



**R Clinic organized by BRBC on  
Awareness of the Current Regulatory Requirements for Medical Products and  
Clinical Trials in India**

<b>Potential gains</b>	<p>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 the respective drugs and medical devices.</p> <div style="text-align: center;"> </div>	
<b>Organized by</b>	<ul style="list-style-type: none"> <li>• BIRAC Regional BioInnovation Center (BRBC) @ Venture Center</li> <li>• PSG Science &amp; Technology Entrepreneurs Park, Coimbatore</li> </ul>	
<b>Supported by</b>	<ul style="list-style-type: none"> <li>• BIRAC (Biotechnology Innovation Research Assistant Council)</li> <li>• Venture Center</li> </ul>	
<b>For whom</b>	<ul style="list-style-type: none"> <li>• BIG grantees, Startups, and researchers.</li> </ul>	
<b>Mentors</b>	<ul style="list-style-type: none"> <li>• Dr. Ravindra Ghooi</li> <li>• Navnath Kadam</li> </ul>	
<b>When</b>	<ul style="list-style-type: none"> <li>• Thursday, 22 Feb 2019   0830 – 1400  </li> </ul>	
<b>Where</b>	<ul style="list-style-type: none"> <li>• Seminar hall - above Central library (1<sup>st</sup> floor), PSG Institute of Medical Sciences &amp; Research, Off, Avinashi Rd, Masakalipalayam, Peelamedu, Coimbatore, Tamil Nadu 641004</li> </ul>	
<b>Registration Details</b>	<p>Registration Process:            Step 1: Interested participants need to fill in registration form at the following link.            Register online at: <a href="https://tinyurl.com/R-Clinic-PSG-STEP">https://tinyurl.com/R-Clinic-PSG-STEP</a>            Step 2: Email invite will be sent post screening of registration details.  <b>Limited seats!!! Total number of seats: 50 Free!!!</b>            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.  <b>NOTE:</b> Registration closes once 50 seats are full or on xx Feb 2019 (whichever is sooner).</p>	
<b>Contact</b>	<b>Technical:</b> Navnath Kadam   020-25865876/77 <a href="mailto:rifc@web.venturecenter.co.in">rifc@web.venturecenter.co.in</a>	<b>Venue:</b> Brindha   0-422-4363300 <a href="mailto:step@psgtech.edu">step@psgtech.edu</a>



Workshop schedule			
Time	Duration	Session title	Venue
0830-0900	30 min	Registration and refreshments	
0900 - 0915	15 min	Session 1 <ul style="list-style-type: none"> <li>Welcome note</li> <li>Opening remarks</li> </ul>	S Ramalingam K Suresh Kumar
0915 - 100	45 min	Session 2 <ul style="list-style-type: none"> <li>Introduction to medical product regulations in India</li> </ul>	Navnath Kadam
1000 - 1030	30 min	Networking and tea break	
1030 - 1200	90 min	Session 3: Awareness on current medical requirements for medical products and clinical trials in India <ul style="list-style-type: none"> <li>Pre Clinical &amp; material characterization</li> <li>Clinical research/clinical investigation/performance evaluation</li> </ul>	Ravindra Ghooi
1200 - 1230	30 min	Session 4: <ul style="list-style-type: none"> <li>Q &amp; A</li> </ul>	S Ramalingam Navnath Kadam Ravindra Ghooi
1230 - 1400	90 min	Lunch	

**Speakers/faculty (in alphabetical order of last names)**



**Dr. Ravindra Ghooi**

**Current positions held:**

Director, Scientia Clinical Services.  
Chairman, Institutional Ethics Committee, Jehangir Hospital, Pune.  
Chairman, Institutional Ethics Committee, Sahyadri Hospitals, Pune.  
Member, Symbiosis International University, Ethics Committee, Pune.  
Member, Cipla Palliative Care Centre, Ethics Committee.  
Member, Editorial Board, Perspectives in Clinical Research.  
Ph. D Guide, Symbiosis International University, Pune.

