Workshop on (Venture Base Camp) on

ISO 13485:2016 Medical Devices Quality Management –Introduction & Internal Auditors Training Course–

- Organized by: RIFC, Social Innovations and BFI-BIOME Networks -

- Supported by: Venture Center, Pune and Blockchain for Impact -

Potential gains	This Venture Base Camp (VBC) *aims to de-mystify QMS audit requirements and help startups chart out an Internal Audit Plan for their company in 3 days.* ● Learn how to audit the processes of an ISO 13485:2016 Quality Management System (QMS). ● Provides guidance and practical experience in planning, executing, reporting and audit follow-up of an internal audit when monitoring the effectiveness and conformity of an ISO 13485:2016 compliant QMS. ● **Camp will be conducted by a senior auditor from BSI Training Academy, India**.
Organized by	● **Regulatory Information and Facilitation Center (RIFC) @ Venture Center.** ● **Social Innovations@ Venture Center** ● **BFI-BIOME Networks**
Supported by	● **Venture Center, Pune** ● **Blockchain for Impact**
For whom	● CEOs/CTOs of innovative technology startups. ● Individual Inventors. ● Inventors from R&D institutes, medium/ large enterprises.
When	**(Mon-Wed) 25-26-27 NOV 2024 | 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***: Aishwarya Varpe | 9156465137 | aishwarya.varpe@venturecenter.co.in
Registration Details	**Limited seats!! Total number of seats: 15** **Category** — **Fees (₹)** A. Companies who have availed RIFC Services** For one person — 35,000/- For the second person of the same company — 40,000/- B. Micro/Small enterprises, startups:Non-profit/R&D/academic orgs;Individuals — 40,000/- C. Others including medium/ large enterprises — 45,000/- D. Venture Center's BFI-BIOME Fellows and Kickstarters — 100% waiver Registration Process: ● Step 1: Interested participants need to fill in the registration form at the following link. **Register online at: https://tinyurl.com/VBC-3days** ● Step 2: Email invites will be sent post screening of registration details. ● Step 3: Attendance only on confirmation of payment of registration fee*. **NOTE: Registration closes once 15 seats are full or on NOV 16, 2024 (whichever comes sooner).** **Preference:** Startup companies (LLC/PLC) vs. individuals if we receive more than 15 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

The focus of this Workshop (Venture Base Camp):

- Only Medical Devices (including diagnostic products)
- Learning how to audit the processes of an ISO 13485:2016 Quality Management System (QMS)

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

An ineffective audit can mean severe consequences; resulting in process failure, patient dissatisfaction and regulatory noncompliance. Optimize your auditing skills with the internationally recognized ISO I3485:2016 and boost your internal audit capabilities. Gain confidence in planning and performing an effective audit, as well as reporting and taking corrective action where necessary.

This course is intended for medical device quality professionals wishing to build on their current knowledge of ISO 13485:2016 and evaluate the effectiveness of their QMS. It teaches the principles and practices of effective audits in accordance with ISO 13485:2016 and ISO 19011:2011.

How will you benefit?
This course will help you:

- Maintain compliance with ISO 13485:2016
- Improve a global benchmark in quality standards
- Be confident that your organization can rely on competent auditors
- Motivate colleagues through CPD and ensure rigorous regulatory internal processes
- Write factual audit reports and suggest corrective actions

Prerequisites

There are no formal prerequisites, however it will be useful for delegates to read the standard before attending the course.

Workshop excludes

***Please note, the participants will have to arrange for their own travel, local transport and accommodation and dinners. For more information on Pune city, travel, transport and stay options, see**
http://www.venturecenter.co.in/puneguide/

Workshop includes

- Workshop includes tea, 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.
- Hands-on case studies
- **On completion, you'll be awarded an internationally recognized BSI Training Academy certificate**.

