Venture Base Camp on

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

- Organized by BRBC at Venture Center -

Potential gains	This event is a Venture Base Camp (VBC) that ***aims to understand the regulatory affairs of medical devices in the EU. e,g, Top management, design, manufacturing, supply, chain, customer service, and sales.*** • 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. • **Camp will be conducted by a senior auditor from BSI Training Academy, India**.
Organized by	• BIRAC Regional BioInnovation Center @ Venture Center. • Regulatory Information and Facilitation Center (RIFC) @ Venture Center.
Supported by	• BIRAC • Venture Center
For whom	• CEOs/CTOs of innovative technology startups. • 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.
When	**(Mon) 19 SEP 2022| Time: 9 am – 6 pm**
Where	Lecture Theatre, 900 NIP, Venture Center, 100 NCL Innovation Park, Dr. Homi Bhabha Road, Pashan, Pune – 411008.
Contact	***Technical queries***: Chetna Dharmavat | 9156465147| chetna@web.venturecenter.co.in ***Registration related***: Meghana B | 956677543|meghana.bhandari@venturecenter.co.in And Lipika Biswas| 9156465137| eventsdesk@venturecenter.co.in
Registration Details	**Limited seats!! Total number of seats: 10** Registration Process: • Step 1: Interested participants need to fill in the registration form at the following link. **Register online at:** https://lnkd.in/drMaTxxK • Step 2: Email invites will be sent post-screening of registration details. • Step 3: Attendance only on confirmation of payment of registration fee*.

Category	Fees (Rs)
A) VC Incubatees, BIRAC Grantees who are small entities *** For one person: For the second person from the same company:	 8000/- 10000/-
B) Micro/small enterprises, startups; Non-profit/R&D/academic orgs; individuals	12000/-
C) Others including medium/ large enterprises	12000/-

NOTE: Registration closes once 10 seats are full or on SEP 16, 2022 (whichever comes sooner).

Preference: Startup companies (LLC/PLC) vs. individuals if we receive more than 10 applications |Organizers reserve the right to select participants so as to optimize the group for better interaction and ensure benefit to as many startups as possible. ***Fee paid is not refundable and non transferable under any circumstances. Maximum of two participants from one company will be allowed to attend.***

Introduction

BIRAC Regional BioInnovation Centre (BRBC) is a joint initiative of BIRAC and Venture Center. It focuses on filling up a few key innovations ecosystem gaps in India for biotech/biomed startups specifically relating to mentoring, regulations, fund raising and BioIncubation practice.

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.

VENTURE BASE CAMP

This VBC will be useful for innovators and startups in the following medical device categories:
Clinical grade screening, diagnostic and recording instruments | Medical devices for clinical intervention or treatment |Surgical tools and aids | Assistive devices or disability aids or image reconstruction or artificial body parts | Molecular in vitro diagnostics | Topical, surface and open wound contact products or products in body orifices | Implants made from polymers, body tissues, metal, plastic, ceramicetc| Sensors, IOT, Big Data, Mobile, Cloud, AI/ML, Analytics, decision support, software etc used for making medical decisions | Supplies&consumables used in diagnostics, preservation, hospital equipment | Recreational and popular diagnostics, wearable.

Course Description
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.

How will you benefit?

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.

Prerequisites
There are no formal prerequisites for this course, but participants will benefit from a basic knowledge of medical device use, design, or manufacture and/or general understanding of quality management.

Workshop includes

- Workshop includes tea, snacks and lunch at the Innovation Café.
- Free membership in mailing list to follow-up on workshop and intimation of relevant events/ funding/ opportunities from Venture Center.
- Case Studies.
- One-year free reference membership to Venture Center Library (http://www.vcenterlibrary.org/)
- **On completion, you'll be awarded an internationally recognized BSI Training Academy certificate**.

