e-Venture Base Camp on

ISO 13485:2016 Medical Devices Quality Management

–Introduction &Internal Auditors Training Course–

- Organized by BRBC -

Potential gains	This event is a Venture Base Camp (VBC) which ***aims to de-mystify QMS audit and Risk Management requirements and help startups chart out an Internal Audit Plan for their companyin3days.*** 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 asenior 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	**(Mon– Tue –Wed) 07-08-09 June 2021| Time: 9 am – 6 pm**
Where	Online. Platform: Cisco WebEx Meetings
Contact	***Technical queries***: Navnath Kadam| +91 91564 65147|navnath@venturecenter.co.in ***Registration related***: Neha K | 89566 77543 | neha@venturecenter.co.in Lipika Biswas| 020-25865877/76| eventsdesk@venturecenter.co.in
Registration Details	**Limited seats!! Total number of seats: 15** Registration Process: • Step 1: Interested participants need to fill in registration form at the following link. **Register online at: https://forms.gle/iS479ETugEsm2hXN8** • 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/-

NOTE: Registration closes once 15 seats are full or on June 05, 2021 (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

You should have a basic knowledge of ISO 13485:2016 and the key principles of a QMS.

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Workshop includes

- 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: June 07, 2021 – Monday

Workshop Schedule: - ISO 13485:2016 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	**Akhil Gupta**
1100-1130	30 min	Break	
1130-1300	90 min	**Session 2:** • Clause 0 – Scope • Clause 1 – Normative references • Clause 3 – Terms and definitions • Clause 4 – Quality management system	**Akhil Gupta**
1300-1400	60 min	Break	
1400-1530	90 min	**Session 3:** • Clause 5 – Management Responsibility • Clause 6 – Resource management	**Akhil Gupta**
1530-1600	30 min	Break	
1600-1730	90 min	**Session 4:** • Clause 7 – Product realization …including risk management • Clause 8 –Monitoring and measurement	**Akhil Gupta**
1730-1830	60 min	**Session 5:** • ISO 13485, FDA, QSR, MDSAP and other regulations • Reflection and feedback	**Akhil Gupta**

DAY 2: June 08, 2021 – Tuesday

Workshop Schedule: Internal Auditor Training Course			
Time	**Duration**	**Session title**	**Lead**
0930-1100	90 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	**Akhil Gupta**
1100-1130	30 min	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	**Akhil Gupta**
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	**Akhil Gupta**
1530-1600	30 min	Break	
1600-1800	120 min	**Session 4:** • Audit techniques Gathering and verifying information • Introduction of audit findings and nonconformities • Conducting an audit(Part 1)	**Akhil Gupta**

DAY 3: June 09, 2021 – Wednesday

Workshop Schedule: Internal Auditor Training Course			
Time	**Duration**	**Session title**	**Lead**
0930-1100	90 min	**Session 5:** • Review of day 1 • Conducting the audit (Part 2) • Generate audit findings	**Akhil Gupta**
1100-1130	30 min	Tea break	
1130-1300	90 min	**Session 6:** • Identify and define nonconformities • Prepare audit conclusions • Write an audit report	**Akhil Gupta**
1300-1400	60 min	Lunch break	
1400-1530	90 min	**Session 7:** • Closing meeting • Conduct audit follow-up • Course summary	**Akhil Gupta**
1530-1600	30 min	Tea break	
1600-1730	90 min	**Session 8:** • Exam and closure	**Akhil Gupta**

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

Akhil Gupta, Client Manager -Lead Tutor & Assessor, BSI Group India.

Summary of Experience

48 years industry work experience in Training,Production/QC/IT | 10 + years in awareness, training, lead auditor courses | Conducted over 2500 Man Days of audits | Training more than 500 candidates

Qualifications:

B. Tech -Electronics Engineering – IIT Kanpur | MBA –Finance-Delhi University | IRCA certified auditor/trainer of ISO 9001,ISO 14001,OHSAS 18001,ISO 50001,ISO 20000- 1, ISO 27001, ISO 22301,ISO 13485,MDR.

Have been trained on: IEC 62366-1:2015 - Part 1: Application of usability engineering to medical devices; IEC/TR 80002-1:2009 guidance on how to apply ISO 14971 to medical device software; IEC/TR 80001-1:2010 risk management for medical devices that are incorporated into IT networks;
AAMI TIR32 Medical device software risk management IEC 61508-3 - Functional safety of electrical/electronic/programmable electronic safety-related systems – Part 3: Software requirements.

Work Experience Highlights:
Production Supervisor-Heraeus GmbH, Germany involved in development of software, involving management of controls implemented for mitigation of risks to patient health and safety. Worked as Production/Quality Manager for handling the Design/Production/QC/ Clinical investigation activities for medical device (Nd-Yag Surgical Lasers).During this tenure, worked for the design of the microprocessor-based control panels and software development and design, coding, testing, validation/integration of the associated software. Worked with various Hospitals/ Surgeons/Researchers for conducting the process validation of the design of these equipment and conducting clinical investigation studies. Software development used was an Agile model for combination of iterative and incremental process models. Steps involved in agile SDLC models were: Requirement gathering, Requirement Analysis, Design, Coding, Unit testing, Acceptance testing #2010 – 2014 – DNV India – Operations.

Manager/Technical Expert for review of Technical Files submitted for CE marking, as per MDD #Dec 2014 –Current - BSI India – Lead Assessor and Tutor of healthcare products, having I417 IRCA-MED, IHC2 Healthcare QMS – advanced, IMDD Medical Devices Directive, IMDR (Med Dev) MDD to MDR, I413 IRCA-ISMS, P37/01 CE Marking Active Medical Devices, P10012L - Personal Information Lead Asse, P27001L- ISO 27001 Lead Assessor. I have been trained on , Updates on 60601-1-4,62304,New Standards for Active Medical Products (AMP),State of Art standards used for AMP, Risk Management in Testing, EU regulatory update, IVD Regulation update, calibration-pitfalls in audit, update REACH,EN ISO 14971-2012,Clinical/Patient benefit, Pitfalls in clinical investigation, clinical data for simple devices, I have been trained on Medical Devices - Cybersecurity & Data Protection- Completed on 17-2-2019.

Have delivered trainings in 2019 on SDLC-IEC 62304 to a batch of 25 Software Engineers of Boston Scientific, 20 Software Programmers of Allengers Medical.
Devices and 15 Software Coders/Testers of Stryker Global. I have delivered several in-house trainings on ISO 31000-risk management for IT organisations. Delivered 4 batches of Lead auditor training courses on ISO 13485:2016, implementation courses on ISO 14971:2019 and transition trainings from MDD to MDR, using the Computer Live Learning platform of Adobe5.

Strengths
Lead Auditor/Tutor | ISO 9001 Quality Management | ISO 14001 Environment Mgmt | OHSAS 18001 OHS Mgnt | ISO 50001 Energy Mgmt | ISO 27001 Info Security | ISO 20001 IT Service Mgmt | ISO 22301 Business Continuity | PAS 99 Integrated MgntSyst | ISO 13485-QMS:MD | CE Marking-MDD 93/42 EU | CE Marking-MDR- 2017/745 EU

Clients Served
Boston Scientific | HCL | Stryker | Philips | Varian | Wipro | Concentrix

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/

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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