Workshop Schedule

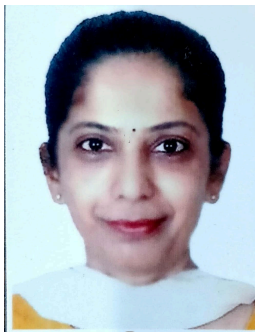
DAY 1: Monday, 25 Nov 2024			
CLASSROOM TUTORING – ISO 13485 Introduction Training Course			
Time	**Duration**	**Session title**	**Lead**
0930-1100	90 min	**Session 1:** ● Welcome and Introductions ● Course aims, objectives and structure ● Quality definitions and the process approach ● Definition of a medical device within the industry ● Introduction to ISO 13485	**Nandinee Khot**
1100-1130	30 min	Tea Break	
1130-1300	90 min	**Session 2:** ● Clause 0 – Scope ● Clause 1 – Normative references ● Clause 3 – Terms and definitions ● Clause 4 – Quality management system	**Nandinee Khot**
1300-1400	60 min	Lunch Break	
1400-1530	90 min	**Session 3:** ● Clause 5 – Management Responsibility ● Clause 6 – Resource management	**Nandinee Khot**
1530-1600	30 min	Tea Break	
1600-1730	90 min	**Session 4:** ● Clause 7 – Product realization …including risk management ● Clause 8 –Monitoring and measurement ● Reflection and Feedback	**Nandinee Khot**

DAY 2: Tuesday, 26 Nov 2024			
CLASSROOM TUTORING – Internal Auditor Training Course			
Time	**Duration**	**Session title**	**Lead**
0900-1100	120 min	**Session 1:** ● Welcome, benefits, delegate introductions and course aim ● Boundaries: Conflict of interest and expertise ● Learning objectives and course structure ● Fundamentals of quality management: ISO 13485 and the relationship to ISO 9000 series of standards and ISO 14971 (risk management) ● Use of ISO 13485 in relation to compliance with worldwide regulatory requirements	**Nandinee Khot**
1100-1130	30 min	Tea Break	
1130-1300	90 min	**Session 2:** ● Introduction to auditing: What is an audit? ● The process approach and process auditing ● Managing an audit programme ● Audit activities	**Nandinee Khot**
1300-1400	60 min	Lunch break	
1400-1530	90 min	**Session 3:** ● Auditor competence and responsibilities ● Plan an internal audit ● Create work documents	**Nandinee Khot**

		• Conducting an (informal) opening meeting • Collecting and verifying audit information	
1530-1600	30 min	Tea Break	
1600-1700	60 min	**Session 4:** • Audit techniques Gathering and verifying information • Introduction of audit findings and nonconformities • Conducting an audit(Part 1)	**Nandinee Khot**

DAY 3: Wednesday, 27 Nov 2024			
CLASSROOM TUTORING & EXAM – Internal Auditor Training Course			
Time	**Duration**	**Session title**	**Lead**
0900-1100	120 min	**Session 5:** • Review of day 1 • Conducting the audit (Part 2) • Generate audit findings	**Nandinee Khot**
1100-1130	30 min	Tea break	
1130-1300	90 min	**Session 6:** • Identify and define nonconformities • Prepare audit conclusions • Write an audit report	**Nandinee Khot**
1300-1400	60 min	Lunch break	
1400-1530	90 min	**Session 7:** • Closing meeting • Conduct audit follow-up • Course summary	**Nandinee Khot**
1530-1600	30 min	Tea break	
1600-1730	90 min	**Session 8:** • Exam and closure	**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 in Healthcare from Table to bedside (Quality Assurance, Quality Control, Regulatory, Production and supportive functions) in Varied Sectors which includes Biopharmaceuticals(rDNA),Vaccines-human and Animal, Injectables, Medical Devices, liquid Orals, tablets, capsules and powders and animal feeds

