



Venture Base Camp on Clinical Study Design for Medical Devices and *In Vitro* Diagnostics *- Organized by BRBC -*

Potential gains	<ul style="list-style-type: none"> This event is a Venture Base Camp (VBC) which aims to de-mystify ethical, regulatory and commercial requirements for clinical studies of medical devices and in vitro diagnostic in India. Learn good clinical practice for designing, conducting, recording and reporting clinical investigations conducted in human subjects to assess the safety or performance of medical devices and clinical performance studies conducted to assess the clinical performance and safety of In Vitro Diagnostic (IVD) medical devices for regulatory purposes. Work on actual documentation required for regulatory approval purposes and submitting to the Central Drugs Standard Control Organisation (CDSCO) and ethics committees viz., Clinical Investigation Plan, clinical performance evaluation plan or study protocol, Investigator's Brochure (IB), and Informed Consent Form. 								
Organized by	<ul style="list-style-type: none"> BIRAC Regional BioInnovation Center @ Venture Center. Regulatory Information and Facilitation Center (RIFC) @ Venture Center 								
Supported by	<ul style="list-style-type: none"> BIRAC Venture Center 								
For whom	<ul style="list-style-type: none"> CEOs/CTOs of innovative technology startups. Individual Inventors. Inventors from R&D institutes, medium/ large enterprises. 								
When	Thursday- Saturday 8- 10 August 2019 Time: 9 am – 6 pm								
Where	Lecture Theatre, Venture Center, 100 NCL Innovation Park, Dr. Homi Bhabha Road, Pashan, Pune – 411008.								
Contact	Technical queries: Navnath Kadam 020-25865877/76 navnath@venturecenter.co.in Logistical queries: Lipika Biswas 020-25865877/76 eventsdesk@venturecenter.co.in								
Registration Details	<p>Limited seats!! Total number of seats: 30</p> <p>Registration and Attendance Process:</p> <ul style="list-style-type: none"> Step 1: Interested participants must fill out the registration form at the following link Register online at: http://bit.ly/aug19-clinicalstudy Step 2: Email invites will be sent post screening of registration details. Step 3: Attendance only on confirmation of payment of registration fee*. Step 4: Download, fill and submit the documents for clinical studies templates at https://bit.ly/2KQf0QV (see page no.: 05 for more details) (Last date of submission is 5 August 2019). Limited number of travel fellowships for up to Rs. 13000 available for Category 'A' participants. Reimbursement upon presenting receipts. Note: Submission of templates for clinical studies is compulsory to attend the base camp. For more information, please contact the organizers. <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Category</th> <th style="text-align: left;">Fees (Rs)</th> </tr> </thead> <tbody> <tr> <td>A) VC Incubatees, BIRAC Grantees who are small entities</td> <td>2001/-</td> </tr> <tr> <td>B) Micro/small enterprises, startups; Non-profit/R&D/academic orgs; individuals</td> <td>5001/-</td> </tr> <tr> <td>C) Others including medium/ large enterprises</td> <td>10,001/-</td> </tr> </tbody> </table> <p>Preference: Startup companies (LLC/PLC) vs. individuals, if we receive more than 30 applications Organizers reserve the right to select participants so as to optimize the group for better interaction and ensure benefit to as many startups as possible. NOTE: Registration</p>	Category	Fees (Rs)	A) VC Incubatees, BIRAC Grantees who are small entities	2001/-	B) Micro/small enterprises, startups; Non-profit/R&D/academic orgs; individuals	5001/-	C) Others including medium/ large enterprises	10,001/-
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closes once 30 seats are full or on 20 July 2019 (whichever comes sooner). **Fee paid is not refundable and non transferable under any circumstances. Maximum of two participants from one company will be allowed to attend.**

Introduction

BIRAC Regional BioInnovation Centre (BRBC) is a joint initiative of BIRAC and Venture Center. It focuses on filling up a few key innovations ecosystem gaps in India for biotech/biomed startups specifically relating to mentoring, regulations, fund raising and BioIncubation practice.

Venture Base Camps are high intensity, focused, theme based camps intended to take a startup from point A to point B in their entrepreneurial journey, prior to their execution on key goals of the company.



