



Mentor Mixer on
Understanding of EU MDR 2017/745 for European Approval
 -Organized by BRBC at Venture Center-

Potential gains	<ul style="list-style-type: none"> ● In-depth understanding of EU MDR 2017/745 and the regulatory requirements ● Knowledge about the process to get CE marking which is a mandate for manufacturers looking to commercialize their devices in the European market. ● EU MDR 2017/745 informational material for further usage ● In-person mentoring for device-specific questions
Stage of startup	<ul style="list-style-type: none"> ● Start-ups who are about to start production of the medical device or already manufacturing the medical device
Organized by	<ul style="list-style-type: none"> ● Regulatory Information & Facilitation Center (RIFC) ● BIRAC Regional BioInnovation Center @ Venture Center (BRBC)
Supported by	<ul style="list-style-type: none"> ● BIRAC ● Venture Center
For whom	<ul style="list-style-type: none"> ● Medical Device Startups ● Medical device manufacturers ● Suppliers of the Medical device manufacturers ● Regulatory Affairs Professionals
When	Friday, 27 April 2023 Time: 10:00 am to 05:00 pm
Where	Lecture Theater, 900 NIP, Pune
Contact	Technical queries: Akash Dhade akash.dhade@venturecenter.co.in Logistics queries: Vineet Joshi vineet.joshi@venturecenter.co.in
Registration Link & other instructions	https://tinyurl.com/EU-MDR-workshop-Apr2023 Limited Seats: 20 Registration fees: Rs. 500/- <ul style="list-style-type: none"> ● Registration is complete only upon payment of registration fees. ● Fees once paid won't be refunded under any circumstances. ● Participants that will opt for one-on-one mentoring; will be informed via a separate email for confirmation of their mentoring slot.



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>. Under the aegis of the BRBC, Venture Center organizes Mentor Mixers. Mentor Mixers are usually sector focused and emphasize specific themes. Mentor Mixers are opportunities for startup founders to meet and network with senior industry professionals, senior entrepreneurs and investors. These are also opportunities senior professionals and investor to connect with the hottest startups in their field of interest. This event aims to initiate contact, introduce people and catalyze mutually rewarding interactions and relationships.



Via this initiative, Venture Center and BRBC hopes to facilitate productive mentor-mentee relationships in different sectors and different regions of the country. Venture Center plans to launch an online mentoring platform to back-end these mentor-mentee interactions and create facilitating "soft" infrastructure for the same.

Schedule			
Time	Duration	Session Title	Speaker
10:00 – 10:20 AM	20 min	Welcome and Introduction to VC	Smita Kale
		Introduction to RIFC	Chetna Dharmavat Dabi
10:20 – 11:20 AM	60 min	Background & Structure of EU MDR 2017/745	Akash Dhade
Tea Break			
11:30 – 12:45PM	75 min	EU MDR 2017/745 Chapters & Annexes	Aaryak Joshi
12:45 – 01:00 PM	15 min	Q&A Session	
Lunch Break			
02.00 - 05.00 PM	180 min	Mentoring Session - Total 12 slots for 2 mentors - 30min per slot	Mentors Akash Dhade Chetna Dharmavat Dabi



About Organizers & Mentors (in alphabetical order of last names)	
	<p>Meghana Bhandari Associate- Bioincubation, Venture Center</p> <p>Meghana is responsible for planning & co-coordinating activities of BRBC. She is actively involved in curating the content for all BRBC activities. She studied M.Tech in Biomedical engineering from IIT Ropar. During her Masters she did her project work on intranasal drug delivery system for treating Alzheimer's Disease. Previously she has worked as a medical writer for a biopharma company.</p>
	<p>Chetna Dharmavat Dabi Senior Associate- Regulatory Services, Venture Center</p> <p>Chetna works for the Regulatory Information Facilitation Center (RIFC) at venture Center and assists various medical device startups in planning regulatory pathways, interpreting standards, and establishing and implementing a quality management system for medical devices. She is a certified lead auditor for ISO 9001 and ISO 13485 QMS by BSI Academy.</p>
	<p>Akash Dhade Associate Manager- Regulatory Services, Venture Center</p> <p>Akash works for 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 QMS by BSI Academy.</p>
	<p>Aaryak Joshi Principal Regulatory Affair Specialist, Medtronic</p> <p>Aaryak has 16+ years of overall work experience of which 14+ years' experience is within the Medical Device regulatory space. He has been helping start-ups, mid to large MedTech companies with Regulatory Road mapping, product development evidence strategy including clinical research planning and market entry.</p> <p>He has gained exposure and experience to a wide range of products and technologies, ranging from simple mechanical to advanced equipment, implantable, diagnostics, biologics, biomaterial, combination products, Software only and general understanding on the Pharmaceutical as well as their regulations and pathways across many major and emerging markets.</p> <p>Aaryak holds a bachelor's degree in Biotechnology and with his interest in engineering and technology, is passionate to provide a holistic perspective by connecting 3 worlds of Clinical (Biology) – Regulatory Compliance – and Technology, while developing Regulatory & Evidence strategies.</p> <p>He worked for an international Regulatory & Clinical Consulting Firm – MakroCare, where he was managing the Global Medical Device Practice for about 7.5 years and is currently working as Principal Regulatory specialist at the Medtronic R&D center in India.</p>



	<p>Smita Kale Manager –Bioincubation, Venture Center</p>
<p>Smita as part of incubation team, facilitates incubator operations by interacting with incubatees, infrastructure and facilities creation and development of the ecosystem. She is leading Bio-incubation activities, Center for Biopharma Analysis (CBA) and BIRAC’s Regional BioinnovationCenter (BRBC) projects at Venture Center. She is actively involved in mentoring startups at Venture Center. She is Ph. D in Pharmaceutical Chemistry from Institute of Chemical Technology, Mumbai and prior to joining Venture Center has had academic experience of 12 years which includes research experience of 3.6 years.</p>	

About the Organizers	
	<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>For more information, visit: http://rifc.venturecenter.co.in/</p>
	<p>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</p> <p>More on: http://www.brbc.venturecenter.co.in/</p>
Supported by	
	<p>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.</p> <p>For more information about BIRAC: www.birac.nic.in</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 & Technology’s National Science & Technology Entrepreneurship Development Board (DST-NSTEDB) and BIRAC.</p> <p>For more information, visit www.venturecenter.co.in</p>