



**Report | Workshop to understand the Substantial Equivalence for 510(k) with the help of a case study by Akshay Joshi |  
Monday | 29 January 2024**

**About the Event**

RIFC@BRBC’s workshop was organized on 29th January 2024. It was organized as a RIFC’s program with Mr. Akshay Joshi, Junior Innovation fellow (IIT Jodhpur - AIIMS Jodhpur), (MTech, IIT Delhi) as the guest speaker talking about Substantial Equivalence section from 510k route. The event was conducted in Online mode.

**Session Description**

The session intended to provide information on the substantial equivalence aspect of the 510k process during the US FDA approval. The 510k route enables the start ups and entrepreneurs to leverage the available market data to establish the safety and efficacy of their medical device. Hence, the workshop emphasized on the techniques that can be utilised to identify the predicate device/c and establish the substantial equivalence.

The session began with an overview of Venture Center and RIFC by Mr. Akash Dhade, and was followed by Akshay’s talk on the Background, details about the US FDA market and explanation of the main routes to get US FDA approvals for medical devices. The session concluded with Akshay showcasing the substantial equivalence format based on the case studies and question answer session.

**Workshop Feedback:**

Criteria	Avg, (Max-Min), Count
Overall satisfaction with the Event	6.3, (7-5), 6
Satisfaction with content	6.3, (7-5), 6
Satisfaction with speakers/mentors etc	6.2, (7-5), 6
Satisfaction with the structure, design and pace of the event	6.3, (7-5), 6