Technical Workshops Series – 2015

Half Day Seminar on
Regulatory Pathway for Bio-medical Devices and Diagnostics
- Organized by Venture Center -

Potential gains	• Overview of regulatory approvals/processes; Framework and categories • Understanding regulatory requirements in India, EU and US in detail • Understanding relevant standards • Process for securing regulatory approval for a CE marking • Overview of Biocompatibility requirements
Organized by	• Bioincubator at Venture Center (Bioincubator at Venture Center is supported by BIRAC, Government of India)
Supported by	• Venture Center • UL India Pvt Ltd • BIRAC via its mentoring program for BIG grantees
For whom	• Entrepreneurs and small businesses working in Biomed sector. • Researchers and inventors in Medical Devices • Students of Pharma, Life Science, Health Science, Biotechnology, Biomed study programs. • Employees of biomed industry.
When	Wednesday, 13 May, 2015 0900-1315 hrs
Where	Training Room, Venture Center, 100 NCL Innovation Park, Dr. Homi Bhabha Road, Pune-411008
Contact	Ms. Lipika Biswas | Phone: +91-20-25865877 | Email: eventsdesk@venturecenter.co.in
Registration	• ***Prior registration is required.*** Register online at: http://vcevents.pandaform.com/pub/m8qggl/new • ***Attendance only on confirmation of registration.*** • First preference to VC incubatees and BIRAC grantees • Organizers reserve the right to select participants so as to maximize learning and networking opportunities for the group.
Cost	Free Limited seats

Introduction

Regulatory approvals and clearances represent one of the largest factors determining time-to-market and costs for innovators and entrepreneurs in the field of biomedical devices and diagnostics. Innovators and entrepreneurs often need to have awareness and clarity on regulatory matters at the very inception of product development and plan to work towards meeting various regulatory requirements from a very early stage.

This workshop aims to introduce innovators and entrepreneurs to the regulatory frameworks, the various needs, how to plan for successfully securing the approvals and best practices. The workshop will cover regulatory frameworks in India, EU and US but emphasize securing CE mark under EU regulations.

Seminar Outline

Time (hrs)	Topic	Speakers
0845-0900	Registration	
0900-0915	• Welcome to Venture Center and BioIncubator. • Introduction to the workshop	Pradnya Aradhye
0915-1100	• Definition of a medical device • Overview of the GHTF regulatory approval process • Overview of the EU- CE marking process	Mr. Sreenath – Technical Consultant
1100-1115	Networking sessions and tea	
1115-1300	• Overview of Medical devices standards • Overview of Biocompatibility requirements	Mr. Sreenath and Mr. Praveen - Technical Consultant and Lead Scientist
1300-1315	Closure of the workshop	

Speakers (in alphabetical order of last names)	
 PRADNYA ARADHYE	Pradnya Aradhye is currently Associate, Bioincubator, Venture Center. She has done her M.Tech in Biological Sciences and Bioengineering from IIT Kanpur. Currently she is handling all BioIncubator activities at Venture Center. She is responsible for creating a pipeline of potential and signing-up incubatees for the Bioincubator. She has also contributesin building scientific support systems and resources for VC incubates including specific expertise. Pradnya also carries out discussions with scientists to understand their competencies and to understand their research work.
 D PRAVEEN	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.
 JIBU MATHEW	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 certificaton, 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.
 S SREENATH	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.

About the Organizers	
	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 http://www.bioincubator. venturecenter.co.in/

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	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.
	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 us: http://www.venturecenter.co.in/index.php**