

REPORT

Awareness Talk

On

Navigating FDA Premarket Notifications (510k) and Preclinical Testing:
A Practical Guide for Indian MedTech Start-ups

Tuesday | 30 September 2025

Contents

- ❖ Acknowledgement
- ❖ Introduction
- ❖ Content
- ❖ List of Speakers & Mentors
- ❖ List of Participants
- ❖ Photo Gallery

Acknowledgment

The **Awareness Talk on Navigating FDA Premarket Notifications (510k) and Preclinical Testing: A Practical Guide for Indian MedTech Start-ups**, led by **Dr. Tanmay Jain** on **September 30, 2025**, was an insightful session. Prior to this talk, a **Regulatory Clinic** which is a **one-on-one mentoring** session with the expert.

Supported By

Venture Center, Pune

Organizer

Regulatory Information and Facilitation Center (RIFC) at Venture Center, Pune

Introduction

The **Awareness Talk** and **RClinic** were designed to equip **medical device innovators and startups** with key insights into the US regulatory landscape. The expert-led talk covered crucial aspects of the US regulatory process, including the **510(k) process** and **pre-clinical testing requirements**.

The accompanying **RClinic**, conducted offline with **Dr. Jain** for selected startups, provided a valuable opportunity for **one-on-one mentoring** on navigating **US Regulatory Pathway**.

Content

Focus:

The awareness talk provided key insights on the following:

- FDA regulatory pathways and resources for med-tech startups, including how to determine substantial equivalence, select a predicate for the 510(k) Premarket Notification process, navigate timelines, and request reviewer feedback.
- Preclinical testing strategies, with focus on performance studies, biocompatibility assessments under ISO 10993, and verification and validation strategies.
- Practical examples on structuring test protocols, justifying sample sizes, documenting verification and validation results, and tips for making a submission “easy to review.”

Outline:

Tuesday, 30 Sept 2025

Session 1:

Regulatory Mentoring Clinic for shortlisted startups:

Date	Time Slot	Name	Startup Name
30 Sept 2025	2:30 - 3:00 PM	Muntazir Merchant	Qtanea Solutions Pvt. Ltd.
30 Sept 2025	3:00 - 3:30 PM	Chinmay Khare	Wissenkraft Labs
30 Sept 2025	3:30 - 3:50 PM	Yogesh Shelke	Keralink

Session 2:

Awareness Talk on “Navigating FDA Premarket Notifications (510k) and Preclinical Testing: A Practical Guide for Indian MedTech Start-ups”

Attendees:

≈ 60 people from various startups attended the talk in online mode, offline mode and on YouTube live stream.

Feedback:

During the Talk, the intentions were met; there was an exchange of information on regulatory requirements for the medical devices and diagnostics.

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

Category	Avg (Min-Max) Count
Section 1 – About the Event	
Overall Satisfaction with Awareness Talk	6.4 (6,7) 17
Satisfaction with Content	6 (6,7) 17
If you have any other suggestions, comments, etc., please share them below.	
Great	
Good information and practical info. sharing	
It would be great to have VC have consultants with US FDA expertise. We know a few consultants with expertise for US 510(k) and CE, but they are very expensive. Maybe VC could on board them as advisors and offer affordable regulated market regulatory services for startups.	
Good	
Training in Risk Management	
Session was good, for more specific questions , where we need to give background of our documents, can we arrange such session	
Informative and detailed.	
Speaker dived into the fundamentals which was very useful. Excellent talk	
Sessions like these are very crucial for startups as it prepares us well for the regulatory journey ahead. Thank you.	
Would be great if a comprehensive workshop on preclinical/clinical trials and regulatory pathways after receiving test licence.	

List of speakers & Mentors

Sr	Name	Affiliation
1	Dr. Tanmay Jain	Polymer scientist Former lead reviewer at CDRH, FDA
2	Akash Dhade	Associate Manager - Regulatory Services, Venture Center

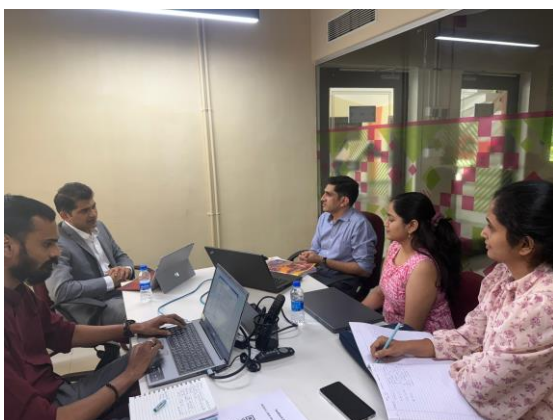
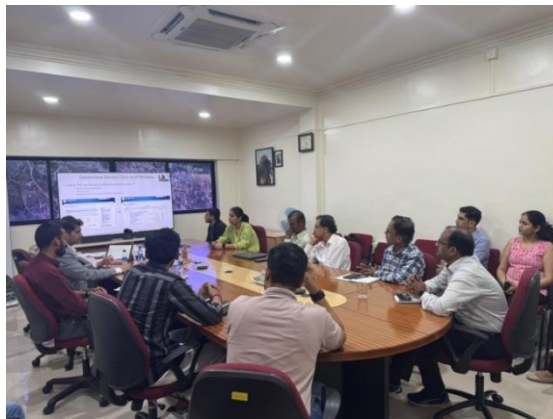
List of Participants

