

R Clinic

- Organized by BRBC -

Potential gains	<ul style="list-style-type: none"> 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.
Organized by	<ul style="list-style-type: none"> BIRAC Regional BioInnovation Center (BIRAC) @ Venture Center
Supported by	<ul style="list-style-type: none"> BIRAC (Biotechnology Innovation Research Assistant Council) (GJBP) Golden Jubilee Biotech Park for Women Society Venture Center
For whom	<ul style="list-style-type: none"> Women entrepreneurs' who are final participants of TiE WInER Award
When	Tuesday , 10 July 2018 1400 – 1800 hrs
Where	<ul style="list-style-type: none"> Golden Jubilee Biotech Park for Women Society Siruseri Village, Inside SIPCOT-IT Park, 4 th Main Road, 2 nd Cross Street, Old Mahabalipuram Road, Navalur Post, Kanchipuram District-603103
Contact	Technical queries: Dr. Priya Nagaraj 020-25865877/75/76; 7410045657 bioincubator@venturecenter.co.in



Workshop Outline				
Time	Duration	Session title	Lead	
1400-1420		Decision on the regulatory paths to follow, relevant regulations (CDSCO, CE, US FDA) Planning tests and data at pre-clinical stage. Selecting partners. Clinical trial design. Budgeting and time lines.		
1420-1530	70 min	Room A	1. Nemocare Wellness Pvt. Ltd. 2. Adiuvo Diagnostics Pvt. Ltd. 3. Bionic Hope Pvt. Ltd. 4. Bioscan Research Pvt. Ltd. 5. Empathy Design Labs Pvt. Ltd. 6. Virtis Bio Labs Pvt. Ltd. 7. NIRAMAI Health Analytix	Shyamni Sasidharan
		Room B	1. CyCa OncoSolutions 2. S.L.S. Cell Cure Technologies Pvt. Ltd. 3. Genext Genomics Pvt. Ltd. 4. OmiX Research and Diagnostics Labs Pvt. Ltd. 5. Inochi Care Pvt. Ltd. 6. NeelAgil Technologies Pvt. Ltd.	Anil Chaudhari
1530-1600	30 min	Tea Break		
1600-1620		Quality systems. Manufacturing site planning and design. Dossier preparation. Certification process. Post-approval documentation and launch.		
1620-1800	100 min	Room A	1. Nemocare Wellness Pvt. Ltd. 2. Adiuvo Diagnostics Pvt. Ltd. 3. Bionic Hope Pvt. Ltd. 4. Bioscan Research Pvt. Ltd. 5. Empathy Design Labs Pvt. Ltd. 6. Virtis Bio Labs Pvt. Ltd. NIRAMAI Health Analytix	Shyamni Sasidharan

		Room B	<ol style="list-style-type: none"> 1. CyCa OncoSolutions 2. S.L.S. Cell Cure Technologies Pvt. Ltd. 3. Genext Genomics Pvt. Ltd. 4. OmiX Research and Diagnostics Labs Pvt. Ltd. 5. Inochi Care Pvt. Ltd. 6. NeelAgil Technologies Pvt. Ltd. 	Anil Chaudhari
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Mentors (in alphabetical order of last names)

 <p>Anil Chaudhari</p>	<p>Anil Chaudhari has over 18 years of experience in the field of Regulatory and Quality assurances of medical devices. Operon Strategist offers service in the areas of Quality management systems, Design and development of medical devices, Regulatory approvals, Marketing authorizations, Validations and Manufacturing setup of Medical devices.</p> <p>CEO and Founder, Operon Strategist https://www.linkedin.com/in/anil-chaudhari-44637412/</p>
 <p>Shyamni Sasidharan</p>	<p>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, cGMP, current requirements of national/international standards /regulations and CE marketing of IVD Medical devices.</p> <p>Executive Quality Assurance at Molbio Diagnostics - India Molbio Diagnostics Pvt. Ltd., Goa</p>

About the Organizers

 A BIRAC - Venture Center Initiative	<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 More on: http://www.brbc.venturecenter.co.in/</p>
	<p>Golden Jubilee Biotech Park for Women Society is a unique venture set up with a mission to provide opportunities to qualified women to take up to a career of remunerative self-employment through biotechnological enterprises. The main focus centers include Agri, Aqua, Food Processing, Medical Devices and Diagnostics, Bioinformatics, Analytical and Quality Center. The park has an incubation facility hosted by BIRAC. More on : http://www.biotechpark.co.in/index</p>

Supported by

	<p>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</p>
	<p>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</p>