10,11 February 2022

Workshop on

Indian Medical Device Regulation

for startups

Course Code : IIPC127

TOPICS

- Indian medical device regulation & Recent changes
- Registration & approval process
- Classification system
- Preclinical requirements
- Clinical investigation
- QMS requirements under ISO 13485
- Sterilization, packaging & labelling requirements
- Regulatory due-diligence
- Post market surveillance

Safety , risk, performance and effectiveness of medical devices is to be ensured throughout it's lifecycle. Indian medical device regulations have seen many recent advancements thereby providing adequate guidance to manufacturers and also the authorities on ensuring the safety of the patients.

Start up ecosystem in India is getting stronger. Apart from any other segments, medical device sector calls for stringent regulations as the patient health cannot be compromised. Start ups in this segment hence requires awareness and guidance on the regulatory status that is existing in India and how to prepare for the regulatory submissions.

Sree Chitra Tirunal Institute for Medical Sciences & Technology who is in the mission of device development for more than four decades now, hereby announces this workshop to match the regulatory requirements by the start ups.

Sessions are handled by experts from the regulatory, various industry and the institute.

Eligibility : Start ups in the medical devices sector

Mode : Online lecture sessions

Registration fees : Rs 750/- inclusive of GST.

Register online : visit www.sctimst.ac.in/iipc

Certificate : Shall be issued on successful completion of training

Bank details of the Institute:

Account Name: SCTIMST,PAN Number: AAAJS0437M,

Account Number: 57001148263,IFSC Code: SBIN 0070032,

GST ID: 32AAAJS0437M1Z4

Last date of registration : 8th February 2022

Industry Institute Partnership Cell (IIPC)

Biomedical Technology Wing,

Sree Chitra Tirunal Institute for Medical Sciences & Technology,

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