

BRBC



Regulatory

Clinic
**Organized by BRBC at Venture Center, Pune.
 27th July 2018**

Potential gains	This event is an R Clinic organized by BRBC. The goal is to understand regulatory requirements and roadmap for securing regulatory approval. The event will also focus on understanding relevant standards applicable to the respective device and the process to conduct clinical trials.
Organized by	BIRAC Regional BioInnovation Center (BIRAC) @ Venture Center
Supported by	BIRAC (Biotechnology Innovation Research Assistant Council) Venture Center, Pune
For whom	BIG grantees
Where	Lecture Theater, 900 NIP, Venture Center, 100 NCL Innovation Park, Dr. Homi Bhabha Road, Pashan, Pune, Maharashtra, 411008
Registration & Breakfast	08:15 – 08:50 am Breakfast will be served at Cafeteria (Venture Center) 08:15 – 08:45 am Registration at Reception desk (Venture Center)
Contact	Technical queries: Dr. Priya Nagaraj 020-25865877/75/76; 7410045657 bioincubator@venturecenter.co.in

Workshop Outline

Time	Duration	Session title	Lead
09:00 am to 10:00 am	60 min	Awareness on the current Regulatory requirements for Medical Devices in India	Shyamni Sasidharan
10:00 am to 11:00 am	60 min	Overview of the regulatory requirements for Clinical trials for Medical Devices in India	Dr. Prasad Kulkarni

Mentors



Shyamni Sasidharan

Shyamni is a highly efficient, methodical and multi talented Electronics and Biomedical Engineer with 5 years of experience in In-Vitro Diagnostics Medical Device manufacturing company. She possesses comprehensive knowledge of Quality Management Systems, Risk Management, GDP, and cGMP, current requirements of national/international standards /regulations and CE marketing of IVD Medical devices.

Executive Quality Assurance at Molbio Diagnostics Pvt. Ltd., Goa - India



Dr. Prasad Kulkarni

Dr. Prasad Kulkarni (MD, FCP) is a clinical pharmacologist with several years experience in new drug development, clinical research, pharmacovigilance, regulatory practices and medical advice.

He works at the **Serum Institute of India Ltd.** Here he has been involved in the successful clinical development of several new vaccines and therapeutic large molecules.

He has more than 60 publications in journals like the New England Journal of Medicine, Clinical Infectious Diseases, Vaccine, etc. He has been a faculty to many national and international conferences.

About the Organizers



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

More on: <http://www.brbc.venturecenter.co.in/>

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Biotechnology Industry Research & Assistance Council 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 about BIRAC: www.birac.nic.in



Entrepreneurship Development Center (Venture Center) – a CSIR initiative – is a Section 25 company hosted by the National Chemical Laboratory, Pune. Venture Center strives to nucleate and nurture technology and knowledge-based enterprises by leveraging the scientific and engineering competencies of the institutions in the Pune region in India. The Venture Center is a technology business incubator supported by the Department of Science & Technology's National Science & Technology Entrepreneurship Development Board (DST-NSTEDB). Venture Center's focuses on technology enterprises offering products and services exploiting scientific expertise in the areas of materials, chemicals and biological sciences & engineering.

For more information, visit www.venturecenter.co.in