Report | Mentor mixer on EU MDR 2017/745 and European regulatory approval process with Akash R. Dhade and Aaryak Joshi| Thursday | 27 April 2023

About the Event

RIFC@BRBC's mentor mixer was organized on 27th April 2023. It was organized as a RIFC's outreach program with Mr. Akash Dhade, Associate Manager, RIFC along with Mr. Aaryak Joshi, Principal Regulatory Specialist as the guest speaker talking about European Medical Device Regulation (EU MDR) 2017/745. The event was conducted in hybrid (Offline + Online) mode.

snippets from the workshop

Session Description

The session intended to provide an in-depth understanding of EU MDR 2017/745 and the regulatory requirements. The workshop also provided knowledge about the process of getting the CE marking which is a mandate for manufacturers looking to commercialize their devices in the European market.

The session began with an overview of Venture Center by Dr. Smita K, an overview of RIFC by Chetna Dharmavat Dabi and was followed by Akash's talk on the Background, details about the European regulatory market and explanation of the major elements from the EU MDR 2017/745. The session concluded with Aaryak providing detailed information about the Chapters and Annexes of regulation.

Workshop Feedback:

Criteria	Avg, (Max-Min), Count
Overall satisfaction with the Event	6.11, (7-5), 9
Satisfaction with content	6.11, (7-5), 9
Satisfaction with speakers/mentors etc	6.11, (7-5), 9
Satisfaction with the structure, design and pace of the event	6.33, (7-5), 9

Other Feedback:

- I am so glad to have participated in this EU MDR 2017/745 training workshop, It has brought me up-to-date on the new skills in my profession. - Darshan Mahale
- Thank you BRBC, A Great start to understand EU MDR! - Gayatri Gurjar
- Thank you BRBC, Very informative session it was! - Ameya Bendre
- It was very nice session that really helpful to me
- Please arrange for talks/sessions in "Offline mode" for better understanding & ease of group. Feels more connected that way
- More such sessions should be organized

The workshop was organized with Mr Akash Dhade and conducted at Venture Center. It presented an opportunity for understanding the EU MDR 2017/745 and a one-on-one discussion between selective entrepreneurs and the mentor.

Meetings schedule

Sr. No.	Date	Time	Name of the participant	Name of the Company	Designation
1	27 April 2023	2.00 - 2.30 PM	Chirag Shah	Rymo Technologies Private Limited	CEO and Co-Founder
2	27 April 2023	2.30 - 3.00 PM	Gayatri Gurjar and Darshan Digambar Mahale	Serigen Mediproducts Pvt Ltd	Manager-Regulatory
3	27 April 2023	3.00-3.30 PM	Pranjali Sahasrabuddhey	Intignus Biotech Pvt Ltd	Operations Manager
4	27 April 2023	3.30-4.00 PM	Adeenay Devarajan	Instavet Biopharm Pvt. Ltd.	NA

Themes discussed:

Timeline and cost involved in getting the European approval, Clinical equivalence and parameters establishing the clinical equivalence, Applicable testing standards for the products, and comparative discussion for EU and US medical device markets.

Overall Feedback: 6.17/7