The base camp is designed by considering the criteria stipulated in the internationally agreed standards for clinical investigation of medical devices for human subjects and clinical performance studies using samples from human subjects.

The focus of this Venture Base Camp: Regulatory requirements | Ethical requirements | Statistics and statistical requirements | Parameters relevant to costs and timelines for conducting clinical investigation of medical devices and conducting clinical performance evaluation of *in vitro* diagnostic medical devices

This VBC will be useful for innovators and startups in the following medical device categories:
Clinical grade screening, diagnostic and recording instruments | Medical devices for clinical intervention or treatment | Surgical tools and aids | Assistive devices or disability aids or image reconstruction or artificial body parts | Molecular in vitro diagnostics | Topical, surface and open wound contact products or products in body orifices | Implants made from polymers, body tissues, metal, plastic, ceramic etc| Sensors, IOT, Big Data, Mobile, Cloud, AI/ML, Analytics, decision support, software etc used for making medical decisions | Supplies & consumables used in diagnostics, preservation, hospital equipment | Recreational and popular diagnostics, wearable.

How will you benefit? This course will help you:

- Understand clinical studies requirements for new treatments using devices and diagnostics.
- Understand design, conduct, recording and reporting of clinical investigations carried out in human subjects to assess the safety or performance of medical devices for regulatory purposes.
- Understand rights, safety and well-being of human subjects, scientific conduct of the clinical investigation and the credibility of the results, responsibilities of the sponsor and principal investigator, ethics committees, regulatory authorities and other bodies involved in the conformity assessment of medical devices.

Workshop includes

- Workshop includes tea, snacks and lunch at the Innovation Café.
- Free membership in mailing list to follow-up on workshop and intimation of relevant events/ funding/ opportunities from Venture Center.
- One-year free reference membership to Venture Center Library (<http://www.vcenterlibrary.org/>)

Workshop excludes

***Please note, the participants will have to arrange for their own travel, local transport and accommodation and dinners. For more information on Pune city, travel, transport and stay options, see <http://www.venturecenter.co.in/puneguide/>**



Workshop Schedule

DAY 1: 08 August 2019 – Thursday

CLASSROOM SESSIONS

Time	Duration	Session title	Lead
0830-0900	30 min	Registration and breakfast	
0900-0930	30 min	Welcome and Opening	Priya Nagaraj
0930-1015	45 min	Session 1 <ul style="list-style-type: none"> Definitions, wording and its interpretation 	Ravindra Ghooi
1015-1100	45 min	Session 2 <ul style="list-style-type: none"> Regulations involved in clinical studies 	Navnath Kadam
1100-1130	30 min	Tea break	
1130-1215	45 min	Session 3 <ul style="list-style-type: none"> The role of statistics in clinical studies 	Chitra Lele
1215-1300	45 min	Session 4 <ul style="list-style-type: none"> Sample size calculations 	Sharayu Paranjpe
1300-1400	60 min	Lunch break	
1400-1445	45 min	Session 5 <ul style="list-style-type: none"> Statistical analysis of data 	Sharayu Paranjpe
1445-1530	45 min	Session 6 <ul style="list-style-type: none"> Available clinical sites around Pune, and Timelines 	Deepti Goel
1530-1600	30 min	Tea break	
1600-1645	45 min	Session 7 <ul style="list-style-type: none"> Panel Discussion and Q&A 	Manjiri Joshi Deepti Goel Ravindra Ghooi
1645-1715	30 min	Administrative Announcements and slotting for one-to-one meetings.	Priya Nagaraj Navnath Kadam



Workshop Schedule cont..

