Report | Awareness Talk on Engineer's Perspective on the 510k Process by Akhilesh Gokhale|
Thursday | 15 February 2024

About the Event

RIFC@BRBC's awareness talk was organized on 15th February 2024. It was organized as a RIFC's outreach program with Mr. Akhilesh Gokhale, Sr. Product Manager, Enovis Foot & Ankle as the guest speaker talking about 510k step by step guide and key considerations. The event was conducted in hybrid (Offline + Online) mode.

snippets from the Awareness Talk

Session Description

The session intended to provide information on the 510k process and the key considerations when interacting with the US FDA . The workshop also provided insights on how the engineers can contribute significantly to the success of their devices in a complex and ever-evolving regulatory environment.

The session began with an overview of Venture Center and RIFC by Mr. Akash Dhade, and was followed by Akhilesh's talk on the Background, details about the US FDA market and explanation of the key considerations of 510k strategy and associated documentation. The session concluded with Akhilesh sharing the information with the case studies and his own experience tackling through the 510k process bottle necks.

Workshop Feedback:

Criteria	Avg, (Max-Min), Count
Overall satisfaction with the Event	6.6, (7-5), 19
Satisfaction with content	6.7, (7-5),1 9
Satisfaction with speakers/mentors etc	6.8, (7-5), 19
Satisfaction with the structure, design and pace of the event	6.3, (7-5), 19

Other Feedback:

- Excellent and very detailed presentation on 510(K) process and submission . Especially the examples given regarding the objections and how they were handled was great. The "DEFEND" part was a great learning. - Aniruddha Atre
- Excellent content, very thoughtful examples applicable for startups. - Chinmay Khare
- It's great to connect VC team , Enthusiastic, expertise speaker and VC Mentors. Insightful session to upskill and new learning strategies Regulatory Affairs domain. - Sambhaji A Khedkar
- Really good knowledge for the new startups - Gaurav Sahoonja
- good for information about documentation and other steps, so nice for me to got these information. - Rupali Jha

The workshop was organized with Mr. Akhilesh Gokhale and conducted at Venture Center. It presented an opportunity for understanding the US FDA 510k process and a one-on-one discussion between selective entrepreneurs and the mentor.

Meetings schedule

Sr. No.	Date	Time	Name of the participant	Name of the Company
1	15 February 2024	2.30 - 2.45 PM	Swarali Hirlekar	Serigen Mediproducts Pvt Ltd
2	15 February 2024	2.45 - 3.00 PM	Chinmay Khare	Wissenkraft Labs
3	15 February 2024	3.00 - 3.15 PM	Jayashree Rao	Intessence Solutions Pvt Ltd
4	15 February 2024	3.15 - 3.30 PM	Aniruddha Atre	Jeevtronics
5	15 February 2024	3.15 - 3.30 PM	Aniket	Avinya NeuroTech Pvt Ltd

Themes discussed:

Timeline and cost involved in getting the US FDA approval, Substantial equivalence and critical document requirements, Applicable testing standards for the products, and comparative discussion for EU and US medical device markets.

Overall Feedback: 6.6/7