



Mentoring Clinics – 2015/02

Regulatory requirements for Biomed devices

Potential gains	<ul style="list-style-type: none">• Understand regulatory requirements and roadmap for securing regulatory approval• Understanding relevant standards applicable to the respective device
Organized by	<ul style="list-style-type: none">• Bioincubator at Venture Center (Bioincubator at Venture Center is supported by BIRAC, Government of India)
Supported by	<ul style="list-style-type: none">• Venture Center• UL India Pvt Ltd.• BIRAC via its mentoring program for BIG grantees
Organized by	<ul style="list-style-type: none">• Bioincubator at Venture Center (Bioincubator at Venture Center is supported by BIRAC, Government of India)
When	Wednesday, 13 May, 2015 1430- 1730 hrs
Where	<ul style="list-style-type: none">• Reception Meeting Room, Venture Center, 100 NCL Innovation Park, Dr. Homi Bhabha Road, Pune-411008• Board Room, Venture Center, 100 NCL Innovation Park, Dr. Homi Bhabha Road, Pune-411008
Contact	Lipika Biswas Venture Center, 100, NCL Innovation Park, Dr. Homi Bhabha Road, Pune – 411008; Phone: +91-20-25865877 Email: eventsdesk@venturecenter.co.in
Cost	<ul style="list-style-type: none">• Participation by invitation only Free but prior registration is required. Attendance only on confirmation of registration. VC Incubatees, BIRAC scheme grantees and BIRAC social innovators would be given preference.• Register here: http://vcevents.pandaform.com/pub/fhzxu9/new• Organizers reserve the right to select participants so as to maximize learning and networking opportunities for the group.



Introduction

This clinic aims to mentor biomed and diagnostics entrepreneurs how to plan for successfully securing the approvals and best practices. The clinic is meant to be one-to-one meeting with the experts from UL India Pvt. Ltd.

Diagnostics entrepreneurs to bring in certain details such as the actual device/prototype [if available], specifications, target markets for sale

Time Slots Available		Venue and Mentors	
Time	Slots		
1430-1500	Innovator no: 1	Reception meeting room	Jibu Mathew
1430-1500	Innovator no: 2	Board room	UL Personnel
1500-1530	Innovator no: 3	Reception meeting room	Jibu Mathew
1500-1530	Innovator no: 4	Board room	UL Personnel
1530-1600	Innovator no: 5	Reception meeting room	Jibu Mathew
1530-1600	Innovator no: 6	Board room	UL Personnel
1600-1630	Innovator no: 7	Reception meeting room	Jibu Mathew
1600-1630	Innovator no: 8	Board room	UL Personnel
1630-1700	Innovator no: 9	Reception meeting room	Jibu Mathew
1630-1700	Innovator no: 10	Board room	UL Personnel
1700-1730	Innovator no: 11	Reception meeting room	Jibu Mathew
1700-1730	Innovator no: 12	Board room	UL Personnel



Mentors (in alphabetical order of last names)

	<p>Praveen Dcruze is the lead scientist with UL India Pvt Ltd. Praveen brings in 14 year of experience and competence in the field of Quality Control, Water technology and Medical devices analytical testing.</p>
<p>D PRAVEEN</p>	
	<p>Jibu Mathew is currently heads the Life &Health Sciences with Underwriters Laboratories India, Bangalore. He has varied experience in IT consulting, regulatory advisory and market access strategy in, Medical Electronics, Healthcare and High tech industry spreading across for more than a decade. At UL his role is to lead a team in developing solutions for Medical Devices regulatory approvals, market access and support the Medical devices &Pharma manufacturer based in the Middle East, India and Emerging markets. The services portfolio include ISO 13485, CE certification, CMDCAS, US FDA, GMP, Clinical Evaluations, Japan New PAL service, Korea FDA, China FDA India CDSCO approvals, IEC 606601 testing, Usability, Pre-Clinical testing and US FDA audit readiness solutions.</p>
<p>JIBU MATHEW</p>	
	<p>Sreenath S, is the Technical consultant for Medical devices safety and Market access with UL India. His Expertise cut across entire life cycle of medical devices such as Design, Development, Systems engineering, manufacturing and regulatory consulting for 8 years. Core medical electronics educational background as well as a post graduate degree in Embedded systems.</p>
<p>S. SREENATH</p>	

About the Organizer

	<p>About Bioincubator The BioIncubator at Venture Center aims to nucleate and nurture technology and knowledge-based enterprises leveraging knowledge in the areas of biotechnology (biopharma, agrobiotech, industrial biotech, clean technology), biomedical engineering/ devices/ diagnostics, biomass value addition/ renewable fuels/chemicals/materials, bioinformatics, bio/medical services and related disciplines. Created with support from DBT-BIRAC under the Bioincubator Support Scheme. For more information, visit HUhttp://www.bioincubator.venturecenter.co.in/UH</p>
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Supported by

	<p>About Underwriters Laboratory (UL) India Private Limited UL is a global independent safety science company with more than a century of expertise innovating safety solutions from the public adoption of electricity to new breakthroughs in sustainability, renewable energy and nanotechnology. Dedicated to promoting safe living and working environments, UL helps safeguard people, products and places in important ways, facilitating trade and providing peace of mind.</p>
	<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 us: http://www.venturecenter.co.in/index.php</p>