



**Venture Base Camp on
ISO 13485:2016 Medical Devices Quality Management
–Introduction & Internal Auditors Training Course–
- Organized by BRBC at Venture Center -**

Potential gains	<p>This Venture Base Camp (VBC) <i>aims to de-mystify QMS audit and Risk Management requirements and help startups chart out an Internal Audit Plan for their company in 3days.</i></p> <ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> BIRAC Regional BioInnovation Center @ Venture Center. Regulatory Information and Facilitation Center (RIFC) @ Venture Center. 										
Supported by	<ul style="list-style-type: none"> BIRAC Venture Center 										
For whom	<ul style="list-style-type: none"> CEOs/CTOs of innovative technology startups. Individual Inventors. Inventors from R&D institutes, medium/ large enterprises. 										
When	(Wed-Fri) 25 – 27 MAY 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	<p>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</p>										
Registration Details	<p>Limited seats!! Total number of seats: 15 Registration Process:</p> <ul style="list-style-type: none"> Step 1: Interested participants need to fill in registration form at the following link. Register online at: https://tinyurl.com/VBC-ISO Step 2: Email invites will be sent post screening of registration details. Step 3: Attendance only on confirmation of payment of registration fee*. <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Category</th> <th style="text-align: left;">Fees (Rs)</th> </tr> </thead> <tbody> <tr> <td>A) VC Incubatees, BIRAC Grantees who are small entities *** For one person:</td> <td>8000/-</td> </tr> <tr> <td>For the second person from the same company:</td> <td>10000/-</td> </tr> <tr> <td>B) Micro/small enterprises, startups; Non-profit/R&D/academic orgs; individuals</td> <td>10000/-</td> </tr> <tr> <td>C) Others including medium/ large enterprises</td> <td>14000/-</td> </tr> </tbody> </table> <p>NOTE: Registration closes once 15 seats are full or on MAY 20, 2022 (whichever comes sooner).</p> <p>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.</p>	Category	Fees (Rs)	A) VC Incubatees, BIRAC Grantees who are small entities *** For one person:	8000/-	For the second person from the same company:	10000/-	B) Micro/small enterprises, startups; Non-profit/R&D/academic orgs; individuals	10000/-	C) Others including medium/ large enterprises	14000/-
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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.



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

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 13485:2016 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 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: Wednesday, 25 May 2022

Time	Duration	Session title	Lead
0930-1100	90 min	Session 1: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • Clause 5 – Management Responsibility • Clause 6 – Resource management 	Nandinee Khot
1530-1600	30 min	Tea Break	
1600-1730	90 min	Session 4: <ul style="list-style-type: none"> • Clause 7 – Product realization ...including risk management • Clause 8 –Monitoring and measurement • Reflection and Feedback 	Nandinee Khot



DAY 2: Thursday, 26 May 2022

Time	Duration	Session title	Lead
0900-1100	120 min	Session 1: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> Auditor competence and responsibilities Plan an internal audit Create work documents Conducting an (informal) opening meeting Collecting and verifying audit information 	Nandinee Khot
1530-1600	30 min	Tea Break	
1600-1700	60 min	Session 4: <ul style="list-style-type: none"> Audit techniques Gathering and verifying information Introduction of audit findings and nonconformities Conducting an audit(Part 1) 	Nandinee Khot

DAY 3: Friday, 27 May 2022

Time	Duration	Session title	Lead
0900-1100	120 min	Session 5: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> Closing meeting Conduct audit follow-up Course summary 	Nandinee Khot
1530-1600	30 min	Tea break	
1600-1730	90 min	Session 8: <ul style="list-style-type: none"> 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 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. July 1992- 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



About the Organizers

	<p>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/</p>
	<p>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/</p>

Supported by

	<p>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</p>
	<p>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</p>