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

Tuesday - Thursday

17 – 19 September 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 17 - 19 Sep 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

Chetna D	Neha K	Vidhya B
Deepa TI	Priya N	
Lipika B	Shiv T	

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Imavayan K	Vivek K

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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.

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 administration & facilities(Please tick)		
1	Quality of pre-event (registration, queries)	5.9 (5,7) 20
2	Quality of Staff responsiveness	6.1 (5,7) 20
3	Pace of the event (time mgmt)	6.3 (5,7) 20
4	Quality of food & beverages	5.7 (4,7) 20
5	Venture Center facility (Was it appropriate, clean & comfortable?)	5.8 (5,7) 20
6	Overall satisfaction with event organization	6.3 (5,7) 19
Section 2 -Sessions & Lectures Day 1		
1	Day 1- Welcome benefits to you, and Introduction: Courses aims, objectives & Structure; Quality definitions and the process approach: Definition of a medical device within the industry: Introduction to ISO 13485; ISO 13485 in detail.	6.6 (4,7) 20
2	Day 1- Clause 0-Scope;clause 1-Normative references; clause 3-Terms and definitions; clause 4-Quality management systems	6.8 (5,7) 20
3	Clause 5-Management Responsibility; Clause 6-Resource Management	6.8 (5,7) 20
4	Clause 7-Product realization-including risk management; clause 8-Monitoring and measurement	6.8 (5,7) 20
5	ISO 13485, FDA, QSR, MDSAP and other regulations; Reflections and feedback	6.6 (5,7) 20
Section 3 -Sessions & Lectures Day 2		
1	Welcome benefits delegates introductions and course aim: Boundaries; conflict of interest expertise; learning objectives and course structure; Fundamental 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.	6.6 (6,7) 20

2	Introduction to auditing: what is audit? The process approach and process auditing; Managing an audit programme: Audit activities	6.7 (5,7) 20
3	Auditor competence and responsibilities: plan an internal audit: create work documents; conducting an informal opening meeting: Collecting and verifying audit information.	6.7 (5,7) 20
4	Audit techniques Gathering and verifying information: Introduction of audit findings nonconformities: Conducting an audit(Part 1)	6.7 (5,7) 20
Section 4 -Sessions & Lectures Day 3		
1	Review of day 1: Conducting the audit (part 2) Generate findings	6.8 (6,7) 20
2	Identify and define nonconformities: prepare audit conclusion: Write an audit report	6.6 (5,7) 20
3	Closing meeting: conduct and follow-up:Course Summary	6.6 (4,7) 20
4	Role Play by participants group 1(45 min): Role play by participants group 2	6.8 (6,7) 20
5	Exam and Closure	6.6 (5,7) 20

What did you enjoy the most	
1	Activities., Case study & Role Play (8)
2	The Role-play & Checklist activities.
3	Interactive Learning was worried that it may not be able to fix it through; but managed well.
Please suggest a topic on which you wish to have a workshop on?	
1	Audit
2	ISO 14971,IEC 60601:1 (2)
3	Risk management (2)
4	Lead Auditor
5	ISO 9001
6	Project management
7	Product Development
8	Regulatory guidelines for new products to be launched.
9	Implementation of standards (QMS) for startups.

Is 3 days too long for a workshop?							
		YES	01	NO	13	Not Mentioned	06
1	Instructor was too good. May be should have done Fri, Sat, Sun						
2	Prefer Workshops on Saturday						
3	I would have preferred one more day						
4	Its Optimum						
5	Not for this topic						

What changes would you like to be seen in the next base camp	
1	More test cases
2	Internet Connectivity
3	More Activities
4	Some Specific Case study
5	Please refer Above(one more day)
6	Nothing much with respect to organization of event

List of speakers & Mentors

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

List of participants

Sr	Participant Name	Affiliation
1	Ranjan Vincent	Achira Labs Pvt Ltd
2	Cheryl Pereira	Agd Biomedicals Pvt Ltd
3	Ashutosh Bagde	Atmen Technovention Pvt Ltd.
4	Rucha Shukla	Biolmed Innovations Pvt Ltd
5	Llewellyn Dsa	Bionic Hope Pvt Ltd
6	Ashlesh Bhat	Blackfrog Technologies Pvt Ltd
7	Pranav Chopra	Crimson Healthcare Pvt Ltd
8	Y V Kanthaiah	Cyonics Cyto Solutions Pvt Ltd
9	Sai Laxman Bharadwaj	Indian Institute Of Technology Hyderabad
10	MADHUKAR S M	Innaumation Medical Devices Pvt Ltd
11	Jyoti Kumbhar	Intignus Biotech Pvt Ltd
12	Manoj Sanker	Nemocare Wellness Pvt Ltd
13	Lokap Sahu	On My Own Technology Pvt Ltd
14	Saiprasad Poyarekar	Pacify Medical Technologies Pvt Ltd
15	Anmol Zimare	Pacify Medical Technologies Pvt Ltd
16	Vikas Garg	Prayasta 3d Inventions Pvt Ltd
17	Amit Salvi	Samarthakrupa Lifesciences Pvt Ltd
18	Neha Lasure	Solitarius Biologicals Pvt. Ltd.
19	Chetna Dharmavat	Venture Center
20	Sujaya Ingale	Venture Center

Photo Gallery

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INCUBATION
PRACTICE


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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

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