DAY 2: 09 August 2019 – Friday

Time	Duration	Session title	Lead
0900-0930	30 min	Registration and breakfast	
0930-1030	60 min	Session 8 • Ethical considerations (MDs and IVDs) by Ravindra Ghooi	
		Track 01 Medical Devices [Lecture Theatre]	TRACK 02 In Vitro Diagnostic Devices [Training Room]
1030-1115	45 min	Session 9A – PART 1 • Clinical investigation planning Vishwas Sovani	Session 9B – PART 1 • Clinical performance study planning Madhur Motwani
1115-1130	15 min	Tea break	
1130-1215	45 min	Session 9A – PART 2 • Clinical investigation planning Vishwas Sovani	Session 9B – PART 2 • Clinical performance study planning Madhur Motwani
1215-1300	45 min	Session 10A • Clinical investigation conduct Sanish Davis	Session 10B • Clinical performance study conduct Arun Bhatt
1300-1400	60 min	Lunch Break	
1400-1445	45 min	Session 11A • Suspension, termination and close-out of the clinical investigation Sanish Davis	Session 11B • Clinical performance study initiation and closeout Manjiri Joshi
1445-1530	45 min	Session 12A • Responsibilities of the sponsor Arun Bhatt	Session 12B • Quality and Auditing -- to evaluate conformity with the CPSP Yashesh Mehta
1530-1600	30 min	Tea break	
1600-1645	45 min	Session 13 • Responsibilities of the principal investigator by Arun Bhatt at LT	
1645-1730	45 min	Session 14 • Budgeting, and costing of clinical studies by Pathik Divate at LT	
1730-1815	45 min	Session 15 Panel Discussion moderated by Premnath V. Panelists: Arun Bhatt, Vishwas Sovani, Madhur Motwani, Sanish Davis, Manjiri Joshi, Yashesh Mehta, Ravindra Ghooi, Aniruddha Atre, Jayant Khandare, Ramesh Paranjpe. Theme: Conducting Clinical studies of Medical Devices in India.	



Workshop Schedule cont..

DAY 3: 10 August 2019 – Saturday

ONE-TO-ONE DISCUSSION WITH EXPERTS ON

1. Clinical Investigation Plan (CIP)
2. Clinical Performance Study Protocol (CPSP)
3. Investigator's Brochure (IB)
4. Informed Consent Form


Note:

1. Templates of the above four documents will be provided to participants after the registration.
2. Participants are required to fill the details requested in the templates and submit it to the RIFC prior to the base camp (last date: 5th August 2019).
3. One-to-one meeting of the participants with the experts is subject to the readiness of the device for the clinical studies and organizers may reserve the rights of the meeting.



Time	Duration	Slots	Panel 1	Panel 2	Panel 3
0900-0930	30 min	Registration and breakfast			
0930-1100	90 min	Slot 1 Slot 2 Slot 3	Arun Bhatt Manjiri Joshi	Madhur Motwani Vishwas Sovani	Ravindra Ghooi Pathik Divate
1100-1115	15 min	Tea break			
1115-1245	90 min	Slot 4 Slot 5 Slot 6	Arun Bhatt Manjiri Joshi	Madhur Motwani Vishwas Sovani	Ravindra Ghooi Pathik Divate
1245-1345	60 min	Lunch break			
1345-1430	90 min	Slot 7 Slot 8 Slot 9	Manjiri Joshi Ravindra Ghooi	Madhur Motwani Vishwas Sovani	Pathik Divate Navnath Kadam
1415-1500	15 min	Tea break			
1500-1430	90 min	Slot 10 Slot 11 Slot 12	Manjiri Joshi Ravindra Ghooi	Madhur Motwani Vishwas Sovani	Pathik Divate Navnath Kadam
1430-1800	90 min	Slot 13 Slot 14 Slot 15	Manjiri Joshi Ravindra Ghooi	Madhur Motwani Vishwas Sovani	Pathik Divate Navnath Kadam






Anchor Faculty and Venture Base Camp Director

 <p>Ravindra Ghooi</p>	<p>Dr Ravindra Ghooi</p> <p>Dr. Ravindra B. Ghooi, is a pharmacologist with over 46 years of experience, in the field of drug discovery and development. He holds a Masters in Pharmacology and a Doctorate in Medicine, and has trained at Haffkine Institute in Mumbai and Max Planck Institute in Gottingen, Germany. Dr. Ghooi spent over twenty years in the pharmaceutical industry, heading the medical department as a Medical Advisor. He has been involved in clinical research for the last 35 years, in the role of a sponsor, CRO, regulatory expert and advisor. He has been teaching clinical research for over a decade and has authored two books on the subject. He presently is a consultant in research, serves a number of ethics committees, and editorial boards of two journals. He has over 65 research papers to his credit, and guides students at the Ph. D level.</p>
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Faculty/ Mentors (in order of last names; alphabetical order)

