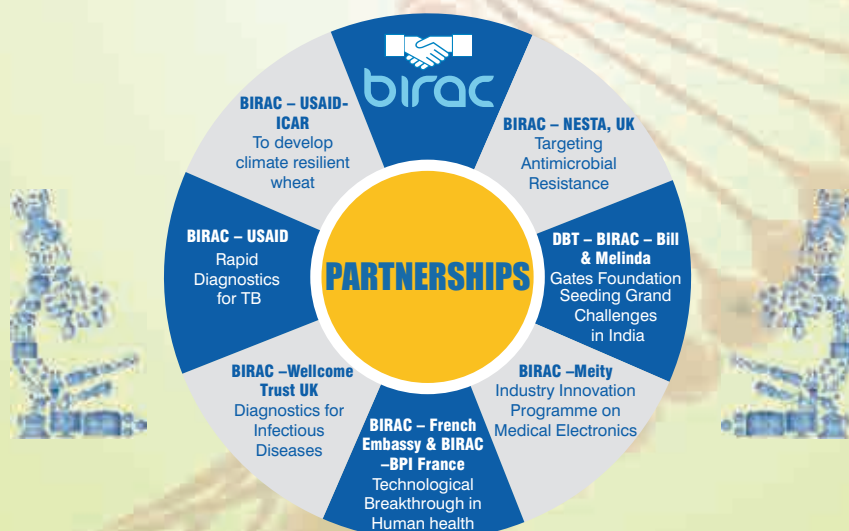
For scheme details please log on to BIRAC Website ([www.birac.nic.in](http://www.birac.nic.in))  
For queries, please contact: GM and Head - Investment, BIRAC | Email: [investment.birac@gov.in](mailto:investment.birac@gov.in)



# BIRAC IMPACT



## Aligning Partnerships for National & Global Impact



### Partnerships For Networks, Platforms & Market Access

WISH – BIRAC – Lords Education and Health Society (LEHS), Through its WISH Initiative : Scaling Innovations through Testing Beds

BIRAC – Business Finland : Enhancing Competitiveness

BIRAC – TISS - (Tata Institute of Social Sciences) : Mentoring innovators and Assessing impact

BIRAC – ICMR ( Indian Council of Medical Research) :

BIRAC AcE Fund Partners : Funding Oxygen for the Next Level

BIRAC – TiE (The Indus Entrepreneurs) : Platform for Global Networking

BioCubaFarma : Transfer of technologies and commercialization of innovative healthcare products

BIRAC – ALEAP, BIRAC – TiE : Promote Women Entrepreneurship

For further information please contact:

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