

# Regulatory Compliances for Medical Devices & Therapeutics

Date: 13.06.2023

An introductory seminar in a hybrid mode was organized on “Regulatory Compliances for Medical Devices & Therapeutics” on 13<sup>th</sup> June 2023. The event was organized on a hybrid mode having participation of faculties, research scholars, residents and students from AIIMS, Delhi.

The topics covered during the event were:

- Introduction to regulatory compliance
- The need for regulatory clearance in healthcare
- Type of regulatory certifications
- Necessary steps to obtain certifications
- Country specific certification (CDSO, US-FDA, EU)

The topics were covered by Mr. Siddharth Jain, CEO, Symbiorph Clinical Trilogy and a consultant for various firms and start-ups working on medical devices and Dr. B. Chakraborty, Emeritus Professor, Ganpat University and a former regulatory consultant to Cadila Pharmaceuticals.

The event was attended by 18 participants in-person and 38 participants over Zoom platform.

**CENTRE FOR MEDICAL INNOVATION & ENTREPRENEURSHIP, AIIMS**  
**Organizes**  
**Workshop on Regulatory Compliances for Medical Devices and Therapeutics**  
13th June 2023 11AM Onwards  
*A Hybrid Mode Event*

**Agenda**  
11:00AM - 01:00PM - Session I - Medical Devices  
a. Indian Medical Device Rule, 2017 Overview  
b. Definition of Medical Device  
c. Classification of Medical Device  
d. Requirements and Step to perform Clinical Research for Investigators  
02:00PM - 04:00PM - Session II - Therapeutics  
a. Introduction to OECD Guidelines (A brief)  
b. Preliminary Data for Initial Clinical Trials  
c. When to approach DCGI for approval?

**SPEAKERS**  
**Siddharth Jain**  
CEO & Chief Medical Device  
Regulatory Advisor  
Symbiorph Clinical Trilogy,  
Ahmedabad,  
**Prof. B. Chakraborty**  
Emeritus Professor  
Ganpat University, Mehsana  
Consultant, Symbiorph Clinical  
Trilogy, Ahmedabad

**Meeting Venue (Max. 50 seats)**  
Centre for Medical Innovation and Entrepreneurship  
9<sup>th</sup> Floor, National Centre for Ageing  
New RAK OPD Campus, AIIMS

**Online Platform**  
zoom  
Link shared post registration

**ONLY for Faculties/ Scientists/Nursing & Technical Staffs/ Residents/Research Scholars/Students of AIIMS, Delhi**

**FREE REGISTRATION, BUT MANDATORY**  
Dr. Madhusudan Bhat  
9560257329  
Mr. Saurabh Aroxa  
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SCAN FOR REGISTRATION

LIMITED SEATS

RSVP