Report

VENTURE BASE CAMP

On

Regulatory Processes and Certifications

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

Tuesday - Thursday

5 – 7 February 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 second Venture Base Camp on Regulatory Processes and Certifications held from 5 - 7 Feb 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

Amruta G	Manisha P	Smita K
Deepa TI	Pallavi A	Vidhya B
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Madhurima H	Shiv T	

External support: Photography and Videographer, IISER, Pune

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 frame the regulatory strategy and roadmap for medical devices in India.

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:

To introduce and define the regulatory requirements for medical devices in India to first-generation scientific entrepreneurs. Innovators should be able to answer questions posed by the reviewers, regulatory bodies and investors on the regulatory path. Aimed to have a fundamental understanding of the processes, essential tasks ahead, expected timelines and costs.

Base Camp outline:

Session 1: Acts, Laws, Standards (Industry Perspective)

- Overview of relevant laws, applicable acts, methods and procedures set in the rules.
- Internationally agreed, device-specific standards. Introduction to BIS, ISO, IEC, ANSI, ASTM, standards for testing.

Session 2: Guidelines & Principles

- Grouping Guidelines for Medical Device Applications.
- Essential Principles for Safety and Performance.

Session 3: Pre-clinical, Characterization & Predicate device

- Planning for regulations in pre-clinical studies.
- Planning for design, materials, and substantial equivalence (predicate device route).

Session 4: Clinical Investigation& Performance Evaluation

- Planning for Clinical study design, statistics, Clinical studies, ethical approvals, hospital partners and ethics committee.

Session 5: Manufacturing, QMS, Facility

- Planning manufacturing process and facility for devices.
- Planning for Quality Management System.

Session 6: Approvals and Post Market Regulations (Regulatory Perspective)

- Planning for marketing approvals and certifications.
- Post-market requirements in India.

Attendees:

29 people from different cities participated in the base camp. Attendees represented a variety of organizations, with the largest to smallest numbers from the startups, technology business incubators, academic sector, not for profit hospitals and research institutes.

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)	6.0 (5,7) 17
2	Quality of Staff responsiveness	6.4 (5,7) 17
3	Pace of the event (time mgmt)	5.7 (4,7) 17
4	Quality of food & beverages	5.8 (4,6) 17
5	Venture Center facility (Was it appropriate, clean & comfortable?)	6.3 (5,7) 17
6	Overall satisfaction with event organization	6.1 (4,7) 17
Section 2 – Sessions & lectures Day 1,2,3		
1	Day 1- Session 1:Acts,Laws,Standards(Industry Perspective)	5.5 (3,7) 17
2	Day - Session 2: Guidelines & Principles	5.9 (4,7) 17
3.1	Day 2- Session 3: Pre-clinical characterization & predicate device (planning for regulations in pre-clinical studies)	5.2 (3,7) 17
3.2	Day 2- Session 3: Pre-clinical characterization & predicate device(Planning for design,materails,and substantial equivalence(predicate device route)	5.8 (4,7) 17
4	Day-2-Session 4:Clinical Investigation & performance Evaluation	6.1 (4,7) 16
5.1	Day-3-Session 5:Manufacturing,QMS,Facility(planning manufacturing process & facility for devices)	5.6 (4,7) 16
5.2	Day-3 Session 5:Manufacturing,QMS,Facility(planning for Quality Management system)	5.5 (2,7) 16
6	Day-3 Session 6:Approvals & Post Marker regulations(Regulatory Perspective)	5.6 (3,6) 16
Section 3 – One on One mentoring for da1 & Day 2 (Please rate your respective mentor)		
1	Electrical Devices	6.0 (5,6) 6
2	Clinical	6.1 (5,6) 9
3	radiology & Imaging	6.1 (5,7) 8
4	QMS & Facility	5.5 (5,7) 9
5	Pre-Clinical	5.3 (4,6) 8
6	Predicate/Substantial Equivalence	5.9 (1,7) 10
Section 4 - Comments & Suggestions. Please include if the talk met your expectations.		
1	**What did you enjoy the most**	
	Regulatory sessions on last day & one-on-one mentoring session.	
	Overall hospitality & Exposure & Expertise of the guests.	
	The sequential organization of talk topics was very helpful in-broader compliance regime structure.	
	Session 2 & 4	
	Clarification of devices & Interacting with other peers.	
	Lecture of Ghooi Sir & Bose Ma'am, meeting likeminded people, food, workshop managed/conducted nicely by Priya Ma'am, Navnath Sir, and Jhaveri Ma'am & Team.	
	Interactive Sessions with experts.	
	Opportunity to interact with speakers on one to one discussion during free tea time.	
	The Talk session & Discussions, 1 &4 sessions & Individual Involvement.	

