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

Venture Base Camp on

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

- Organized by BRBC at Venture Center -

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	• 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. • Inventors from R&D institutes, medium/ large enterprises.
When	**(Wed-Fri) 30 NOV, 1 & 2 DEC 2022 | Time: 9 am – 5.30 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: 12** **Registration fees – INR 20,000 /- per person** Registration Process: • Step 1: Interested participants need to fill in registration form at the following link. **Register online at:** https://tinyurl.com/VBC-3day • 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 12 seats are full or on NOV 18, 2022 (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

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

The focus of this 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
- 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**.

Workshop Schedule

DAY 1: Wednesday, 30 November 2022

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	**Anita Joshi**
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	**Anita Joshi**
1300-1400	60 min	Lunch Break	
1400-1530	90 min	**Session 3:** • Clause 5 – Management Responsibility • Clause 6 – Resource management	**Anita Joshi**
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	**Anita Joshi**

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DAY 2: Thursday, 1 December 2022			
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	**Anita Joshi**
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	**Anita Joshi**
1300-1400	60 min	Lunch break	
1400-1530	90 min	**Session 3:** • Auditor competence and responsibilities • Plan an internal audit • Create work documents • Conducting an (informal) opening meeting • Collecting and verifying audit information	**Anita Joshi**
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)	**Anita Joshi**

DAY 3: Friday, 2 December 2022			
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	**Anita Joshi**
1100-1130	30 min	Tea break	
1130-1300	90 min	**Session 6:** • Identify and define nonconformities • Prepare audit conclusions • Write an audit report	**Anita Joshi**
1300-1400	60 min	Lunch break	
1400-1530	90 min	**Session 7:** • Closing meeting • Conduct audit follow-up • Course summary	**Anita Joshi**
1530-1600	30 min	Tea break	
1600-1730	90 min	**Session 8:** • Exam and closure	**Anita Joshi**

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

Anita Joshi
Lead Tutor & Assessor, BSI Group India.

Work Experience Highlights
Founder, Dr. Anita's BioConsultancy and working as a Consultant with ZenBiomed Inc., Celegence Inc.

Offering25+ years of Cross Functional high level experience –

- 10 years Research & Academics Experience from National Institute of Virology, Pune and University of Pune (viral vaccine and diagnostics)
- 20+years,working as an Independent Biotechnology Professional (Dr.Anita's BioConsultancy) forShort term/ Long term Assignments with reputed commercial organizations on strategic projects in the Pharma-Healthcare and Life science Industry

Dr. Anita has worked with more than 85 organizations since 2001 including: Span Diagnostics Ltd., Thermo Fisher Scientific, Merck Millipore, HCL technologies, Celegence, Operon Strategist, Futuron, Iziel Healthcare in CE marking and IVDR domain. To date, Anita has 38 publications.

Strengths:

- BSI India: 290+ audits, both domestic and international organizations; including medical device industry; also a Trainer.
- She has been an auditor with BSI for ISO 13485 and regulatory audits like MDSAP, GMP etc. for the past 15 years.
- Recently she has conducted Internal audits for two of ZenBioMed's US clients- completed 4 audits

About the Organizers	
	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/
	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	
	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 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