Venture Base Camp on

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

- Organized by BRBC -

Potential gains	• This event is a Venture Base Camp (VBC) which ***aims to de-mystify QMS audit requirements and help startups chart out an Internal Audit Plan for their company in 3 days.*** • Gain better insight into the use of ISO 13485:2016 as the basis for a Quality Management System (QMS) implemented by medical device manufacturers. • Learn how to audit the processes of an ISO 13485:2016 Quality Management System (QMS). This course 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	**Tuesday, Wednesday, Thursday | 17, 18, 19 September 2019 | Time: 9 am – 6 pm**
Where	Lecture Theatre, Venture Center, 100 NCL Innovation Park, Dr. Homi Bhabha Road, Pashan, Pune – 411008.
Contact	***Technical queries***: Navnath Kadam| 020-25865877/76 navnath@venturecenter.co.in ***Logistical queries***: Lipika Biswas| 020-25865877/76 eventsdesk@venturecenter.co.in
Registration Details	**Limited seats!! Total number of seats: 20** Registration Process: • Step 1: Interested participants need to fill in registration form at the following link. **Register online at: https://forms.gle/atbXpjdVoFRSup3WA** • 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:	 6260/- 8260/-
B) Micro/small enterprises, startups; Non-profit/R&D/academic orgs; individuals	12390/-
C) Others including medium/ large enterprises	12390/-

***Limited number of travel fellowships for up to Rs. 13000 available for Category 'A' participants. Reimbursement upon presenting receipts.

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. NOTE: Registration closes once 20 seats are full or on 10 September 2019 (whichever comes sooner). ***Fee paid is not refundable and non transferable under any circumstances.***

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, 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.

Course Description

This course explores the requirements of the ISO 13485:2016 Quality Management System standard, discussing key principles and how the standard interacts with ISO 9001:2015, the European Medical Device Directives and US FDA's Quality System Regulation. The relationship with ISO 14971 'Application of Risk Management to Medical Devices' is also explored during the course.

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

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

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**.

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 Schedule

DAY 1: 17 September 2019 – Tuesday

CLASSROOM TUTORING -- ISO 13485:2016 Introduction Training course

Time	Duration	Session title	Lead
0900-0930	30 min	Registration and breakfast	
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 • ISO 13485 in detail	**Vinayak Khandeparker**
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	**Vinayak Khandeparker**
1300-1400	60 min	Lunch break	
1400-1530	90 min	**Session 3:** • Clause 5 – Management Responsibility • Clause 6 – Resource management	**Vinayak Khandeparker**
1530-1600	30 min	Tea break	
1600-1730	90 min	**Session 4:** • Clause 7 – Product realization …including risk management • Clause 8 –Monitoring and measurement	**Vinayak Khandeparker**
1730-1830	60 min	**Session 5:** • ISO 13485, FDA, QSR, MDSAP and other regulations • Reflection and feedback	**Vinayak Khandeparker**

DAY 2: 18 September 2019 – Wednesday
CLASSROOM TUTORING -- Internal Auditor Training Course

Time	Duration	Session title	Lead
0900-0930	30 min	Registration and breakfast	
0930-1100	90 min	**Session 1:** • Welcome and Introductions • 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	**Vinayak Khandeparker**
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	**Vinayak Khandeparker**
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	**Vinayak Khandeparker**
1530-1600	30 min	Tea break	
1600-1800	120 min	**Session 4:** • Audit techniques Gathering and verifying information • Introduction of audit findings and nonconformities • Conducting an audit (Part 1)	**Vinayak Khandeparker**

Workshop Schedule cont..

DAY 3: 19 September 2019 – Thursday

CLASSROOM TUTORING & EXAM -- Internal Auditor Training Course

Time	Duration	Session title	Lead
0900-0930	30 min	Registration and breakfast	
0930-1100	90 min	**Session 5:** • Review of day 1 • Conducting the audit (Part 2) • Generate audit findings	**Vinayak Khandeparker**
1100-1130	30 min	Tea break	
1130-1300	90 min	**Session 6:** • Identify and define nonconformities • Prepare audit conclusions • Write an audit report	**Vinayak Khandeparker**
1300-1400	60 min	Lunch break	
1400-1530	90 min	**Session 7:** • Closing meeting • Conduct audit follow-up • Course summary	**Vinayak Khandeparker**
1530-1600	30 min	Tea break	
1600-1730	90 min	**Session 8:** • Role Play by participants group 1 (45 min) • Role Play by participants group 2 (45 min)	
1730-1830	60 min	**Session 9:** • Exam and closure	**Vinayak Khandeparker**

Anchor Faculty and Venture Base Camp Director

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

Vinayak Khandeparker

Vinayak Khandeparker, B.E. (Elect) from Mumbai University

Thirty five years of total experience in Engineering and Healthcare sector with core competency in Quality management and Regulatory Affairs. Completed Lead Auditors Course qualification in ISO 9001:2015 and ISO 13485:2016 from BSI.

Worked in the manufacturing set up for 12 years as Head of Quality Management and Regulatory Affairs. Implemented ISO 13485, MDD and EC. Obtained CE mark for four products. Obtained SFDA from China for 3 products.

Worked for Sales and Service Organization as Head of Quality Management and Regulatory affairs for 8 years. Implemented ISO 9001: 2008 for Sales and Service organization earlier and one year back migrated to ISO 9001: 2015. Handled product registration of CT, MR, Cath lab, X ray machine, C arms and IVD's.

Work Experience Highlights

Sept 1998 – June 2018 Siemens Healthcare Pvt Ltd.

Nov 1985 – Aug 1998 - Automobile Corporation of Goa Ltd.

Strengths:
Lead Auditor/Tutor• ISO 9001 Quality• ISO 13485 Medical Devices• ISO 27001 Information Security• ISO 20001 IT Service Mgmt• ISO 22301 Business Continuity• PAS 99 Integrated Management• Systems ISO 15489 Record Management• BS 10012 Personal Information Management

Summary of experience:
22 years IT work experience 7 + years in awareness,• training, lead auditor courses Conducted over 1300 Man• Days of audits Training more than 2,000• candidates Training conducted in India and• Kuwait

RIFC	BRBC A BIRAC - Venture Center Initiative	VENTURE CENTER	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	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