1	**What did you enjoy the most**
	Open Interactions, ease to approach, excellent responsiveness of Organizing committee.
	One-One on Mentoring along with Lectures.
	Overall event was excellent extremely informative.
	Regulatory clarity by Dr.Rubina Bose & what does a regulator does. Study Material.
	All Sessions are very useful.
	Interactions with speaker's one on one.
2	**Please suggest a topic on which you wish to have a workshop on?**
	Pricing Strategy
	Regulations only but taking one product as example tells us the regulations required.
	Case study from start to end (of compliance) of any medical Device.
	Wireless Communication & Security for Medical Devices(BLE,WiFi)
	Molecular biology basics(like the one conducted in May 2018,complete hands on, I missed it)
	Brief on ISO,QMS
	Preclinical & Clinical testing of medical devices: Regulations & Guidelines.
	Predicate Device Requirement differences between us FDA & Indian Standards.
	Funding
	FCRA, Foreign funding & their legal implication for Startups.
	Pre-Clinical & Clinical Research.
	Case Studies by Entrepreneurs on how they successfully did their regulatory pathway.
3	**How did you hear about the workshop?**

Incubator		Website		LinkedIn(2)	
Invitation		Friend		Website	
BIRAC Website		VC Mailing List (6)			
Colleague		Social Media			

4	**Was this workshop helpful in preparing your roadmap for Regulations?**								
		YES	13		NO	1	NA	1	
5	**Would you attend similar workshop on these topics?**								
		YES	14	NO	1				
6	**Is 3 days too long for a workshop?**								
		YES	2	NO	12				

7	**What changes would you like to be seen in the next base camp**
	At least 80% benefit to attend out of 100%.
	Additional templates for popular standard performance/sample documents for different standards.
	Nothing Much
	Mentorship slot allotment based on 1st day of workshop.
	It is based on Molecular Biology...
	Presentation should be on separate day, not to merge with seminar.
	Some talks with actual examples like in case of waterfall diagram.
	Something for others who are not attending one-to-one mentoring.
	One-One Mentoring More time.
	Longer duration justify the magnitude & Complexity of task.
	One mentor should work with the startup to build the case fully.
	More Mentoring
	More case studies

List of speakers & Mentors

Sr	Name	Affiliation
1	Kiran Sonaje	Axio Biosolutions Pvt Ltd, Ahmedabad
2	Saurabh Rawat	Axio Biosolutions Pvt Ltd, Ahmedabad
3	Rubina Bose	CDSCO - West Zone, Mumbai
4	P. Manickam	Consultant, Bangalore
5	Mukul Pore	INTOX Private Limited, Pune
6	Anil Chaudhari	Operon Strategist Pvt Ltd, Pune
7	Neena Sonavane	Philips India Limited, Pune
8	Ravindra Ghooi	Scientia Clinical Services, Pune
9	Arvind Savargaonkar	Streben Healthcare Pvt Ltd, Chennai
10	Navnath Kadam	Venture Center, Pune
11	Nikita Jhaveri	Venture Center, Pune
12	Premnath V	Venture Center, Pune
13	Priya Nagaraj	Venture Center, Pune

List of participants

Sr	Participant Name	Affiliation
01	Anmol Saxena	Ashva Wearable Technologies Pvt Ltd, Bangalore
02	Pratik Bhalerao	Dee Dee Labs Pvt Ltd, Pune
03	Mamta Gandhi	FastSense Diagnostics Pvt Ltd, Pune
04	Preeti Joshi	FastSense Diagnostics Pvt Ltd, Pune
05	Deval Karia	Indian Institute of Science, Bangalore
06	Manish Arora	Indian Institute of Science, Bangalore
07	Srinivas Madhusudhan Kandada	Indian Institute of Science, Bangalore
08	Kabeer Das Mandala	LV Prasad Eye Institute, Hyderabad
09	Madhava Tirukovela	LV Prasad Eye Institute, Hyderabad
10	Komal Belwade	MediAsha Technologies Pvt Ltd, Pune
11	Mayur Sanas	MediAsha Technologies Pvt Ltd, Pune
12	Sachin Dubey	Module Innovations Pvt Ltd, Pune
13	Usman khan	Module Innovations Pvt Ltd, Pune
14	Ajay Suryavanshi	Nayam Innovations Pvt Ltd, Pune
15	Tanuj Gigras	Nayam Innovations Pvt Ltd, Pune
16	Manoj Sanker P R	NeMocare Wellness Pvt Ltd, Hyderabad
17	Piyush Joshi	Orthocrafts Innovations Pvt Ltd, Pune
18	Waheed	Orthocrafts Innovations Pvt Ltd, Pune
19	Saiprasad Poyarekar	Pacify Medical Technologies Pvt Ltd, Mumbai
20	Praveen Kumar Gupta	PRADO Pvt Ltd, Pune
21	Yogesh Aher	PRADO Pvt Ltd, Pune
22	Vikas Garg	Prayasta 3D Inventions Pvt Ltd, Bangalore
23	Chirag Shah	Robo-Rehab, Mumbai
24	Sourabh Walvekar	Robo-Rehab, Mumbai
25	Nilesh Joshi	Tardigrade Private Limited, Mumbai
26	Albeena Nisar	Tata Memorial Hospital, Mumbai
27	Parag Mulye	Tenon meditech LLP, Pune
28	Aashish Mokashi	WeInnovate Biosolutions Pvt Ltd, Pune
29	Sandeep Sonawane	WeInnovate Biosolutions Pvt Ltd, Pune

Photo Gallery


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Winners of the “Best Regulatory Strategy Award”

Vikas Garg of Prayasta 3D Inventions Pvt Ltd, Bangalore
Receiving the Best Regulatory Strategy Award from Prof. Ravindra Ghooi

Tanuj Gigras and Ajay Suryavanshi of Nayam Innovations Pvt Ltd, Pune
Receiving the Best Regulatory Strategy Award from Dr. Rubina Bose

Regulatory Information and Facilitation Center

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