**Education:**

Graduation (B.Sc) : Seksaria Science College, Belgaum.  
Chemistry and Zoology, Karnataka University.  
Post Graduation (M.Sc. Pharmacology):Karnataka Medical College, Hubli, Karnataka University  
Doctorate: HaffkinInstitute, (Ph.D. Medicine), University of Bombay.

**Specialties: Clinical Research Consultation**

Setting up of CR academies  
Consultation in setting up IECs  
Upgrading clinics to trial sites.





**Navnath Kadam**


**Asst. Manager at RIFC- Venture Center.**

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.

 <p><b>Dr S Ramalingam</b></p>	<p><b>Dean, PSG Institute of Medical Sciences &amp; Research &amp; PSG Hospitals</b></p> <p>Dr Ramalingam also the Founder Chair of the Department of Clinical Research and Bioethics and is a Professor of Pharmacology in the same Institute. He obtained an International Fellowship in Medical Education (IFME) offered by the ECFMG of USA. He is the founder of Population Approach Group of India (PAGIN) which looks at applications of mathematics, statistics, and pharmacological science in drug development. He underwent intensive training in bioethics, and clinical trials under the HHMI – NIH – ICMR sponsored programs.</p>
 <p><b>Dr. K Suresh Kumar</b></p>	<p><b>Executive Director, PSG-STEP</b></p> <p>Dr Suresh Kumar manages PSG-Science &amp; Technology Entrepreneurial Park (PSG-STEP) – The Technology Business Incubator (TBI) associated with PSG College of Technology, Coimbatore, India with the focus to support start-ups in the areas of IT, Electronics, Biotech &amp; Nanotech. He has been a part of establishing and managing the incubation facility, handholding start-ups, implementing the innovation fund, managing the seed fund support system, coordinating the Outreach Centre activities for promoting innovations and identifying &amp; executing the consulting assignments</p>

## About the Organizers

 <p><b>BRBC</b> A BIRAC - Venture Center Initiative</p>	<p>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>More on: <a href="http://www.brbc.venturecenter.co.in/">http://www.brbc.venturecenter.co.in/</a></p>
 <p><b>RIFC</b></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: <a href="http://rifc.venturecenter.co.in/">http://rifc.venturecenter.co.in/</a></p>
 <p>PSG INSTITUTE OF MEDICAL SCIENCES &amp; RESEARCH HEALTH HAPPINESS</p>	<p>A teaching hospital and research institute focuses on promoting cutting-edge, state-of-the-art, socially relevant biomedical research. Our faculty and students work in a cordial and collaborative manner to develop medical devices and tools that can be practiced in a human-setting and can create an impact in the society. The Center for Biomedical Innovations (CBMI) at PSG IMS&amp;R enables co-creation between startups, academia and healthcare industry with the right kind of clinicians, researchers and patients. The Center shall lay the methodical way of handling risks and uncertainties to achieve rapid and continuous translational innovation – from identification of needs and opportunities to clinical and commercial full-scale implementation.</p> <p>For more information on PSG IMS &amp; R: <a href="http://www.psgimsr.ac.in/">http://www.psgimsr.ac.in/</a></p>

	<p>PSG College of Technology, in the year 1998, established PSG-Science &amp; Technology Entrepreneurial Park (PSG-STEP) – the incubation center of PSG Tech with the support from National Science &amp; Technology Entrepreneurship Development Board (NSTEDB), Department of Science &amp; Technology, Government of India. To promote and accelerate entrepreneurship, PSG-STEP extends various support to startups/innovators through the initiatives such as capacity building training programs, mentoring support, funding support, networking with other agencies, participations in national &amp; international challenges and access to lab facilities of the institution.</p> <p>For more information on PSG-STEP: <a href="http://www.psgstep.org/">http://www.psgstep.org/</a></p>
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Supported by	
 <p><b>birac</b> Ignite Innovate Incubate</p>	<p>Biotechnology Industry Research &amp; 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: <a href="http://www.birac.nic.in">www.birac.nic.in</a></p>
 <p><b>VENTURE</b> CENTER</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 &amp; Technology's National Science &amp; Technology Entrepreneurship Development Board (DST-NSTEDB) and BIRAC.</p> <p>For more information, visit <a href="http://www.venturecenter.co.in">www.venturecenter.co.in</a></p>