Report

VENTURE BASE CAMP

On

ISO 13485: 2016

Medical Devices Quality Management

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

Monday - Tuesday

26 – 28 October 2020

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

Contents

RIFC

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 fourth Venture Base Camp on ISO 13485:2016 Medical Devices Quality Management, Internal Auditor Training Course held from 26 – 28 Oct 2020 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: *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.

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:

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

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)

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:

18 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 (Max-Min) Count**
Section 1 - Event	
Overall Satisfaction with Event	6.3 (5,7)18
Satisfaction with Content	6.3 (5,7)18
Satisfaction with Speakers/mentors etc	6.2 (3,7)18
Satisfaction with structure, design and pace of event	6.2 (5,7)18

Section 2- Sessions & Lectures	
Day 1 sessions	6.2 (4,7)18
Day 2 sessions	6.2 (4,7)18
Day 3 sessions	6.4 (5,7)18
Please Provide any other suggestions, comments etc here	
Best wishes for future endeavors	
Sir was excellent in teaching the breakout sessions were quite helpful and that's where most of the learning happened. I would be great if the session was planned for a week with same content with more activities and time to go through the material. If I don't pass through the exam it will be great if we get a second chance sooner in one or two months. Because as sir said one should be eligible to conduct an audit.	
VC always carries out relevant workshops and events for entrepreneurs to the medical device industry. Keep up the work.	
Well if the session could be done for 5 days that would be much more interactive to cover all topics. I am very happy with the training received...looking forward for many more	
Instructor was too aggressive and needs to treat attendees with respect	
It was much-needed learning for a person like me who will be looking after the regulatory affairs of their organization. Thanks to the organizers and the tutor for their efforts. I would like to suggest the following improvements: 1. Share the course material much in advance, something like a week prior to the actual event. That will allow enough time to prepare it thoroughly. 2. Discuss with the participants what to expect from the activities, role plays, etc. well in advance. Although everything got somewhat clear towards the end of the course, it was quite confusing for the first two days. 3. I would have preferred a slightly different instruction style. Instead of focusing on slides content, emphasis could have been given to conceptual learning. Thanks!	
It would be great if we get the material in advance (may be 3-4 days). So as to go through it.	
Please mention more examples or real world scenario during lecture. Case study should be more relevant to startups.	
Testimonial for the RIFC activities	
RIFC is doing a great job. Keep doing the great work.	
Very nicely conducted session by Vinayak Sir. Navnath Kadam Always available during the session was very helpful for over-all sessions	
Excellent	
One of the best sessions I have attended till date. Session was very interactive & Informative. RIFC Events always helps in development of medical devices.	
This is my 1st RIFC activity My experience is great. And the learning experience is valuable. It will also be great if workshops in future will be on 1. Medical Design File documentations and Risk Management Documentation before we go for Pre-compliance, compliance and CE Marking. 2. Clinical trial documentation planning and execution workshop. These we have to learn the hard was with many failures and such intense workshops will help us.	
Very relevant for medical device startups, great initiative	
This is a nicely compiled program	
Running pillar to post to find answers to regulatory requirements for two years. RIFC has provided the best platform to deal with it and also provide trainings and workshops. These are absolutely the need of the hour for product release. Navnath and team are doing an excellent job at it. The best part is providing guidance hand-in-hand to entrepreneurs and startups. I shall recommend some startups to RIFC.	
I am very happy for being a part of this session. Infact the CISCO WebEx didn't make me feel i was a part of this event remotely.	

Very constructive workshop-a nice blend of theory and hands-on activities.	
RIFC is making great efforts for improving regulatory understanding of all startups. Thanks for organizing this. Appreciate it.	
This was my first workshop regarding to ISO. Speaker Vinayak was did a great job and Navnath put his 100% to make it happen. Thank you so much	
How did you hear about the event	
WhatsApp	1
Email	15
LinkedIn	1
Others	1

List of speakers & Mentors

Sr	Name	Affiliation
1	Vinayak Khandeparkar	BSI Group India Pvt Ltd, Pune

List of participants

Sr	Participant Name
1	Wasia Rizwani
2	Tejas Shah
3	Usman Khan
4	Smita Kale
5	Shilpa Malik
6	Shailesh Patidar
7	Sayali Kothmire
8	Sathiya V
9	Rayyan Ramrajkar
10	Md Samheel
11	Fiona Fernandes
12	Dhanashree M
13	Chinmay Khare
14	Ashish Gawade
15	Apurva Vaidya
16	Anupam Lavania
17	Anupam Bam
18	Akitha Kolloju

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