 <p>Aniruddha Atre</p>	<p>Aniruddha Atre Co-Founder, Jeevtronics</p> <p>Aniruddha is an engineering wizard. He has designed medical devices to automotive systems to renewable energy products to energy storage. His expertise ranges from systems engineering to electronics engineering to mechanical engineering to Product Launch to Business. He brings 19 years of total industry experience in United States and India. His expertise spans product development, sourcing, product planning /program management and launch in high volume manufacturing plants in North America at Ford Motor Company. He is passionate about social entrepreneurship.</p> <p>Aniruddha holds Bachelors and Masters Degree in Mechanical engineering and MBA from Ross School of Business at the University of Michigan, Ann Arbor. During his MBA he was a student of legendary thinker Late Prof C.K.Prahalad.</p>
 <p>Arun D Bhatt</p>	<p>Dr Arun D Bhatt, MD (Med), FICP (India), FICR (UK) Consultant – Clinical Research and Development, Mumbai.</p> <p>Dr Arun Bhatt is a retired after extensive experience of over three decades in the Indian pharmaceutical industry in clinical research, drug development, and regulatory affairs. Currently he is consulting for clinical development of novel molecular entities in diverse therapeutic areas in all clinical development phases. Dr Bhatt has worked as a consultant in pharmaceutical medicine and clinical pharmacology.</p> <p>His past positions held include President, Clininvent Research Private Limited – a CRO, CEO of CMI (India) Private Limited and Medical Director of Novartis India Limited.</p> <p>Dr Bhatt has been active in industry associations and was earlier the President of Indian Society for Clinical Research (ISCR). He is Editor-in-Chief of Perspectives in Clinical Research – the journal of ISCR.</p> <p>In 2009, the Institute of Clinical Research UK nominated Dr Bhatt for the Honorary Fellowship of Institute of Clinical Research.</p> <p>Dr Bhatt is the recipient of Drug Information Association Outstanding Service</p>

	<p>award 2012 for his immense contributions in his field of specialization.</p> <p>Dr Bhatt was awarded ISCR Special Award 2017 for Notable Contribution to Clinical Research Fraternity in India.</p> <p>Dr Bhatt delivered the prestigious Prof U K Sheth Oration in 2013.</p> <p>Dr Bhatt is a qualified assessor for NABH Accreditation for Clinical Trials – sites, investigators and Ethics Committees.</p> <p>Dr Bhatt has more than 150 publications in national and international journals. He runs a regular monthly column on “Good Clinical Practice – Question Answers” and has published a book “Clinical Trials and “Good Clinical Practice in India – Questions and Answers”.</p>
 <p>Sanish Davis</p>	<p>Dr Sanish Davis MD, DM,FCP Head, GCTO, India and Senior Medical Director, Covance, Pune; General Secretary, Indian Society for Clinical Research (ISCR)</p> <p>Dr Sanish Davis has been in the clinical Research industry for over 14 years and has worked on both sides of the fence - in academia as well as in Pharmaceutical Industry. He is currently Head, GCTO Covance India and Senior Medical Director, Cardiovascular, Metabolism & Endocrine portfolio globally for Covance Drug Development Services (a division of Lab Corp.) He has experience in managing early and late phase clinical development in both Indian as well MNC Pharma R&D environments in NCE, Innovative generics and Branded Generics space. He has worked in the domains of clinical development & Regulatory strategy for development of compounds for Emerging markets. He has an active interest in external environment shaping activities in clinical research and in operationalizing “ethics” in Industry research. He is also General Secretary of Indian Society for Clinical Research (ISCR) for 2017-19. He has a Postdoctoral degree in Clinical Pharmacology (D.M) and postgraduate and graduate degrees in Pharmacology and Medicine (M.D). He is also a Fellow of American College of Clinical Pharmacology (FCP).</p> <p>Sanish is actively involved in training clinical research professionals of the future through his association with the Maharashtra University of Health Sciences, Nashik, Indian Society of Clinical Research, Rashtriya Uchchatar Shiksha Abhiyan (RUSA), Govt. of Maharashtra, South Asian Chapter of American College of Clinical Pharmacology and Academy of Clinical Excellence at Bombay College of Pharmacy.</p>
 <p>Pathik Divate</p>	<p>Pathik Divate CEO and Co-Founder, Jehangir Clinical Development Centre (JCDC) and LinqLabs, Pune.</p> <p>Pathik has 20+ years of experience in leadership, strategy, client service and business development. Under his leadership at JCDC Pvt Ltd which is a well-established clinical research centre with experience of over 300 clinical trials, Pathik has taken JCDC from a five people team in 2007 to 100 people in 2019 and acquired numerous accolades and awards.</p> <p>Pathik is a Chartered Accountant and an MBA from Thunderbird, The Garvin School in USA. He started his career at Deloitte in Auditing and consulting. Thereafter, he moved to the outsourcing industry where he worked in India and the UK. After his MBA he worked with Pfizer Inc. in New York.</p>

