

Regulatory Clinic on Medical Devices and Diagnostics at Atal Incubation Centre - Centre for Cellular and Molecular Biology, Hyderabad

- Organized by BRBC -

Potential gains	This event is an R Clinic organized by BRBC. The goal is to understand regulatory requirements and roadmap for securing regulatory approval for medical products in India. The Clinic will also focus on understanding the relevant Acts/ Laws/ Rules and standards applicable to medical devices and diagnostics. The Clinic will provide a practical understanding of regulatory pathways and timelines for approvals.		
Organized by	 BIRAC Regional BioInnovation Center (BRBC)@ Venture Center Atal Incubation Centre - Centre for Cellular and Molecular Biology (AIC-CCMB) ASPIRE-BioNEST, University of Hyderabad 		
Supported by	BIRACVenture Center		
For whom	 CEOs/CTOs of innovative technology startups. Incubatees at AIC-CCMB Potential entrepreneurs (Researchers, students, clinicians) Individual Inventors. Inventors from R&D institutes, medium/ large enterprises 		
Mentors	 Ravindra Ghooi Sudhakar Bangera Navnath Kadam 		
When	• Friday, 15 Nov 2019 09:00 – 17:00 Hrs		
Where	Lecture Hall, Atal Incubation Centre - Centre for Cellular and Molecular Biology 1st Floor, Medical Biotechnology Complex, CCMB Annex 2, Genpact Road, IDA Uppal, Habsiguda, Hyderabad - 500039. Telangana. INDIA. Phone (Off.): +91-40-2719-5630		
Registration Details			
	 Step 1: Interested participants need to fill in registration form at the following link. Register online at: <u>http://bit.ly/15novRClinic</u> Step 2: Email invite will be sent post screening of registration details. Preference: Startup companies (LLC/PLC) vs. individuals if we receive more than 50 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 closes once 50 seats are full or on 10th Nov 2019 (whichever is sooner). 		
Contact	Technical queries and registrations: Neha K. 020-25865877/76; <u>neha@venturecenter.co.in</u> Venue queries: Ritika Marampalli <u>ritika@ccmb.res.in</u> 040-27195609		



R Clinic schedule				
Time	Duration	Session title	Lead	
09:00-09:30	30 min	Registration and refreshments		
09:30-09:45	15 min	Introductions		
09:45 - 10:45	60 min	 Session 1: Introduction to medical products regulations in India Pathway Assessment – Development, Approvals 	Navnath Kadam	
10:45 – 11:15	60 min	 Session 2: Awareness on current medical requirements for medical products and clinical trials in India Clinical research/clinical investigation/performance evaluation 	Ravindra Ghooi	
11:15 - 12:45	60 min	 Session 3: Documentation Required for Clinical Development of Medical Devices 	Sudhakar Bangera	
12:45 - 14:00	60 min	Lunch		

Slots for Mentoring

Session 4: One-on-one meetings				
		Ravindra Ghooi	Navnath Kadam	
14:00 - 17:00	30 min			
	30 min			



Speakers/faculty (in alphabetical order of last names)



Mr. Bangera is a Clinical Development Strategist for Pharmaceuticals, Vaccines and Medical Devices. He has extensive work experience of 28 years in health-care (Hospitals and Medical Schools), of which 23 years are in global and local Clinical/ Contract Research Organisations, Academic Research Organisation, Site Management Organisation, Medical Imaging, Clinical Bioavailability and Bioequivalence (BA-BE), Public Health, Pharmaceutical and Vaccine Manufacturing companies.

Dr Ravindra Ghooi

Mr. Sudhakar Bangera



Dr. Ravindra Ghooi

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.

Mr. Navnath Kadam



Navnath Kadam

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.



About the Organizers		
BBBBC 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 : <u>http://www.brbc.venturecenter.co.in/</u>	
ATAL INCUBATION CENTRE CENTRE FOR CELLULAR MOLECULAR BIOLOGY Supported by Atal Innovation Mission, NITI Aayog	The Atal Incubation Centre- Centre for Cellular & Molecular Biology (AIC- CCMB) is a premier technology business incubator supporting deep science startups. Established at CSIR-CCMB, Hyderabad under the Atal Innovation Mission of NITI Aayog, GoI in 2017, this incubation centre has become a hub for life-sciences and biotechnology startups and MSME's in a very short time. AIC-CCMB has been actively working with its host institution, CSIR – Centre for Cellular & Molecular Biology to create a physical space for startups to work and creating a high impact ecosystem with policy makers, mentors, alumni, fund providers, experts, consultants and industry. More on: <u>http://aic.ccmb.res.in/</u>	
EIONEST OF AFORMATION	 BioNEST at the University of Hyderabad (UoH) is a life sciences incubator, set-up with the Support of the Biotechnology Industry Research Assistance Council (BIRAC), a Government of India Enterprise under Department of Biotechnology, Ministry of Science & Technology of the size of 20000 sq.ft size, located on the 3rd floor of the School of Life Sciences, University of Hyderabad. Formed as a knowledge-base incubator in life sciences, it nurtures innovation and entrepreneurship in scaling technologies of Agriculture, Biotechnology, Healthcare, Pharmaceutical, IT, and allied areas. In association with UoH, it provides a plug-and-play life science ecosystem of incubation. More on: http://bionest.uohyd.ac.in/ 	



Supported By -		
	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 <u>https://www.venturecenter.co.in</u>	
RIFC	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.	
birac 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 : https://www.birac.nic.in	