




Online R Clinic On Essential Requirements For Regulatory Compliance & Regulatory Landscape For Medical And In-Vitro Diagnostic Devices

- Organized by BRBC -

Potential gains	<ul style="list-style-type: none"> The event is an online R Clinic organized by RIFC at BRBC, Venture Center P. <div style="text-align: center;">  </div>
Organized by	<ul style="list-style-type: none"> BIRAC Regional BioInnovation Center (BRBC) @ Venture Center
Supported by	<ul style="list-style-type: none"> BIRAC (Biotechnology Innovation Research Assistant Council) Venture Center
For whom	<ul style="list-style-type: none"> Entrepreneurs, early stage startups, Venture Center incubatees
Mentors	<ul style="list-style-type: none"> Mr. Atonu Dutta - CEO and Partner at Alceon Mr. Ravi Sarangpani - Sales and Marketing Expert
When	<ul style="list-style-type: none"> Monday 15 November 2021 11.00 am – 01:00 pm (Talks by Mentors) One-One Meetings 02:00 pm – 05:00 pm (1 Hr. each 3 participants / mentor)
Where	This is an online Clinic - to be held on online platform; Link to the event will be shared with selected participants
Registration	<p>Register at : https://bit.ly/RC15Nov2021</p> <p>Registration Process:</p> <p>Step 1: Interested participants need to fill in registration form at the following link.</p> <p>Step 2: Email invite will be sent post screening of registration details.</p> <p>NOTE: Registration closes once 80 seats are full for Talk! Request for 1-1 meetings if interested by selecting the same in registration form participants will be selected & informed via email about their meeting slot.</p>
Contact	Technical queries: Neha K neha@venturecenter.co.in + 91-8956677543



R Clinic Schedule		
Time	Session title	Speaker
11:00 am – 12:00 pm	Regulatory Landscape In India For Medical And In-Vitro Diagnostic Devices	Atonu Dutta
12:00 pm – 01:00 pm	Risk Management and Design Control - Essential Requirements for Regulatory Compliance	Ravi Sarangapani
01:00 pm – 02:00 pm	LUNCH BREAK	
One-One Meetings		
02:00 pm – 05:00 pm	3 meeting slots -1 hr each	Atonu Dutta VC -Coordinator : Smita K
02:00 pm – 05:00 pm	3 meeting slots -1 hr each	Ravi Sarangapani VC -Coordinator : Neha K

Mentor : (In alphabetical order of last name)



Mr. Atonu Dutta

CEO and Partner at Alceon

Mr. Dutta is an experienced professional with 30 years of industrial experience including over 14 years in the field of medical device regulatory affairs. He has worked as a medical device assessor and auditor for ISO13485 and MDSAP with DNV (Norway), Intertek (Sweden) and SZUTEST (Turkey). His key areas of expertise include risk management and clinical evaluation of medical devices, regulatory submissions in the US and EU and Quality Management System requirements. Currently he is CEO and Partner at Alceon, a company set up exclusively for regulatory and QA. He has cumulative experience of auditing medical devices in multiple areas such as cardiac, dental, ophthalmic, orthopedic, medical disposables and contraceptives. He was also lead trainer in areas of quality management systems and regulatory requirements.



Mr. Ravi Sarangapani

Consultant Medical Devices Product Development

Mr. Ravi has previously held senior positions for Sushrut / Adler in Product Development, Sales and Marketing, Regulatory affairs. 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. 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 Organizers (in alphabetical order of last names)



Dr. Smita Kale

Manager –Bioincubation, Venture Center

Smita as part of incubation team, facilitates incubator operations by interacting with incubatees, infrastructure and facilities creation and development of the ecosystem. She is leading Bio-incubation activities, Center for Biopharma Analysis (CBA) and BIRAC’s Regional Bioinnovation Center (BRBC) projects at Venture Center. She is actively involved in mentoring startups at Venture Center. She is Ph. D in Pharmaceutical Chemistry from Institute of Chemical Technology, Mumbai and prior to joining Venture Center has had academic experience of 12 years which includes research experience of 3.6 years.



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.




	<p>Dr.Premnath V Director, Venture Center Head, NCL Innovations</p> <p>Premnath V is currently the Head, National Chemical Laboratory (NCL) Innovations - the group within NCL charged with the responsibility of championing the cause of technology innovation within NCL. Dr Premnath is also the Founding 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. 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 (two successfully commercialized families of products), working with start-up companies (in Cambridge-UK and India) and engaging with large corporations on research and consulting projects as project leader.</p> <p>More information at: www.premnath.org</p>
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About the Organizers

	<p>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</p> <p>For more information, visit www.brbc.venturecenter.co.in</p>
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Supported by

	<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>
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	<p>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.</p> <p>For more information, visit : www.birac.nic.in</p>
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