Awareness Talk on

Understanding of EU MDR 2017/745 (For CE Marking)

- Organized by BRBC at Venture Center-

Potential gains	• Understanding of EU MDR 2017/745 (For CE Marking) to identify the most appropriate regulatory pathway for the medical devices • Understanding the documentation requirements as per the applicable regulations • Understanding the ISO 13485 (Quality Management System standard) compliance • requirements for medical device manufacturers
Stage of startup	• Early stage inventive enterprises, • Established Start-ups
Themes	• Regulatory requirements to enter the European Medical device market
Organized by	• Regulatory Information and Facilitation Center (RIFC) @ Venture Center (BRBC)
Supported by	• Venture Center • BRBC
For whom	• Medical device manufacturers/ suppliers, • Bioentrepreneurs/ventures related to scientific products seeking regulatory information & assistance • Regulatory affairs professionals
When	**Monday, 16 October 2023 |Time: 11:00 am to 01:15 pm**
Where	This is an **online** event | Link to the Event will be shared with selected participants post registration
Contact	**Technical queries**: Akash R. Dhade| |akash.dhade@venturecenter.co.in **Logistics queries**: Meghana B| |meghana.bhandari@venturecenter.co.in
Registration	Register here: **Free Event…Registration is Mandatory!** Acceptance on confirmation by organizers after registration. Selected participants will be informed via email

Introduction

Venture Center (http://www.venturecenter.co.in) is India's largest inventive enterprises and scientific business incubator. It is the winner of the National Award for TBI, 2015 and AABI's Incubator of the Year Award, 2018. Venture Center is home to the BIRAC Regional Bioinnovation Center (BRBC). More information at: http://brbc.venturecenter.co.in/

Venture Base Camps are high intensity, focused, theme-based camps intended to take a startup from point A to point B in their entrepreneurial journey, prior to their execution on key goals of the company.

The focus of this Venture Base Camp:

To create awareness within the medical device entrepreneurs and business owners on medical device regulations in the European Union. The session also aims to provide one-on-one mentoring guidance regarding CE marking and other compliances for startups that are already in the process of venturing into the international medical device markets.

Schedule

Time	Duration	Session Title	Speaker
11:00 am -11.10 am	10 min	• Introduction to Venture Center & RIFC	Chetna Dharmavat-Dabi
11:10 am -11.30 am	20 min	• Overview of medical device regulatory market across the world	Akash R. Dhade
11.30 am - 12.15 pm	45 min	• European market and regulatory approach for medical device	Akash R. Dhade
12.15 pm - 01.15 pm	60 min	• One on One mentoring sessions for startups	Akash R. Dhade

About Organizers &Mentors (in alphabetical order of last names)	
	**Chetna Dharmavat Dabi** **Assistant Manager- Regulatory Services, Venture Center** Chetna works for the Regulatory Information Facilitation Center (RIFC) at venture Center and assists various medical device startups to strategize & plan regulatory pathways, interpreting standards, and establishing and implementing a quality management system for medical devices. She has experience with the securing the licenses for commercialization of medical devices. She is a certified lead auditor for ISO 9001 and ISO 13485 QMS by BSI Academy.
	**Akash Dhade** **Associate Manager- Regulatory Services, Venture Center** Akash is a part of the Regulatory Information Facilitation Center (RIFC) at Venture Center and has assisted multiple organizations in choosing regulatory pathways, creating technical documentation, and submitting the documentation to the notified bodies for the European market. He has experience drafting over 20 technical documentation for different types of medical devices and also has the lead auditor certification for ISO 13485 and ISO 9001 QMS by BSI Academy.

About the Organizers	
A BIRAC - Venture Center Initiative	BIRAC Regional Bioinnovation Centre (BRBC) is the third regional centre of BIRAC and is located in Venture Center. BRBC aims to fill up key innovation ecosystem gaps for bio-based industry sectors and thus significantly impact the translation of high quality innovative ideas into viable and sustainable business enterprises. Some key BRBC initiatives are Venture Mentoring Service; Venture Base Camps; Regulatory Information and Facilitation Centre; Bio Incubation Practice School More on: http://www.brbc.venturecenter.co.in/

Supported by	
birac Ignite Innovate Incubate	Biotechnology Industry Research & 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. For more information about BIRAC: www.birac.nic.in
VENTURE CENTER	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 & Technology's National Science & Technology Entrepreneurship Development Board (DST-NSTEDB) andBIRAC. For more information, visit www.venturecenter.co.in