













Global Bio-India 2019 Road Show – Pune Theme - Going Global with your Med-Tech Innovations

- Organized by BRBC at Venture Center-

	BRBC			
	Mentor			
	Mixer			
Focus Areas	 This Road Show intends to publicize the upcoming Global Bio-India Summit 2019, taking place in Aerocity Delhi from 21 to 23 November 2019. This Road Show is focused on understanding regulatory and market requirements for commercializing med-tech products (Medical Devices and Invitro Diagnostics) globally (EU, USA, Japan, Mexico, Canada and Australia) Sessions as part of this event will focus on the Medical Device Single Audit Program (MDSAP)* mechanism to enable entry in Australia, Mexico, Canada, Japan and the United States markets and EU regulations for In-vitro Diagnostics. Sessions will also include insights into market entry decision making, knowledge of sales and marketing channels, mechanisms to establish connects with importers and challenges likely faced in global markets. *The Medical Device Single Audit Program (MDSAP) is a program that allows the conduct of a single regulatory audit of a medical device manufacturer's quality management system that satisfies the requirements of multiple regulatory jurisdictions. 			
Stage of startup	 Concept/ POC/ Prototype/ sharpening offerings and value propositions Post-prototype/ product ready/ early revenue/ scale-up 			
Organized by	BIRAC Regional BioInnovation Center @ Venture Center (BRBC)			
Supported by	BIRAC Venture Center			
For whom	Startup founders and CXO level team members of startups			
	Senior entrepreneurs who have already built companies in the sector			
When	Tuesday, 12 th November 2019 Time: 8:30 – 16:00			
Where	Training Room, 100 NCL Innovation Park, Dr. Homi Bhabha Road, Pashan, Pune - 411008			
Contact	Technical queries: Ms Neha K. 020-25865877/76 neha@venturecenter.co.in			
Registration	Registration Process:			
	Attendance is free. Registration is mandatory Register here - http://bit.ly/12novgbi			















Introduction

Venture Center (http://www.venturecenter.co.in) is India's largest inventive enterprises and scientific business incubator. It is the winner of the National Award for TBI, 2015 and AABI's Incubator of the Year Award, 2018. Venture Center is home to the BIRAC Regional Bioinnovation Center (BRBC). More information at: http://brbc.venturecenter.co.in/. Under the aegis of the BRBC, Venture Center organizes Mentor Mixers. Mentor Mixers are usually sector focused and emphasize specific themes. Mentor Mixers are opportunities for startup founders to meet and network with senior industry professionals, senior entrepreneurs and investors. These are also opportunities senior professionals and investor to connect with the hottest startups in their field of interest. This event aims to initiate contact, introduce people and catalyze mutually rewarding interactions and relationships.



Via this initiative, Venture Center and BRBC hopes to facilitate productive mentor-mentee relationships in different sectors and different regions of the country. Venture Center plans to launch an online mentoring platform to back-end these mentor-mentee interactions and create facilitating "soft" infrastructure for the same.

Why you should attend?

For Startups:

- Meet potential mentors/ senior entrepreneurs and get advise/ inputs on various themes
- Meet other entrepreneurs/ peers in similar industry spaces
- Meet and interact with other mentors/investors in the field

Workshop includes

• Workshop will include tea & Lunch at Venture Center















Schedule	Schedule					
Time	Duration	Session title	Venue			
8:30-09:00	30 min	Registrations & Tea				
09:00 - 9:30	30 min	IntroductionVenture CenterGlobal Bio-India 2019 by BIRAC Representative	Priya Nagaraj Ginny Bansal			
9:30 - 10:30	60 min	Session 1: EU Regulations for In-vitro Diagnostics	Lakshman Balajepalli			
10:30 - 11:00	30 min	Tea Break				
11:00 - 12:00	60 min	Session 2:Taking Medtech products Global: Focus on Medical Device Single Audit Program	Anita Joshi			
12:00 - 13:00	60 min	Session 3: • Entering Overseas Markets: A Staged Approach	Ravi Sarangapani			
13:00-14:00	60 min	Lunch				
14:00-15:30	90 min	Session 4: • Moderated panel discussion with mentors	Mentors : Lakshman Balajepalli Ravi Sarangapani V. Premnath (moderator)			
15:30 – 16:00	30 min	Tea & Networking				















Mentors (in alphabetical order of last names)



Ms. Ginny Bansal Communication Consultant- BIRAC

Ms. Ginny has 8+years in the field of Health and Communication. She has completed her Bachelors in Journalism & Mass Communication & M.A in Mass Communication from Guru Gobind Singh Indraprastha University. Prior working with BIRAC Ginny was working as Communication Assistant at National Health Portal, Ministry of Health and Family Welfare, Senior PR Executive at Varshyl Technologies, Communication Coordinator- National Center for Promotion of Employment for Disabled People.



