Report

VENTURE BASE CAMP

On

ISO 13485: 2016

Quality Management System Introduction & Internal Auditor Training Course

RIFC BRBC

A BIRAC - Venture Center Initiative

VENTURE CENTER

birac

Ignite Innovate Incubate

Wednesday - Friday

25 – 27 May 2022

Venture Center,
100 NCL Innovation Park
Dr Homi Bhabha Road,
Pashan, Pune- 8

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Acknowledgment

BIRAC Regional Bioinnovation Center (BRBC) is stepping forward to filling up key innovation ecosystem gaps for Biotech/Biomed startups across the country and the Venture Base Camp on ISO 13485:2016 Medical Devices Quality Management Introduction & Internal Auditor Training Course held from 25 – 27 May 2022 was a pleasing demonstration.

BRBC is thankful to the base camp logistics organizers, speakers, and participants

Financial Support

BIRAC Regional Bioinnovation Center (BRBC) at Venture Center, Pune

Venture Center, Pune

Organizer

Regulatory Information and Facilitation Center (RIFC) at Venture Center, Pune

Introduction

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, before their execution on key goals of the company.

The focus of this base camp was to provide the hands on internal auditors training against the ISO 13485: 2016 for checking the effectiveness of Quality Management System (QMS).

This VBC was useful for innovators and startups in the following medical device categories: Medical devices for clinical intervention or treatment |Surgical tools and aids | Assistive devices or disability aids or image reconstruction or artificial body parts | 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.*

Content

Focus:

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.

Base Camp outline:

DAY 1: Wednesday, 25 May 2022

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

Session 2:

- Clause 1 – Scope
- Clause 2 – Normative References
- Clause 3 – Terms and definitions
- Clause 4 – Quality management system

Session 3:

- Clause 5 – Management responsibility
- Clause 6 – Resource management

Session 4:

- Clause 7 – Product realization
- Clause 8 – Monitoring, measurement & improvement
- Reflection & feedback

DAY 2: Thursday, 26 May 2022

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

Session 2:

- Introduction to auditing: What is an audit?
- The process approach and process auditing
- Managing an audit programme
- Audit activities

Session 3:

- Auditor competence and responsibilities
- Plan an internal audit
- Create work documents
- Conducting an (informal) opening meeting
- Collecting and verifying audit information

Session 4:

- Audit techniques Gathering and verifying information
- Introduction of audit findings and nonconformities
  Conducting an audit (Part 1)

DAY 3: Thursday, 26 May 2022

Session 5:

- Review of day 1
- Conducting the audit (Part 2) & generate audit findings

Session 6:

- Identify and define nonconformities
- Prepare audit conclusions & write an audit report

Session 7:

- Closing meeting
- Conduct audit follow-up
- Course summary

Session 8:

- Exam and closure

Attendees:

15 people from different startups participated in the base camp.

Evaluation:

During the base camp, the intentions were met; there was an exchange of information on regulatory obligations for the medical devices.

Rating Scale			
1	Bad	2	Well below average
3	Below average	4	Average
5	Good	6	Very Good
7	Excellent		

Category	**Avg (Min-Max) Count**
Section 1 – About the Event	
Overall Satisfaction with Event	6.4 (6,7)15
Satisfaction with Content	6.5 (6,7)15
Satisfaction with Speakers/mentors etc	6.7 (6,7)15
Satisfaction with structure, design and pace of event	6 (5,7)15
Satisfaction with food and beverages	5.5 (4,7)15
Section 1 – Sessions & Lectures	
Day 1 sessions	5.8 (5,7)15
Day 2 sessions	6.5 (6,7)15
Day 3 sessions	6.6 (6,7)15
Did the workshop help you understand the concept(s) better?	Yes
If you have any other suggestions, comments, etc., please share them below.	
for elaboration time could have been more	
It was a great learning experience regarding ISO certification	
Program was very engaging, very well crafted and the organizers and the instructors were absolutely brilliant!	
Testimonial for RIFC activities	
Very well organized and very well structured event.	
The arrangements and the plan was very well executed with great learning experience and having new perspective about ISO standards	
Well structured course, helped me to understand the QMS	
How did you hear about the event?	
Email	8
LinkedIn	3
Whatsapp	1
Others	3

List of speakers & Mentors

Sr	**Name**	**Affiliation**
1	Nandinee Khot	BSI Group India Pvt Ltd, Pune

List of participants

Sr	Participant Name
1	Prajakta Chitnis
2	Anita Mangesh Nimbalkar
3	Harshesh Gokani
4	Zoheb Waheedur Rahman
5	Prerit Mittal
6	Divyakshi Kaushik
7	Pralay Mallelawar
8	Nikhil Mamoria
9	Himanshu laddha
10	Pooja Mehta
11	Ashwin Kumar U.A
12	Yogesh Gajendra Dalvi
13	Anita Patil
14	Harshini Zaveri
15	Jayant N Savaji

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