Report

VENTURE BASE CAMP

On

ISO 13485:2016 Medical Devices Quality Management

-- Internal Auditor Training Course --

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

Tuesday - Thursday

28-30 – May 2019

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 28 - 30 May 2019 was a pleasing demonstration.

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

Internal support: Logistics and management, Venture Center, Pune

Deepa TI
Lipika B
Pallavi A
Vidhya B

External support: Photography and Videographer, IISER, Pune

Imavayan K
Vivek K

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:

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 and tutoring on the auditing skills for the medical devices; Quality Management Standard.

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

Section 1 - Event administration & facilities(Please tick)		
1	Quality of pre-event (registration, queries)	5.9(5,7)15
2	Quality of Staff responsiveness	6.2(5,7)15
3	Pace of the event (time mgmt)	5.2(4,7)15
4	Quality of food & beverages	5.7(4,7)15
5	Venture Center facility(Was it appropriate, clean & comfortable?)	6.2(5,7)15
6	Overall satisfaction with event organization	6.4(5,7)15
Section 2 – Sessions ,Instructor and One on one		
1	Content of the Workshop	6.4(5,7)15
2	Satisfaction with structure, design & Pace of event	6.4(5,7)15
3	Satisfaction with speakers/mentors etc	6.1(4,7)15
4	1 to 1 Meeting with Auditor	6.0(3,7)11

Section 3 - Comments & Suggestions. Please include if the talk met your expectations.				
1	**What did you enjoy the most**			
	Role Play			
	Activities			
	Role plays & learning			
	Activities & Role Plays			
	Role Play & Practical experience.			
	Role Play			
	Role Play was a good exercise. Rushed through slides.			
	Activities related to Internal Audit			
	Activities, Role plays input from Auditor on mistake, listening to others activities was also interesting.			
	Role Plays/Activities.			
	Practical sessions, Role Plays for audits			
	Role Plays, Gave good understanding of auditing requirements.			
	The Practical Sessions			
	Activities, Enacting as auditors/auditor's in more audit.			
2	**Please suggest a topic on which you wish to have a workshop on?**			
	Implementation & Documentation of ISO 13485:2016			
	External Auditor & Risk Management, Validation			
	Risk management, Validation & Process			
	Risk management & its management			
	Risk management , Validation			
	More in-depth Training on regulations & requirement for medical device commercialization.			
	Regulatory			
	ISO 13485 Documentation Training			
	External Auditing			
3	**How did you hear about the Base Camp ?**			
	Email-9			
	VC News Letter			
	BRBC			
	Friends, Peers, Website			
	Friends, Peers, Website			
	Friends & Peers			
	VC			
4	**Is 3 days too long for a workshop?**			
	Yes -4			
	No-10			
5	**What changes would you like to be seen in the next base camp**			
	Clearly Communicate. Base camp Objective.			
	More case studies			
	Improvised Quality in section 1			
	An actual/ fictional case study & internal audit risks & its management			
	Better Venue, Food.			
	Emphasis on Implementation techniques/documents of ISO 13485			
	Technical Management on day 1(Laptop-Projector)			
6	**Would you like to get notified about similar events from Venture Center**	**YES 11**	**NO 02**	**NM 02**

List of speakers & Mentors

Sr	Name	Affiliation
01	Vinayak Khandeparker	BSI India Group, Mumbai
02	Navnath Kadam	Venture Center, Pune

List of participants

Sr	Participant Name
01	Raeesa Sayyad
02	Swati Shukla
03	Vishal Patil
04	Prateek Bhalerao
05	Preeti Joshi
06	Nitesh D
07	Jilma Peruvangat
08	Komal Belwade
09	Sachin Dubey
10	Tanuj Gigras
11	Ajay Suryavanshi
12	Piyush Joshi
13	Niketa Chauhan
14	Prasad Bhagat
15	Aashish Mokashi

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