	<p>Pathik has ranked seventh in Maharashtra state in the Higher Secondary School Certificate Exam; Ranked first in Economics in B.Com, and under his leadership JCDC is awarded the 'Best Research Centre' by the Indian Society of Clinical Research.</p>
 <p>Deepti Goel</p>	<p>Deepti Goel, PMP® Executive Director at Harrison's Tech Consultants- A GMP and GCP Consultancy firm for Healthcare Industry, Mumbai.</p> <p>Dipti is a M. Pharm (Pharmacology) and PMP® by training with over 19 years of experience in Clinical Research specializing in the areas of Clinical Operations, Site Management, Project Management, Quality Management, People Management, Learning and Development etc.</p> <p>Therapeutic areas include Dermatology, Oncology (Breast Cancer, Hodgkin's (NHL), Colorectal Cancer, Rheumatoid Arthritis, Pain Management, Hemorrhoids, Dermatology, Pulmonology (Upper Respiratory Tract Infections).</p> <p>Deepti has developed over 100 sites out of which more than half are Government Sites. She has built these sites from scratch i.e. Developing Ethics Committee, Building Processes, Expanding knowledge base of Investigators, Creating a framework of Clinical trials at site(s) and support in execution of trials as per sponsor expectations.</p> <p>She has developed ~50 Clinical Trial Coordinators, ~20 Clinical Research Associates and ~10 Project Mangers. Mentoring them navigating through their career path in their respective fields with zeal and passion.</p>
 <p>Manjiri Joshi</p>	<p>Manjiri Joshi Director Learning & Development at Sciformix, a Covance company, Pune.</p> <p>Manjiri Joshi has over 27 years of diverse experience encompassing Pharmaceutical Sales, Marketing, Clinical Trial Operations and leading Learning and Development department of a global organization. A keen planner with expertise in clinical research management, training; and module content creation.</p> <p>Previous to Sciformix, was handling site operations for SCRDC, a clinical research unit of Sahyadri Speciality hospitals. Has worked for JCDC, Bicare research Academy, Cytel statistical solutions, Ranbaxy and Roche, earlier. Manjiri is affiliated with ERI, ISCR training council and a member of board of studies, dept of Biotechnology, Fergusson College.</p>
 <p>Navnath Kadam</p>	<p>Navnath Kadam Asst. Manager at RIFC - Venture Center, Pune.</p> <p>Navnath provides leadership to the RIFC at Venture Center, Pune. He regularly advises startups on planning their regulatory roadmap and facility planning. He is developing a suite of services and resources of use to startups. He has multifaceted working experience in managing Quality and Regulatory operations at Medical Device startup Axio Biosolutions Pvt Ltd. He has completed PG Diploma in Entrepreneurship and Business Management from EDI, Ahmedabad and Master of Pharmacy with specialization in Quality Assurance Techniques from Poona College of Pharmacy, Pune.</p>



Jayant Khandare

Dr Jayant Khandare

Managing Director (MD) and Chief Scientific Officer (CSO) of Actorius Innovations and Research Pvt Ltd.

After earning his bachelor's and masters degree in Pharmacy. Jayant received a Ph.D. (Polymer Chemistry) in Chemical Engineering from the prestigious National Chemical Laboratory, Pune, in 2003.

Post Ph.D., Jayant completed two postdoctoral tenures in the School of Medicine, Wayne State University, Detroit, MI, USA and the Dept. of Pharmaceutics, Rutgers, The State University, Piscataway, New Jersey, USA. He worked extensively on targeted nano polymeric drug delivery systems for Cancer.