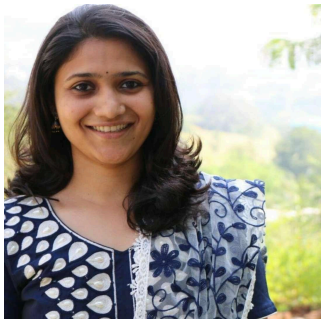
- Auditor and Trainer with BSI for the last 15 years for various QMS Standards and for audits of Microbiology for CE for standards of sterilization- Good knowledge of Sterilization by Heat, Steam, radiation and ETO, clean rooms and environment control.
- Faced Audits from MHRA, WHO, FDA, ISO and International 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 (by British Standard Institute.)
- IRCA Certified Lead Auditor for ISO 9001-2008 for Quality Management Systems (by British Standard Institute.)
- MR of the organization for ISO -9001-2008
- Task force member for implementation of ISO Standards

Organizing Team (in alphabetical order of last names)	
	**Chetna Dharmavat** Associate Manager – Regulatory Services Chetna 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 Indian market. She has experience drafting over 20+ technical documentation for different types of medical devices and also has the lead auditor certification for ISO 13485 QMS by BSI Academy.
	**Niruta Killedar** Senior Associate - Social Innovations Niruta is primarily responsible for assisting in the implementation of the Social Innovation Immersion Program at Venture Center. Overall 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** Head - Social Innovations Mugdha is responsible for driving the Social Innovations activities and providing technical mentoring for startups at Venture Center. She has done Ph.D from School of Health Sciences, University of Pune and has teaching and has research experience in a State Government medical university. She 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 was also part of the Aritra Accelerator Program for Leadership in the Social Sector at IIM Bangalore. She serves as the nominee director on the boards of Synthera Biomedical Pvt Ltd (a dental biomaterials startup), Pragmatech Healthcare Solutions Pvt Ltd (a medical diagnostics startup) and Spot Healthcare Solutions Pvt Ltd (a medtech startup).
	**Aishwarya Varpe** Associate – Regulatory Services Aishwarya works 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 Ajeenkya DY Patil University, Pune. She holds a Bachelor of Technology in Bioengineering from MIT School of Bioengineering Science and Research, Pune.

Organized by	
	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/
	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. More:http://www.venturecenter.co.in/socialinnovations
	BFI-BIOME's mission cuts across traditional boundaries by encompassing both upstream and deep science, driving innovation that leads to transformative health solutions. BFI-BIOME aims to bring leading researchers, technologists, and innovators together in the form of a network to discuss, identify, collaborate and innovate in the biomedical sector to solve pressing health challenges. More: https://www.venturecenter.co.in/bfi-biome/

Supported by	
	‘Blockchain for Impact’ carries forward the baton of the Crypto Relief Fund, a phenomenon that came to the fore at the peak of the second COVID wave in 2021. The relief fund mobilized resources from the global blockchain community and managed to make a positive dent in the healthcare system of India. More: https://www.blockchainforimpact.in/
	Venture Center is a national award winning deep tech and science-based business incubator approved by the Ministry of Science and Technology, Govt of India. It aims to nucleate and nurture knowledge based enterprises. It does this by creating and maintaining a rich and supportive ecosystem for inventive enterprises that includes a large mentor network, funding options including 4 seed funds, scientific/ analytical/ prototyping facilities, specialized advisory capabilities, numerous events etc. It empowers scientists, engineers, clinicians and other knowledge workers to take their ideas from lab to market. It is structured as an independent, non-profit company and charitable organization that is hosted by CSIR-National Chemical Laboratory, Pune. The Venture Center was founded in 2007. Venture Center has been recognized with the National Award for Technology Business Incubators (2015), AABI (Asian) Incubator of the Year Award (2018), National Entrepreneurship Award under Ecosystem Builder Category (2019), Biospectrum No 1 Bioincubator of India (2022) and National Award for Incubators for Nurturing IP (2021 & 2022). More: http://www.venturecenter.co.in/