



National Institute of Training for Standardization (NITS) Bureau of Indian Standards

5 DAY LEAD AUDITOR COURSE on MEDICAL DEVICES QUALITY MANAGEMENT SYSTEM (IS/ISO 13485:2016) 21 – 25 August 2023 at NITS, Noida



LEARNING OBJECTIVES

- Appreciate the purpose and benefits of a Medical Devices Quality Management System.
- Understand the requirements of ISO 13485:2016 in the context of an audit.
- Understanding MDQMS Principles in the context of the Risk Assessment and the requirements of various acts and rules applicable in the industry sector.
- Learn the role of an Auditor to plan, conduct, report and follow up on Medical Devices Quality Management System Audit in accordance with ISO 19011:2018.
- To effectively perform a full 1st, 2nd or 3rd party assessment of Medical Devices Quality Management System and generate audit findings.
- To assess the overall conformity (or otherwise) of a MDQMS to the audit criteria.

TRAINING METHODOLOGY

- Interactive Classroom Sessions.
- Workshops, case studies and auditing exercises.
- Copy of all training material.



WHO SHOULD ATTEND

- Professionals wanting to gain comprehensive knowledge about Medical Devices Quality Management System.
- Personnel responsible for implementing MDQMS.
- Expert advisors/ Consultants for Medical Devices Quality Management Systems.
- Auditors / Internal Auditors.

COURSE OUTLINE



- Structure and Overview of IS/ISO 13485:2016
- ISO 13485:2016 requirements.
- PDCA / Process approach/ Quality Management principles /Risk-based thinking.
- Audit definition and principles.
- Planning, preparation, tools, and techniques of audit.
- Post audit activities including corrective actions.
- Exercises / Workshops.
- Examination

PRE-REQUISITES

- Familiarity with the requirements of IS/ISO 13485:2016 before attending the course.

EXAMINATION/CERTIFICATION

- IRCA/NBQP accredited Lead Auditor Certificate with BIS logo on completion of course and successful qualification in an examination conducted at the end of the course.



FEE AND DISCOUNTS



- Rs. 21,000 + GST @ 18 % per participant.
- Discount of 10% for 2-5 persons and 15 % for more than 5 persons from same organization.



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PROCEDURE

The Application has to be made through BIS "Training Portal" as explained below

VISIT the E-BIS Website: www.manakonline.in

CLICK on the "Training" Head

LOGIN by clicking on the blue "LOGIN" button on the top right corner

SIGNUP by clicking on "SIGNUP" on the Member Login Page if you are not a member otherwise "SIGN IN" using your credentials

FILL OUT all the fields and click on "REGISTER" and complete the registration process.

CHOOSE the course you want to apply for, fill in the required information and "PAY" the requisite fee.

WHY CHOOSE NITS AS YOUR TRAINING PARTNER

- Advantage of being the National Standards Body of India.
- Industry-recognized Courses accredited by IRCA/NBQP.
- Rich pool of Trainers with decades of auditing experience across disciplines.
- Course contents developed by subject matter experts.
- Proven track record of delivering public, in-house, e-Learning for leading companies and recognized Government and private organizations.
- Focus on the provision of practical training using real life scenarios.
- Availability of customized training solutions.



For any further queries, you may contact:

Ruchi Gautam
Course Coordinator
nits@bis.gov.in
Mobile: 8004480245



राष्ट्रीय मानकीकरण प्रशिक्षण संस्थान, नौएडा
NATIONAL INSTITUTE OF TRAINING FOR STANDARDIZATION, NOIDA
भारतीय मानक ब्यूरो
BUREAU OF INDIAN STANDARDS

Nomination Form

Name of the Programme			
Date of the Programme		Venue:	
Sponsoring Organization (OR In Individual Capacity) with complete Address			
Telephone /Mobile Number			
Organization/Firm GST No.			
Email ID			

Participants Details

Sl. No	Name (IN CAPITAL LETTERS)	Designation	Contact No.	Email
1.				
2.				
3.				
4.				
5.				

Will you stay in Hostel ?		If Yes, Please mention the date and time					
Yes	No	Arrival	Date	Time	Departure	Date	Time

Details of Payment (in Rupees)

Training Fees *	Hostel Charges *	GST ##	Discount, if any	Total amount

Mode of Payment

Name of Bank	UTR No. & Date of transaction # (for NEFT/Net banking/ IMPS/UPI payment)	Amount (in Rs.)

* For Training/hostel fees, see NITS Training Calendar at BIS website www.bis.gov.in. (Stay in hostel is charged on Night stay basis).

For payments by **NEFT**, Payment should be made to **Bureau of Indian Standards, Savings A/c No. 712210100000650, Bank of India, Sec-62 Noida, Branch Code 7122, IFSC Code BKID0007122.**

NITS GST No. 09AAATB0431G2Z8 , SAC Code: 999294 Applicable GST@ 18% on Training fee and Hostel fee.

Date: _____

Signature and Seal _____

The nomination form should preferably be scanned and e-mailed to nits@bis.gov.in, hnits@bis.gov.in. and reach NITS at least one week before the programme date. For sending hard copy may be addressed to:

**Head , National Institute of Training for Standardization (NITS), Bureau of Indian Standards,
A – 20 & 21, Institutional Area, Sector – 62, NOIDA - 201309, U.P.**

Phones: 0120 – 4670227 , 4670232, Email: nits@bis.gov.in, hnits@bis.gov.in, Website: <http://www.bis.gov.in>

Important :

1. Participants are requested to get the confirmation from NITS, whether, nomination has been accepted or not **before attending the programme.**

2. Rules for Refund of Training & Hostel Fees :

- A refund of full fees shall be made when cancellation/withdrawal of nomination is made **at least 15 days** in advance of the date of the training.
- Cancellation/withdrawal of nomination is made **less than 15 days** in advance of the date of the training programme or is not informed, a **cancellation charge of 25%** of the training fees would be levied. The balance amount after deducting the cancellation charges would be returned.
- Hostel fees if any, paid in advance shall be returned in full.