Jayant's excellent work resulted in him being awarded the prestigious Alexander Von Humboldt Experienced Researcher Award and he worked for one year in Germany with Prof.Dr.Rainer Haag at Freie University, Berlin, Germany in the field of Macromolecular Chemistry. He then established and led the Polymer Chemistry Group at Piramal Life Sciences.

Jayant has published more than 40 papers in peer-reviewed journals and has 14 US patents to his credit. Jayant brings to the table an eclectic mix of knowledge in subjects as diverse as pharmaceuticals, chemical engineering, polymer chemistry and cancer biology.



Chitra Lele

Dr Chitra Lele

Chief Scientific Officer at Sciformix Technologies Private Limited, Pune.

Chitra Lele has a distinguished academic background with a PhD in Statistics from Stanford University, and over 20 years of experience in the healthcare industry. Prior to the inception of Sciformix, Chitra was with Pfizer for 10 years, where she was Executive Director responsible for India operations of Pfizer Global R&D. Chitra established India's first Biometrics Center providing services in clinical data management, statistics, programming and medical writing, and successfully grew it to a size of over 400 staff.

Chitra's previous experience includes work as a biostatistician in cancer epidemiology at Stanford University and University of California, San Francisco and as a faculty member at the School of Statistics, University of Minnesota and the Indian Institute of Technology, Mumbai.








Yashesh Mehta

Dr Yashesh Mehta

Director Delivery Partner at Sciformix Pvt Ltd, Pune.

Sr Director Process Excellence at CyteSpace Research Private Limited, Mumbai.

Dr Yashesh Mehta, is a PhD in Immunohematology from Mumbai University. He has 17+ years of industry experience of having worked at Hospital sites, Pharma Cos. and Service Provider (CRO and SMO) domains primarily the field of clinical trials and related services. He has the unique exposure to have worked for substantial years in Operations, Quality Assurance, Country Head and Business Development roles over these years. He started his career as a CRC working at sites and is currently designated Director, Delivery Partner at Sciformix.

 <p>Madhur Motawani</p>	<p>Dr Madhur Motwani Translational Research Lead, Jehangir Clinical Development Centre, Pune.</p> <p>Dr Madhur is a MBBS (Bachelor of Medicine; Bachelor of Surgery), Grant Medical College, Mumbai. PhD Immunopharmacology, University College London, UK. MRes Clinical and Experimental Medicine, University College London, UK.</p> <p>He worked as a Co-Investigator, Centre for Clinical Pharmacology, University College London, UK. Clinical trial research assistant, Division of Medicine, University College London, London, UK.</p> <p>He has several publications and patents in the area of infection and inflammation. He was a finalist (Top 8), Olympic 10m Air Pistol Shooting League Competition, National Sports Rifle Association (UK) - ELEY, 2017.</p>
 <p>Priya Nagaraj</p>	<p>Dr Priya Nagaraj Bio incubation Manager - Venture Center, Pune.</p> <p>Priya holds a Ph.D. in Cell Biology from University of Virginia, USA. She worked with Advinus Therapeutics Ltd, a pharmaceutical drug discovery company for over 5 years. She has research experience in biochemistry, cell biology, developmental biology, molecular biology and drug discovery.</p>
 <p>Ramesh Paranjpe</p>	<p>Dr Ramesh Paranjpe</p> <p>Ramesh Paranjpe was Director at National AIDS Research Institute, Pune. He received his Ph.D in Microbiology from University of Madras and was the recipient of National Science Talent Search Scholar (1969-1975) award. He did his Post-Doctoral Fellowship at the Laboratory of Parasitic Diseases, NIH and WHO Fellowship at Case Western Reserve University, Cleveland, Ohio, USA. Immunology of HIV infection is his main area of interest and established the presence of strong, poly-clonal cross-clade cytotoxic T lymphocyte response in the early sero-converters. He has more than 50 scientific publications in peer reviewed national and international journals and has contributed to WHO (South East Asia) laboratory guidelines.</p>
 <p>Sharayu Paranjpe</p>	<p>Dr Sharayu Paranjpe Principal Statistician at Cytel Statistical Software & Services Private Limited, Pune.</p> <p>M.Sc. Ph.D. Has over 25 years of experience as teacher and consultant in statistics. Her initial training and research was in biometry (Ph.D. from Pune University, under DR. P. V. Sukhatme). Later she became interested in problems in ecology and wrote &#39; A Course on Mathematical and Statistical Ecology (Kluwer) & #39; jointly with Prof. A. P. Gore. She has published over 40 research papers. Has been a consultant to researchers in many fields including bio and social sciences. She has conducted several training programs for non-statisticians at industries like Hindustan Unilever, research institutes like Wildlife Institute of India. Last 12 years working as consultation statistician at Cytel, a software development and services company.</p>
 <p>Vishwas Sovani</p>	<p>Dr Vishwas Sovani Founder Director, Pharmawisdom, Pune.</p> <p>30 yrs in Pharma industry in medical field, responsible for research, regulatory & medico marketing, 3 yrs in TCS BPO as Vice President of Pharma delivery, Country Manager of Revogenex Inc., Medical Director of Wyeth Limited - Pfizer India.</p>

