

(An Association of Management System Consultants - Registered under Society Act)

**Online Training Sessions on
Medical Devices Quality Management Systems - ICMED 13485 & ISO
13485 Certifications**

Batch 4 from June 1st 2020 to June 16th 2020

Total No of Modules – 7

Total Number of Sessions – 13

Daily Schedule: 4 pm – 6 pm for 13 days

Training Modules :

Module	Trainer	Session Details
Module 1 – 2 days Regulations for PPEs in India, US & EU, EUA and Normal route Birds eye view of Standards , Conformity Assessments, Test Methodologies to be followed in India and Global Markets Introduction to ISO 13485 & ICMED 13485 Standards Requirements	Mr Karthi Thyagarajan Mgmt Systems Consultant Lead Consultant for AS 9100, NADCAP, ISO/TS 22163 IRIS, ISO 13485, IATF 16949 & Other Management System Consultant	Dates : June 1 st and 2 nd 2020 Time : 4 pm – 6 pm Online Test : June 3 rd 2020
Module 2 – 3 days ISO 13485 & ICMED 13485 - Product Standards, Regulatory	M G Sathyendra , Elec Engineer with 39 years of exp in Product Certification, Systems Certification.	Dates : June 4 th , 5 th & 6 th 2020

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Requirements for PPEs Planning of Product Realization and Design and Development of PPEs CE Marking Introduction	Conversant with 17025, 17020, 13485, CE Marking.	Time : 4 pm – 6 pm Online Test : June 7th 2020
Module 3 – 2 days ISO 13485 & ICMED 13485 - Risk Management Risk based thinking approach, Corrective Action based on ISO 13485	Mr Karthi Thyagarajan Mgmt Systems Consultant Lead Consultant for AS 9100, NADCAP, ISO/TS 22163 IRIS, ISO 13485, IATF 16949 & Other Management System Consultant	Dates : June 8th & 9th 2020 Time : 4 pm – 6 pm Online Test : June 10th 2020
Module 4 – 2 days ISO 13485 & ICMED 13485 - Bio compatibility & Biological Evaluation - ISO 10993:2009 requirements Sterilisation Practices	M G Sathyendra , Elec Engineer with 39 years of exp in Product Certification, Systems Certification. Dr Aniruddha Chimote Anesthesiologist & Med Equips Advisor, Health Facilities Planner	Dates : June 11th 2020 Time : 4 pm – 6 pm June 12th 2020 Time : 4 pm – 6 pm Online Test : June 13th 2020

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Module 5 – 1 day Coveralls Manufacturing – 1 day Technical Requirements , Test Standards and Practices	Industry Expert	Date : June 14 th 2020 Time : 4 – 6 pm
Module 6 – 1 day User Industry Inputs- What do ICU Teams, Critical Care Experts, Healthcare teams look for in PPEs – usability features, comfort, safety, quality etc. ISO 13485 & ICMED 13485 - Labelling Requirements Clean Room Standards & Guidelines.	Dr Aniruddha Chimote Consultant – Anaesthesiologist, Med Equip Advisor, Health Facilities Planner Mr Karthi Thyagarajan Mgmt Systems Consultant Lead Consultant for AS 9100, NADCAP, ISO/TS 22163 IRIS, ISO 13485, IATF 16949 & Other Management System Consultant Dr Aniruddha Chimote Consultant – Anaesthesiologist, Med Equip Advisor, Health Facilities Planner	Dates : June 15th 2020 Time : 4pm – 4 15 pm 4 15 – 4 45 pm 4 45 – 5 15 pm Q & A Session Online Test June 16th 2020

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Module 7 : 1 day CE Certifications USFDA Approvals ISO 13485 & ICMED 13485 Approach to ICMED Certification	Notified Body Regulatory Professional QCI PADD & NABCB Dr Manish Pandey, CEO, QCI PADD By Mr Mrutunjay Jena, Director, QCI NABCB	June 16th 2020 Time : 4 – 6 pm
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Contact Co-ordinator :

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