Report

VENTURE BASE CAMP

On

ISO 13485: 2016

Medical Devices Quality Management

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

Tuesday - Thursday

23 – 25 June 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 23 – 25 June 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:

20 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.

(23-25 June 2020) e-Venture Base Camp on ISO 13485:2016 Medical Devices Quality Management - Internal Auditors& Risk Management Training Course –	
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	6.4 (5,7)16
Satisfaction with Content	6.6 (5,7)16
Satisfaction with Speakers/mentors etc	6.6 (4,7)16
Satisfaction with structure,design and pace of event	6.2 (4,7)16
Section 2- Sessions & Lectures	
Day 1 sessions	6.7 (5,7)16
Day 2 sessions	6.4 (5,7)16
Day 3 sessions	5.9 (4,7)16
Please Provide any other suggestions,comments etc here	
None	
Co-ordination by the organizers could be improvised	
The last day sessions lingered with technical glitches and audio drops throughout. This significantly hampered the learning experience. Also, a walk through of the case study would have been helpful in correlating learnt knowledge with its application.	
Voice was breaking..some connection issues were there.	
Great interactive session. Gained good insight on ISO 13485 quality management system and risk management. Thank you Mr. Akhil Gupta and organizers for this opportunity.	
Just that the audio troubled a lot in few sessions!!	
Found overall difficult to understand need to include simple presentation and more case studies	
All the sessions were really good and informative. But the sessions should have been more activity based. Different online activities or few home activities would have helped to understand practical aspects of auditing. Online activities could have planned in better way to increase participation and interaction among participants.	
We were facing some audio problems. The voice was breaking.So a lot of time gone because of this.	

The instructor (Akhil Gupta) is very good with knowledge and experience but somehow the session's intent was not met. He wasted lot of time in asking someone to read each slide and asking several others to summarize. I understand the intent behind making people interactive but this should not be at the cost of losing somuch of time. Instead, he could have crisply explained the intent behind the slide, involving people inbetween if needed, but not for each and every slide. Having wasted precious time in asking several people to keep summarizing, what we really wanted to learn from the session which is how to conduct audit was lost. I really wish the case study was taken up and some video planned to show a mock auditor and auditee interact , the scenarios recorded could be with both positive and negative aspects covering. What I really wanted to see was an active audit session from panning to closure enacted by someone for a case study (a video recording of the same can be flashed) which would have been enough rather than going through the slides. This could have demonstrated how an auditor view a situation, how he asks the questions etc., because we need to learn these skills of asking questions and probing further based on auditiee's response, which is key to an audit which can only be shown by someone mimicking the same. This is my feedback for any future training.
I couldn't attend event completely because of network problem in my village, but whatever I could attend that was excellent.
Looking forward to more workshops on crafting the regularly pathways of medical devices

How did you hear about the event	
Whatsapp	2
Email	11
LinkedIn	1
From my company/ Through a collegue	3

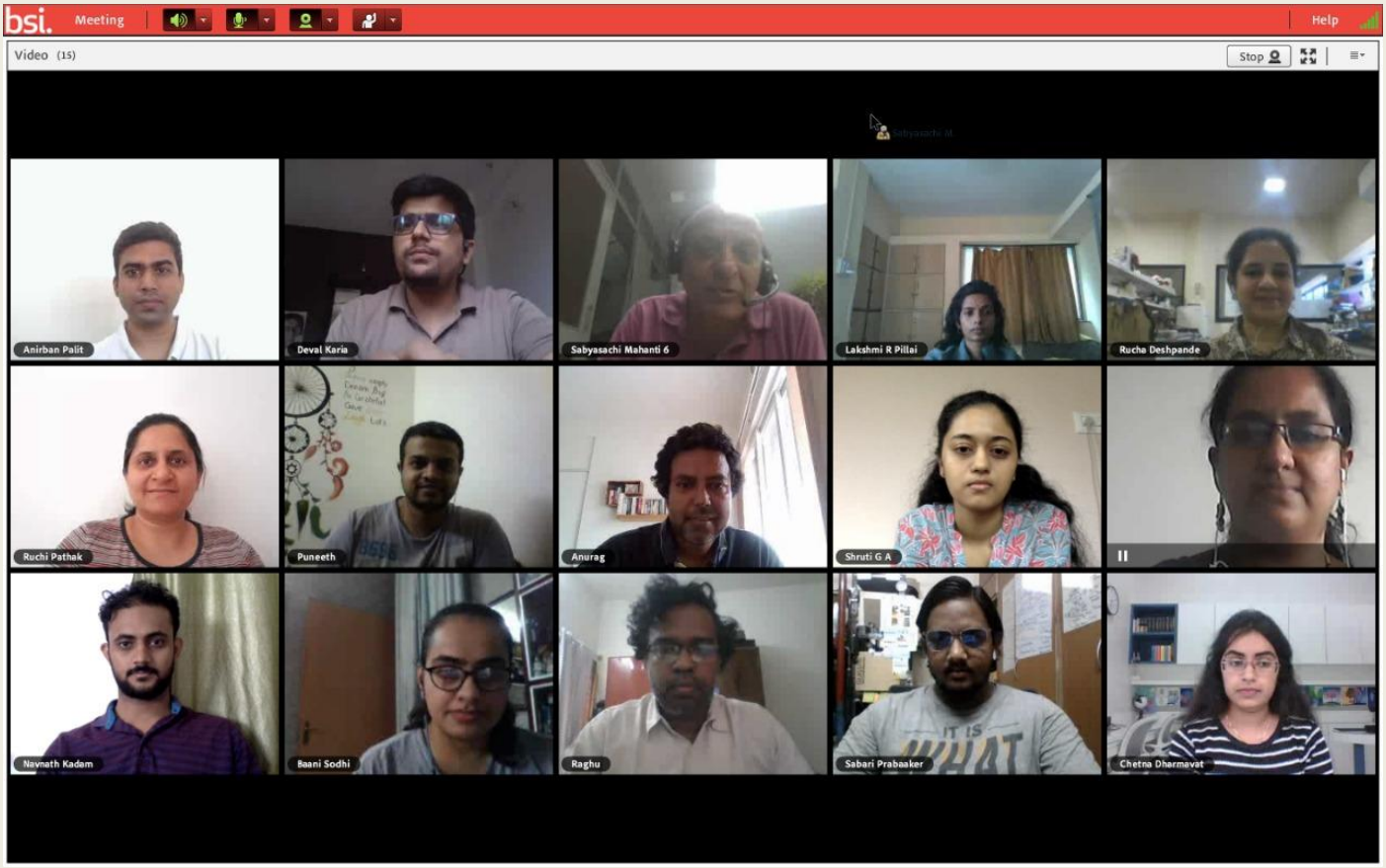
List of speakers & Mentors

Sr	Name
1	Akhil Gupta

List of participants

Sr	Participant Name
1	Neha Harishchandra Lande
2	Puneeth Kannaraya
3	Baani Sodhi
4	Sabari Prabaaker
5	Deepthi Subbaraya
6	Anirban Palit
7	Deval Karia
8	Jijnasa Panigrahi
9	Sandeep Dahake
10	Rucha Deshpande
11	Lakshmi Pillai
12	Raghu Menon
13	Shruti G A
14	T.N.Kousthuba
15	Anurag Verma
16	Ruchi Pathak Kaul
17	Anirban Dutta

Photo Gallery



Regulatory Information and Facilitation Center

100, NCL Innovation Park,
Dr. Homi Bhabha Road,
Pashan, Pune – 411008.

020-25865877 /76 E 3030
rifc@web.venturecenter.co.in
rifc.venturecenter.co.in

RIFC