



KPR Institute of
Engineering and
Technology



Report On Webinar “Regulations for Medical Devices”

Date of the Event	: 09.04.2022
Event	: Webinar
Title of the Event	: Regulations for Medical Devices
Beneficiaries	: CSE & BME Students
Objective	: 1. Fast Tracking of Registration Process – Class A & B Non-Sterile and Sterile Products Manufacturers 2. FAQs by MSME Manufacturers - an overview 3. ISO 13485 Certification - What did the Regulator Prescribe? How to choose ABs, CBs, Consultants? 4. Clean Room Guidelines - Class A & B Products (Sterile & Non-Sterile) - What needs to be addressed by Manufacturers?
KPR BME Participants	: 40
Guest Speaker - 1	: 1. Mr. Manmohan Taneja State Drug Controller – Haryana
Guest Speaker – 2	: 2. Mr. Anil Jauhri, Ex CEO – NABCB International Conformity Assessment Expert
Guest Speaker – 3	: 3. Dr. Sanjeev Kumar Gupta Managing Consultant & MedDev QMS & Regulatory Expert, InTrust Consulting LLP
Faculty Coordinator	: Mr. Rajiv Nath

A Webinar for assisting in registration process of Class A & B Medical Devices on 9th April, 2022 at 3 PM (as enclosed) followed by an FAQ Session to address the queries of Manufacturers who are challenged to register themselves online or find Consultants or get Certification to comply with regulatory requirements and CDSCO Website tour as well as introduce the various forms and online registration, payment, challan, registration numbers and modus operandi for Liason with SLA etc. and also

explanation of CDSCO organizational structure. Plus, our experts will explain on Clean Rooms, ISO Certification, Fake Certification and Classification Criteria etc.

Please find below the Agenda of the Webinar – Regulations for Medical Devices - 9th April, 2022 - 3 PM to 5.30 PM.

Registration link: https://us06web.zoom.us/webinar/register/WN_PZK83VWqTJeuOwDBdqhvZQ

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Regulations
for
Medical Devices

WEBINAR

9TH APRIL 2022, SAT

03:00 PM - 05:30 PM

**MEDICAL DEVICE
MANUFACTURERS**

**REGISTRATION OF
CLASS A & B
NON STERILE &
STERILE PRODUCTS**

**ROADMAP &
TIMELINES**

Who Should Attend ?
Medical Device Manufacturers
of Class A & B,
Non Sterile and Sterile
Products

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**PROGRAM
AGENDA**

TIME	TOPIC	SPEAKER
03:00 PM - 03:10 PM	Welcome Note	Mr Rajiv Nath, Forum Co-ordinator - AIMED
03:10 PM - 03:40 PM	Fast Tracking of Registration Process - Class A & B Non Sterile and Sterile Products Manufacturers	DG CDSCO / DDG - CDSCO
03:40 PM - 04:00 PM	Navigating through the SLA Portal for Registration Process - Virtual Tour	CDSCO Or SLA
04:00 PM - 04:20 PM	FAQs by MSME Manufacturers - an overview	Mr Manmohan Taneja State Drug Controller - Haryana
04:20 PM - 04:40 PM	ISO 13485 Certification - What did the Regulator Prescribe ? How to choose ABs, CBs, Consultants?	Mr Anil Jauhari, Ex CEO - NABCB International Conformity Assessment Expert
04:40 PM - 05:00 PM	Clean Room Cuidelines - Class A & B Products (Sterile & Non Sterile) - What needs to be addressed by Manufacturers ?	Dr Sanjeev Kumar Gupta Managing Consultant & Med Dev QMS & Regulatory Expert InTrust Consulting LLP
05:00 PM - 05:15 PM	Q & A - Audience Session	
	Vote of Thanks	

Courtesy :



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