Terms and Conditions for Participants

- Participants shall arrange their own devices (preferably Laptop/ Tablet) and ensure the good internet connectivity during the online course.
- Attendance is mandatory for all sessions to take part in the exam. Certificate will only be issued once the course has been successfully completed and the criteria for passing the exam have been met.
- No sessions will be repeated if a participant is unable to join during the course due to poor internet connectivity or any other reasons.

Workshop Schedule

DAY 1: Monday, 19 Sep 2022			
Time	**Duration**	**Session title**	**Lead**
0900-0930	30 min	Registration & Introduction	**VC Team**
0930-1100	90 min	**Session 1:** • Introduction to CE and European legislation o What is CE Marking?, Responsibilities of key players, MDR responsibilities • General obligations under MDR o Manufacturers' responsibilities	**Nandinee Khot**
1100-1115	15 min	Tea Break	
1115-1300	75 min	**Session 2:** • Scope of the MDR o Definition, Relation to other EU Directives/Regulations • Determine risk class of device o Risk-based classification, Classification rules	**Nandinee Khot**
1300-1400	60 min	Lunch Break	
1400-1530	75 min	**Session 3:** • Select & describe the key steps of a conformity assessment procedure o Quality system assessment • Amend and maintain QMS o ISO 13485, Harmonised standards, Common Specifications • Identify applicable safety and performance requirements o Risk management process o Information supplied with the device	**Nandinee Khot**
1530-1545	15 min	Tea Break	
1545-1730	90 min	**Session 4:** • Assemble Technical Documentation o Content of Technical Documentation under the MDR o Clinical evidence and clinical evaluation • Apply conformity assessment procedure • Assign unique identifications o EUDAMED, SRN, UDI Types • Complete Declaration of Conformity (DoC) and affix CE mark • Post-market surveillance (PMS) • Transition arrangements	**Nandinee Khot**

Faculty/ Mentors (in order of last names; alphabetical order)

Nandinee Khot
Lead Tutor & Assessor, BSI Group India.

Nandinee Khot has completed MSc in Microbiology from Pune University. Technically accomplished with rich and wide, cross functional Industrial experience of 30 years inHealthcare from Table to bedside (Quality Assurance, Quality Control, Regulatory, Productionand supportive functions) in Varied Sectors which includes Biopharmaceuticals(rDNA),Vaccines-human and Animal, Injectables, Medical Devices, liquid Orals, tablets, capsules and powders andanimal feeds

- Auditor and Trainer with BSI for last 15 years for various QMS Standards and for audits ofMicrobiology for CE for standards of sterilization- Good knowledge of Sterilization by Heat,Steam, radiation and ETO, clean rooms and environment control.
- Faced Audits from MHRA, WHO, FDA, ISO and International customers like- Vetter – Germany,Croma-USA, Pfizer, Novartis, etc.
- Biological, immunological, Physical & Chemical, microbiology, in vitro and in vivo (preclinical)and Clinical studies

Work Experience Highlights

1. June 2010 – today -- VanirBio Pte Ltd
2. September 2005 - May 2010 -- SciGen India Ltd.
3. December 1995 - June 1998; August 2000-2005 -- Sewa Medicals Ltd
4. Litaka Pharma, Pune
5. SPB Pharma Pvt Ltd, Pune
6. July1992- November 1994 -- Famy Care Pvt Ltd (Pregna Pvt Ltd), Pune
7. Serum Institute of India, Pune
8. 1984-1986 -- BAIF-(now Intervet-Azko Nobel group), Pune

Strengths:

- IRCA Certified Lead Auditor for ISO 13485-2016 for Quality Management Systems (byBritish Standard Institute.)
- IRCA Certified Lead Auditor for ISO 9001-2008 for Quality Management Systems (byBritish Standard Institute.)
- MR of the organization for ISO -9001-2008
- Task force member for implementation of ISO Standards

RIFC	BRBC A BIRAC - Venture Center Initiative	VENTURE CENTER 15 years of service to the Nation	birac Ignite Innovate Incubate	Bio-NEST

About the Organizers	
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/
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. More on: http://rifc.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 15 years of service to the Nation	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.For more information, visit www.venturecenter.co.in