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VENTURE CENTER	Social Innovations at Venture Center; RIFC; BRBC A BIRAC - Venture Center Initiative	thsti Translational Health Science and Technology Institute

Mini Workshop Series:

Planning the Regulatory Pathway for Medical Devices and Diagnostics

- Hosted by Social Innovations & RIFC-BRBC @ Venture Center -

Gains	• Understanding of USFDA and Indian Regulations 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 • Understanding of the clinical investigation and clinical performance requirements for medical devices
Course Coordinator	• Chetna Dharmavat- Dabi and Akash Dhade
Organized and Hosted by	• Venture Center • Regulatory Information Facilitation Center (RIFC), BIRAC Regional Bioinnovation Center, Venture Center • Social Innovations @ Venture Center
Supported by	• Department of Biotechnology • Translational Health Science and Technology Institute (THSTI), Faridabad
For whom	• Early stage inventive enterprises and science-based startups, medical device manufacturers/ suppliers, bioentrepreneurs/ventures related to scientific products seeking regulatory information & assistance • Budding/ aspiring entrepreneurs (Researchers, students, engineers, clinicians etc)
When	***Wednesday | 11 Dec 2024 |Time: 0930 – 1300***
Where	• Workshop will be held in **hybrid mode** • Online via ZOOM platform • Venue @ Venture Center: Lecture Theatre, 900, NCL Innovation Park
Contact	**Technical:** Niruta Killedar |niruta.killedar@venturecenter.co.in | +91-8956226080 **Registration & Payment:** Vineet Joshi| Vineet.joshi@venturecenter.co.in |+91- 9156465141
Cost and Registration	**Registration Fees Rs 500/-** (Registration fees will be waived off for Biodesign fellows from THSTI) Registration Process: • Step 1: Interested participants need to fill in registration form at the following link. • **Register online at: https://tinyurl.com/SLAP2024** • Step 2: Payment details will be shared with candidates who successfully complete the verification process. Attendance only on confirmation of payment of registration fees **NOTE:** • More details at: https://www.venturecenter.co.in/socialinnovations/events/ • **REGISTRATIONS AND FINAL PAYMENT DEADLINE Registration closes once 10 seats are full or 4 days prior to the workshop (whichever comes sooner)** • ***Fees paid is not refundable and non-transferable under any circumstances*** • The organizers reserve the right to accept or refuse or delay registrations so as to optimize the composition of the group and hence maximize learning for all participants

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Introduction

Workshop is focused on helping participants to plan the regulatory pathway for their medical devices and diagnostic products. It will provide the participants an understanding of EU MDR 2017/745 and Indian MDR 2017 along with the regulatory requirements, give knowledge about the regulatory pathway to get CE marking and CDSCO approvals which is a mandate for manufacturers looking to commercialize their devices in the European and Indian market respectively. Workshop will also help understand the challenges involved in obtaining CE mark/Approvals and ways to navigate these challenges based on different scenarios and understand the ISO 13485 (Quality Management System standard) compliance requirements.

Terms and Conditions for Participants

- Participants shall arrange their own devices (preferably Laptop/ Tablet) to work on the workshop assignments.
- Attendance is mandatory for all sessions once registration is confirmed.
- No sessions will be repeated if a participant is unable to attend due to any reasons

Program Includes

- Free membership in mailing list to follow-up on program and intimation of relevant events/ funding opportunities from Venture Center
- **E-Certificates will be given to only those candidates who have 100% attendance for all the sessions in the workshop**.

Program Schedule

Time	Session	Faculty
0915 – 0930	Registration, Welcome and Introduction to the workshop	Mugdha Lele
0930 – 1100	Overview of the USFDA regulations and roadmap, documentation and compliance requirements, Overview of the India MDR 2017, Roadmap for Licence Approval and Documentation requirements. Clinical investigation and clinical performance evaluation	Chetna Dharmavat-Dabi Akash Dhade
1100 – 1130	Networking Tea/Coffee @ Foyer Area, 900, NIP	
1130 – 1300	Introduction to ISO 13485 – Why is it necessary? Introductory clauses - Clause 1, 2, 3 and 4 requirements Clause 5, 6, 7, 8 requirements, MDSAP Introduction and benefits	Chetna Dharmavat-Dabi Akash Dhade
1300 – 1400	Lunch Break: Innovation Cafe	

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Speakers (in alphabetical order of last names)	
	**Akash Dhade** **Associate Manager- Regulatory Services, Venture Center** 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 and ISO 9001 QMS by BSI Academy.
	**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 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.