A BIRAC - Venture Center Initiative
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MD (Pharmacology), Mumbai University and Diploma in Management, IIM Ahmedabad.

Reviewer for the journal, "Perspectives in Clinical Research". Ex Member Chairman of Institutional Review Board of Bombay College of Pharmacy, Mumbai. Ex Referee and examiner for M. Pharm. (Pharmacology) & Ph. D (Pharmacology) course of University of Mumbai Worked on various committees to help formulate DCGI guidelines.

Publications: JOURNALS 38 publications in various therapeutic areas.

BOOKS: Updates in Ophthalmology as editor

Dr Sovani offers consultation and training in areas of Clinical Research , Data management, Pharmacovigilance, Patents and Food laws, Manufacturing and product development of formulations, food products and Marketing and sales promotion.



Premnath V

Dr Premnath V
Founding Director - Venture Center and Head, NCL Innovations.

He holds a B. Tech from the Indian Institute of Technology - Bombay and a Ph.D. from the Massachusetts Institute of Technology, USA. He has also been a Chevening Technology Enterprise Fellow with the Centre for Scientific Enterprises, London Business School and Cambridge University, UK. He brings with him considerable experience in technology development and commercialization, working with start-up companies (in Cambridge-UK and India) and engaging with large corporations on research and consulting projects as project leader.



About the Organizers

 A BIRAC - Venture Center Initiative	<p>BIRAC Regional Bioinnovation Centre (BRBC) is the third regional centre of BIRAC and is located in Venture Center. BRBC aims to fill up key innovation ecosystem gaps for bio-based industry sectors and thus significantly impact the translation of high quality innovative ideas into viable and sustainable business enterprises. Some key BRBC initiatives are Venture Mentoring Service; Venture Base Camps; Regulatory Information and Facilitation Centre; Bio Incubation Practice School.</p> <p>More on: http://www.brbc.venturecenter.co.in/</p>
	<p>The Regulatory Information and Facilitation Center (RIFC) is a joint initiative of the Venture Center and BIRAC under the BIRAC Regional Bio-Innovation Center (BRBC) program. The RIFC aims to assist bio-entrepreneurs in planning, seeking and securing regulatory approvals. The RIFC plans to achieve this by providing information in an entrepreneur-friendly manner, providing access to experts and regulators, providing access to practical insights from other entrepreneurs, providing services and organizing relevant and useful events.</p> <p>More on: http://rifc.venturecenter.co.in/</p>

Supported by

 Ignite Innovate Incubate	<p>Biotechnology Industry Research & Assistance Council is a non-profit company created by the Department of Biotechnology (Government of India) with a mandate to develop the national ecosystem for biotechnology innovation and entrepreneurship and provide targeted support to innovators and entrepreneurs.</p> <p>For more information about BIRAC: www.birac.nic.in</p>
	<p>Venture Center is India's largest inventive enterprises and scientific business incubator. Venture Center is a technology business incubator hosted by CSIR-NCL and supported by the Department of Science & Technology's National Science & Technology Entrepreneurship Development Board (DST-NSTEDB) and BIRAC.</p> <p>For more information, visit www.venturecenter.co.in</p>