

5- Day Lead Auditor Course on Quality Management System requirements and Essential Principles of Safety & Performance for Medical Devices as per IS 23485:2019

Course Name	Date	Venue	Course Fee (Rs.)	Contact Details
Lead Auditor Course on Quality Management System requirements and Essential Principles of Safety & Performance for Medical Devices as per IS 23485:2019)	17-21 June 2019	National Institute of Training for Standardization Bureau of Indian Standards A 20&21, Institutional Area, Sector 62, NOIDA 201301. Phone: +91 120 4670232	Rs.26,000/- + 18% Tax = Rs.30,680/- per person Discount (10% for 2-5 persons, 15 % for more than 5 persons from the same organization)	Course Coordinator Mr. D.P. Kumar, Scientist-D Email- nits@bis.org.in Phone No 0120-4670230

Course Content

Course covers essential Principles of Safety & Performance for Medical Devices

IS 23485:2019 specifies safety requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements. Requirements of IS 23485:2019 are applicable to organizations regardless of their size and regardless of their type except where explicitly stated. Wherever requirements are specified as applying to medical devices, the requirements apply equally to associated services as supplied by the organization.

The processes required by IS 23485:2019 that are applicable to the organization, but are not performed by the organization, are the responsibility of the organization and are accounted for in the organization's quality management system by monitoring, maintaining, and controlling the processes.

The medical devices industry is one of the most highly regulated sectors in the world. Significant quality systems and product requirements must be satisfied to ensure the medical devices produced are fit for their intended purpose. Quality and safety are non-negotiable in the medical devices industry. IS 23485:2019, Medical devices - Quality management systems – Requirements for regulatory purposes, intends to help keep that level of quality up to scratch.

Who Should Attend.

Organizations certified to IS 23485:2019 wishing to transition to the new version may nominate their executives for this training programme.

How to Apply

Download [Nomination form](#) from BIS website at www.bis.org.in and submit the 'filled in' form to NITS duly filled along with requisite fee. Advance copy may be sent through email to nits@bis.org.in or dpk@bis.org.in

How to pay Course fee

Through a Demand Draft drawn in favour of Bureau of Indian Standards, payable at Noida through NEFT in the NITS savings account no 712210100000650 Bank of India Sector 62 Noida , Branch Code 7122 IFSC Code BKID0007122 mentioning name of the participant and organization and course Ref. No. LA on QMS and MNS on EPSP 17-21 JUNE 2019

Please note that NITS GST No. 09AAATB0431G2Z8 and PAN is AAATB0431G

#Hostel Facility is available and Charges per day are
For Single occupancy (inclusive of meals) Rs 2,000/-+ GST @18% per person
Double occupancy Rs 1500/- + @18 Tax per person on twin sharing basis.