Organizing team (in alphabetical order of last names)	
	**Niruta Killedar** Niruta is Senior Associate for Social Innovations at Venture Center. She assists in driving the Social Innovations portfolio at Venture Center and coordinates events and related mentoring activities. She is a Microbiologist by training and has more than 7 years of experience in interdisciplinary areas of science. She has been passionately working in border areas for the last 15 years as a volunteer through the NGO Aseem Foundation, which adds value to the Social Innovations portfolio at Venture Center.
	**Mugdha Lele** Mugdha is Head – Social Innovations at Venture Center. She is a Ph.D from School of Health Sciences, University of Pune and has teaching and research experience in a State Government medical university. At Venture Center, she is responsible for driving the Social Innovations and related activities and is responsible for providing technical mentoring for incubatees at Venture Center. Mugdha has been a Fellow of the Chevening Rolls Royce Science, Innovation, Policy and Leadership Programme (CRISP) at the Said Business School, University of Oxford, UK in 2016. In 2018 she has also been part of the Aritra Accelerator Program for Leadership in the Social Sector at IIM Bangalore with Phicus Solutions and Dr. Reddy's Foundation.
	**Aishwarya Varpe** Aishwarya works as Associate for the Regulatory Information Facilitation Center (RIFC) at Venture Center. Aishwarya is responsible for providing support for regulatory advisory services for MedTech Startups. She is also involved in assisting and supporting operations for the ISO 13485 certified MedTech Cleanroom Facility at venture center. She is responsible for assisting in conducting workshops, training and events for startups to understand regulatory affairs. She has completed her Master of Technology in Biomedical Engineering from

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	Ajeenkya DY Patil University, Pune. She holds a Bachelor of Technology in Bioengineering from MIT School of Bioengineering Science and Research, Pune.

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VENTURE CENTER	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: http://www.venturecenter.co.in/
Social Innovations at Venture Center	Venture Center is committed to Social innovation and entrepreneurship. We actively nucleate and nurture enterprises that focus on solving socially important problems and build sustainable entities (for profit or not-for-profit) to deliver the solutions to society. Focus areas at Venture Center include affordable health and nutrition, empowering farmers, clean energy, sustainable resource utilization, environment and circular economy, water, sanitation, hygiene and any other social sectors that can leverage Venture Center's innovation ecosystem. For more information:http://www.venturecenter.co.in/socialinnovations
RIFC	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. For more information, visit: http://rifc.venturecenter.co.in/
BRBC 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/

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Funded by सत्यमेव जयते Department of Biotechnology	The Department of Biotechnology (DBT), Government of India is completely devoted wholly to achieve excellence in the promotion of biotechnology in the country. DBT provides services in the areas of research, infrastructure, generation of human resource, popularization of biotechnology, promotion of industries, creation of centers of excellence, implementation of biosafety guidelines for genetically modified organisms and recombinant DNA products and biotechnology-based programs for societal benefits. Bioinformatics is a major mission to establish an information network for the scientific community, nationally and internationally. DBT's mission include realising full potential of biotechnology, undertake significant investment for generation of products, processes and technologies, enhance efficiency and productivity and cost-effectiveness of agriculture, nutritional security, molecular medicine, environmentally sustainable technologies,

	scientific and technological empowerment of human resource, a strong infrastructure for research and commercialization, enhance the knowledge base, nurture leads of potential utility, bring bioproducts to the market place, socio-economic development and promote biotech industry. For more information: https://dbtindia.gov.in
thsti Translational Health Science and Technology Institute	As a networked organization linking many centers of excellence, THSTI is envisioned as a collective of scientists, engineers and physicians that will effectively enhance the quality of human life through integrating a culture of shared excellence in research, education and translational knowledge with the entrepreneurial spirit to take technologies into the public sphere. In fulfilment of its vision, the THSTI will work with other constituents of the technology cluster at Faridabad such as the Regional Centre for Biotechnology Training, Education and Research (RCB) through long term partnerships. By integrating the fields of medicine, science engineering and technology into translational knowledge and making the resulting biomedical innovations accessible to public health, to improve the health of the most disadvantaged people in India and throughout the world. For more information: https://www.thsti.res.in

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