Sr	Participant Name	Sr	Participant Name
1.	Dr Prasad Bhawe	2.	Dr. Rinky singh
3.	Sneha Asai	4.	Vaishnavi Salunke
5.	Chinmay Khare	6.	Manjushree S P
7.	Poornima Shyam	8.	Deval Karia
9.	Varsha	10.	Deven Siddhpura
11.	Dr. S. Gandhiya Vendhan	12.	Samay Gurjar
13.	Zahir jaffer	14.	Mahadevan T
15.	Ashwin Kuchekar	16.	Dr Manjusha Joshi
17.	Aditya Kulkarni	18.	Garvit Dahiya
19.	Yogesh Dalvi	20.	Akanksha Rohit
21.	SAIPRASAD BABHALE	22.	Anuradha M
23.	Vardhan Phadnis	24.	Krishnanga Kalita
25.	Prajakta Chitnis	26.	Jayant Khandare
27.	Dr.A.Michael	28.	Sakshi Gore
29.	Amey Desai	30.	Rahul Parmar
31.	Dr. Ameya Pathak	32.	Jay
33.	RAHUL KSHIRSAGAR	34.	Kedar Badnikar
35.	Shitalkumar Zambad	36.	Nagesh C. Shanbhag
37.	Priyadarshini Parthiban	38.	Dr. Vaishali
39.	Shuchi Maitraya	40.	Yash Dadhich
41.	Abanis Nayak	42.	Sasmita Samal
43.	Anmol Saxena	44.	Jibin Varghese
45.	Saladi Pravallika	46.	Harikrishnan
47.	Roshan	48.	Prashansha Agarwal
49.	Vaibhavi Bagade	50.	Dr Pranav Agrawal
51.	Sathiya V	52.	Mahesh
53.	Dr. Mamatha M Pillai	54.	Dhanashri Oza
55.	Prajakta Ingale	56.	Dr Mukul Pore
57.	Suganth Murugaraj	58.	Devhuti Palan
59.	Gaurav Barua	60.	sonika meharval
61.	Harsh Prasad	62.	Aishwarya Yadav

63. MARIAPPAN.S	64. Suhani Sharma
65. Dr Roshan Sakharkar	66. Deepika Yadav
67. Aniruddha Atre	68. Piyush Shah
69. Subrai Pai	70. Dr. Saveen kumar S
71. Apurva Gaikwad	72. Vijay Mamtani
73. Rimzhim Arora	74. Pankaj Wani
75. Aditya Kolte	76. Indrajeet Nikam
77. Anupama Bhat	78. Rahul Kulkarni
79. Santosh Kumbhar	80. Prasad Kapadne
81. Komal Shah	82. Akanksha Deore
83. Sanjay Ingale	84. Vaishnav Wagh
85. ANSHIKA BANSAL	86. Avinash Patil
87. Sahil Chopra	88. Dr Sheebu Nair
89. Krishnadas ganapathy	90. Dr Santosh singh
91. Sivasanthosh A	92. Manish Sabharwal
93. Jayanthan Kingsley	94. Dr Neetika Ashwani
95. Manoj Sanker	96. SUCHARITHA K
97. Manoj kandpal	98. Vamsi Karatam
99. Himanshu Saxena	100. Yogesh Shelke
101. Gaurav Sharma	102. Narendra Patidar
103. Ravi Shah	104. Paras Patidar
105. samuel	106. Harshit Desai
107. Muntazir Merchant	108. Arati Deshmukh
109. Rayyan	110. Dr. Swati Shukla
111. Swardha Ghodake	112. Dr. Madhavi Pusalkar

Photo Gallery





Regulatory Information and Facilitation Centre

100, NCL Innovation Park, Dr. Homi Bhabha Road, Pashan, Pune – 411008.	+91-9156465137 rifc@web.venturecenter.co.in https://www.venturecenter.co.in/services/advisory-and-consulting/regulatory-information-and-facilitation
--	---