Report

RIFC BRBC
A BIRAC - Venture Center Initiative

VENTURE CENTER

birac
Ignite Innovate Incubate

Monday

19 September 2022

Venture Center,
100 NCL Innovation Park
Dr Homi Bhabha Road,
Pashan, Pune- 8

VENTURE BASE CAMP

On

Requirements of the Medical Device Regulation (MDR) for CE marking Certified Training Course–

Contents

Acknowledgment

BIRAC Regional Bioinnovation Center (BRBC) is stepping forward to filling up key innovation ecosystem gaps for Biotech/Biomed startups across the country and the Venture Base Camp on **Requirements of the Medical Device Regulation (MDR) for CE marking Certified Training Course** held on 19 September 2022 was a pleasing demonstration.

BRBC is thankful to the base camp logistics organizers, speakers, and participants

Financial Support

BIRAC Regional Bioinnovation Center (BRBC) at Venture Center, Pune

Venture Center, Pune

Organizer

Regulatory Information and Facilitation Center (RIFC) at Venture Center, Pune

Introduction

The course conveys key concepts of the European Medical Device Regulation. All medical devices will need to undergo a Conformity Assessment Procedure based on the MDR requirements to be placed on the European Union market. You will gain an understanding of the requirements stipulated within MDR.

This VBC was useful for innovators and startups in the medical device categories like Surgical tools and aids | Assistive devices or disability aids or image reconstruction or artificial body parts | Topical, surface and open wound contact products or products in body orifices | Implants. CEOs/CTOs of innovative technology startups and Individual Inventors or in the position of top management, or a manager or project member in QM/QA, R&D, design, manufacturing, supply chain, customer service, and sales.

Content

Focus:

This course will help you an understanding of key requirements, which will provide:

- Essential knowledge to understand Regulatory Affairs of medical devices in the EU, e.g. in the position of top management, or a manager or project

member in QM/QA, R&D, design, manufacturing, supply chain, customer service, and sales.

- The ability to understand the demands of the subcontractor, supplier, OEM, authorized representative, importer, and distributor, allows for better relationships with them and the legal manufacturer.
- A basis to learn later about the implementation of CE marking projects.

Base Camp outline:

Session 1:

- Introduction to CE and European legislation
  - What is CE Marking?, Responsibilities of key players, MDR responsibilities
- General obligations under MDR
  - Manufacturers' responsibilities

Session 2:

- Scope of the MDR
  - Definition, Relation to other EU Directives/Regulations
- Determine risk class of device
  - Risk-based classification, Classification rules

Session 3:

- Select & describe the key steps of a conformity assessment procedure
  - Quality system assessment
- Amend and maintain QMS
  - ISO 13485, Harmonised standards, Common Specifications
- Identify applicable safety and performance requirements
  - Risk management process, Information supplied with the device

Session 4:

- Assemble Technical Documentation
  - Content of Technical Documentation under the MDR
  - Clinical evidence and clinical evaluation
- Apply conformity assessment procedure
- Assign unique identifications
  - EUDAMED, SRN, UDI Types
- Complete Declaration of Conformity (DoC) and affix CE mark
- Post-market surveillance (PMS), Transition arrangements

Attendees:

11 people from different startups participated in the base camp.

Evaluation:

During the base camp, the intentions were met; there was an exchange of information on regulatory obligations for the medical devices.

Rating Scale			
1	Bad	2	Well below average
3	Below average	4	Average
5	Good	6	Very Good
7	Excellent		

Category	Avg (Min-Max) Count
Section 1 – About the Event	
Overall Satisfaction with Event	6.4 (6,7)11
Satisfaction with Content	6.1 (6,7)11
Satisfaction with Speakers/mentors etc	6.7 (6,7)11
Satisfaction with structure, design and pace of event	6.2 (5,7)11
Satisfaction with food and beverages	5.8 (4,7)11
Did the workshop help you understand the concept(s) better?	Yes
If you have any other suggestions, comments, etc., please share them below.	
Overall it was a good event	
Excellent workshop, just in time for my work	
Very nicely organized workshop. A good first step towards understanding MDR and CE marking	
All good. Looking forward to 5 day deep dive sessions.	
Testimonial for RIFC activities	
Very nicely organized workshop. A good first step towards understanding MDR and CE marking	
How did you hear about the event?	
Email	5
LinkedIn	5
Whatsapp	1
Others	0

List of speakers & Mentors

Sr	Name	Affiliation
1	Nandinee Khot	BSI Group India Pvt Ltd, Pune

List of participants

Sr	Participant Name
1	Vaishnavi Kulkarni
2	Jyoti Kumbhar
3	Gayatri Gurjar
4	Saurabh Kumar Srivastava
5	Whaeed Rahman
6	Abde Manaf
7	Shabbir Husain Moiyed Tailor
8	Prateek Jain
9	Apoorva Bedekar
10	Jijnasa Panigrahi
11	Johnson Dominic

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