Mr. Lakshman Balajepalli Head, Quality and Regulatory, RAS Lifesciences Pvt Ltd.

A Master of Sciences (Biochemistry) from a prestigious medical school in India. Over 28 years' experience in Life sciences industry (IVD and Human vaccines) which includes in over 20 years in IVD industry in R&D, manufacturing, QC, QA, Regulatory as well as of 8+ years' experience in process development, QA of human vaccines. Highly experienced in Regulatory, QMS including ISO 13485, ISO 9001, ISO 15189 systems. Faced many WHO and GMP audits. Was Consultant to overseas Biotech company for QMS. Has extensive experience in Indian MDR and QA as well as in EU IVDR, EU-MDR



Dr. Anita Joshi External Resource Auditor, BSI Group India Pvt. Ltd.

An exciting career spanning around 18+ years in Biotech industry and 10 years in academics (NIV and Pune University). Cross functional experience of working with more than 80 organizations till date since 2001. Publications: 26 till date. Esteemed Companies I worked for include: BSI India, Thermo Fisher Scientific, Merck Millipore, Lonza India, Span Diagnostics Ltd, Advanced Enzyme Technologies, etc. I am an external resource auditor with BSI - (British Stds Institution) as an auditor and trainer for ISO 13485; MDSAP; trainer for CE marking ie IVDR



Mr. Ravi Sarangapani Consultant Medical Devices Product Development

Mr. Ravi previously held senior positions for Sushrut / Adler in Product Development, Sales and Marketing, Regulatory affairs. He is an accomplished professional with over 25 years in the medical device industry encompassing leadership roles in New Product Development, Quality Management and Regulatory affairs, Marketing, Sales and Business Development. Mr. Ravi has proven track record of managing the new product development process from conceptualization and market analysis through development, risk management, pre-clinical evaluation, verification and validation, test marketing to commercialization. Outstanding communication talents with proven ability to build and lead highly efficient teams, train technical professionals and to convey complex concepts in understandable terms. Especially skilled at problem analysis and resolution, strategic planning and budget controls. Strong background of interactions with Key Opinion Leaders, customers and trade channels throughout Asia, Middle East, Africa and some areas of Europe















About the Organizers:

Dr. Premnath Venugopalan

Head - NCL Innovations; Director - Venture Center



Dr V Premnath is currently the Head, NCL Innovations — the group within National Chemical Laboratory (NCL) charged with the responsibility of championing the cause of technology innovation within NCL. Dr Premnath also provides leadership for the Intellectual Property Group at NCL — one of India's leading IP management groups based out of research institutions. Dr Premnath is also the Director of the Venture Center — a technology business incubator on NCL campus. Dr Premnath is also a Scientist, Polymer Science & Engineering Division at NCL with an interest in technology development for biomedical products. Dr Premnath has helped found and be the first Director of Venture Center, CSIR-Tech (a technology commercialization company), Orthocrafts Innovations (degradable synthetic polymer based biomed products start-up) and BiolMed Innovations (silk based biomaterials start-up). Dr. V. Premnath holds a B.Tech. from the Indian Institute of Technology - Bombay and a Ph.D. from the Massachusetts Institute of Technology, USA.



Dr. Priya Nagaraj Bio incubation Manager-Venture Center

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.



Mr. Navnath Kadam
Asst. Manager at The Regulatory Information and Facilitation Center (RIFC)

Navnath Kadam 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.



Ms. Neha Khaladkar

Asst. Manager at BRBC- BIRAC Regional Bio-Innovation Center

Neha is responsible for planning & co-coordinating activities of BRBC. She studied MSc. in Microbiology. During her Masters she did her project work in National Chemical Laboratory, Pune. Neha is a qualified healthcare/Lifescience expert with cross functional expertise. She is an experienced professional in Business Development and has 7+ years of experience working with a Healthcare IT.















Organized by				
BBBC A BIRAC - Venture Center Initiative	BIRAC Regional Bio-Innovation Center (BRBC) is a resource intensive center set up by BIRAC at Venture Center. Through its diverse initiatives, BRBC aims to significantly impact the translation of high quality innovative ideas across diverse ecosystems into viable and sustainable business enterprises. BRBC Initiatives: Venture Mentoring Service; Venture Base Camps; Regulatory Information and Facilitation Center; BioIncubation Practice School For more information, visit www.brbc.venturecenter.co.in			
RAFC	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. For more information, visit: http://rifc.venturecenter.co.in/			
Supported by				
VENTURE C E N T E R	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. For more information, visit www.venturecenter.co.in			
DICOC Ignite Innovate Incubate	Biotechnology Industry Research & Assistance Council (BIRAC) is a new industry-academia interface and implements its mandate through a wide range of impact initiatives, be it providing access to risk capital through targeted funding, technology transfer, IP management and handholding schemes that help bring innovation excellence to the biotech firms and make			

them globally competitive.

For more information, visit : www.birac.nic.in