Hands-on Mini-Workshop Series on

Regulatory Requirements for Medical Devices

How to write a Quality Manual?

Good Documentation Practice, SOPs and Quality Manual

- Organized by RIFC at Venture Center -

Potential gains	• Good Documentation Practice (GDP) that is necessary for regulations • Writing Standard Operating Procedure (SOP) to meet regulatory requirements • Quality Manual – learn from examples; Use our templates to get started • Know your device specific procedures, forms, work instructions • Includes feedback and comments from RIFC on your own manual *****
Organized by	• Regulatory Information & Facilitation Center (RIFC), Venture Center
Supported by	• BIRAC Regional Bio-Innovation Center (BRBC) • Venture Center
For whom	• Individuals, startups small industries with ready POC or post POC stage, Quality and regulatory personnel responsible for documentation.
When	**Saturday | 08 Dec 2018 | Time 1345-1830 Hrs**
Where	Training room, Venture Center, 100 NCL Innovation Park, Dr. Homi Bhabha Road, Pashan, Pune, Maharashtra, 411008
Contact	***Technical queries***: Navnath Kadam| 020-25865877/75/76|navnath@venturecenter.co.in ***Registration related queries:*** Lipika Biswas |020-25865875/76/77|eventsdesk@venturecenter.co.in
Terms	Registration required. Maximum 15 seats! Attendance only after confirmation by organizers. **Fees:** • For BIRAC supported startups and VC Incubatees: ₹ 5,000/- per participant! 50% discount for second participant from same firm. • For others: ₹ 10,000/- per participant! 50% discount for second participant from same firm. **Registration Process:** • Step 1: Register online at: https://tinyurl.com/RIFC-workshop02 • Step 2: Organizers will screen applications for suitability for the program based on information provided. Preference will be given to startups and micro/small enterprises. • Step 3: Selected participants will be sent email invitations. Participants will need to make a payment of registration fee (online or in person) to book/confirm their seats.

Introduction

Most medical devices and diagnostics companies have to seek regulatory approvals and secure necessary certifications. One of the most important documents companies will need to develop their Quality Manual before they approach the government agencies for regulatory approvals. This mini-workshop focuses on how to write a quality manual and related procedures.

Quality Manual is a document specifying the quality management system of an organization. Quality manual contains information and its supporting medium, a detailed way to carry out an activity or a process. The quality manual requires documentation of the organization's quality policy, quality objective, and documented procedures.

You will benefit from this workshop if you are developing any Medical Devices and/or In Vitro Diagnostic Devices. (30+ device categories and 600+ notified devices)

This Mini-Workshop 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, ceramic etc| 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.

Workshop Outline

This ***mini-workshop*** will focus on the writing a documents aligned with the regulatory requirements,

- Structure of a Standard Operating Procedure (SOP)
- Overview of Good Documentation Practice (GDP)
- Structure of a Quality Manual –examples and templates
- Device specific procedure and applicable standards references
- **(SPECIAL!)** You will be able to start writing your manual in the workshop and get more detailed inputs from RIFC team over the next 8 days (one 1-to-1 meeting of 90 minutes) ******

Workshop includes

- Workshop will include tea and snacks.
- Certificate of Participation

Workshop Schedule

Time	Duration	Session title	Speakers	Venue
1345 – 1400	15 min	Registration		TR, 100 NIP
1400 – 1410	10 min	Introductions. Workshop plan.	Priya Nagaraj	TR, 100 NIP
1410– 1510	60 min	Good Documentation Practices and SOP: Principles, guidelines and examples.	Navnath Kadam	TR, 100 NIP
1510 – 1530	30 min	Tea and Networking Break		First floor foyer
1530 – 1700	90 min	Quality Manual: Structure, terminology, templates, examples.	Navnath Kadam	EC, 100 NIP
1700 – 1800	60 min	Writing exercise: Write SOPs using our templates for-- • Documentation control • Procedure for document control 4.2.4 • Procedure for record control 4.2.5 • Procedure for management review 5.6.1 • Requirements for the maintenance activities 6.3 • Procedure for Classification of Medical Device 7.1 • Procedure for Product Recall 7.1 • Procedure for design and development 7.3.1 • Procedure and methods for the control of production 7.5 • Procedure for analysis of data 8	Navnath Kadam	EC, 100 NIP
1800--1830	30 min	Sign up for 1-to-1 meeting (for meetings in next 8 days)	Navnath Kadam	EC, 100 NIP

Speakers

Navnath Kadam

Navnath Kadam
Asst. Manager at RIFC, Venture Center.

Navnath Kadam provides leadership to the RIFC at Venture Center, Pune. He regularly advises startups on planning their regulatory roadmap and facility planning. He is developing a suite of services and resources of use to startups. He has multifaceted working experience in managing Quality and Regulatory operations at Medical Device startup Axio Biosolutions Pvt Ltd. He has completed PG Diploma in Entrepreneurship and Business Management from EDI, Ahmedabad and Master of Pharmacy with specialization in Quality Assurance Techniques from Poona College of Pharmacy, Pune.

Priya Nagaraj

Priya Nagaraj
Bioincubation Manager, Venture Center.

Priya holds a Ph.D. in Cell Biology from University of Virginia, USA. She worked with Advinus Therapeutics Ltd, a pharmaceutical drug discovery company for over 5 years. She has research experience in biochemistry, cell biology, developmental biology, molecular biology and drug discovery.

About the Organizers

BRBC is a resource intensive center set up by BIRAC at Venture Center. Through its diverse initiatives, BRBC aims to significantly impact the translation of high quality innovative ideas across diverse ecosystems into viable and sustainable business enterprises. BRBC Initiatives: Venture Mentoring Service; Venture Base Camps; Regulatory Information and Facilitation Centre; Bio Incubation Practice School
More on: http://www.brbc.venturecenter.co.in/

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 about RIFC: www.rifc.venturecenter.co.in

Supported by

Biotechnology Industry Research & Assistance Council is a new industry-academia interface and implements its mandate through a wide range of **impact initiatives,** be it providing access to risk capital through targeted funding, technology transfer, IP management and handholding schemes that help bring **innovation excellence** to the biotech firms and make them globally competitive.
For more information about BIRAC: www.birac.nic.in

RIFC	BRBC A BIRAC - Venture Center Initiative	VENTURE CENTER	birac Ignite Innovate Incubate

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 www.venturecenter.co.in