2 Day Capsule Course on

Medical Device Quality and Risk Management

21-22 October 2024 at NITS, Noida

BUREAU OF INDIAN STANDARDS
National Institute of Training for Standardization (NITS), A 20 &21, Institutional Area, Sector 62, NOIDA - 201309

Bureau of Indian Standards (BIS) being the National Standards Body of the country discharges multitude of functions and services for enhancing the quality ecosystem in the Country. The activitiesof BIS include standards formulation at national and international level, conformity assessment schemes (Product Certification, Systems Certification, Registration and Hallmarking) testing and training. All these activities are carried out through their network of headquarters, regional and branch office and labs spread throughout the country.

Development of technical expertise of the producers and processors involved in various field of activities involved in the supply chain of products, works and services is crucial for adoption of best practices in the sector. Non-compliance to the best practices affects work or service, compromises on the health, safety and environmental impact of the process.

BIS has formulated National Standards on codes of practices almost in every field; be it Civil, Electronic, Information Technology, Food & Agriculture, Mechanical, Chemical, Petroleum, Coal & related products, Medical. It plays a vital role in promoting goods and service management through various standards that focus on general Requirements. These standards provide the guidelines and specifications for the deliverables to society and enhance the resilience and safety of goods and services offered to the community.

This 2-day course provides comprehensive insights into the quality and risk management of medical devices, focusing on international and Indian standards that govern regulatory requirements, risk management, guidance on risk application, and post-market surveillance. The training will equip participants with the knowledge and tools needed to ensure compliance with the latest standards, improve the safety and performance of medical devices, and implement robust quality management systems.

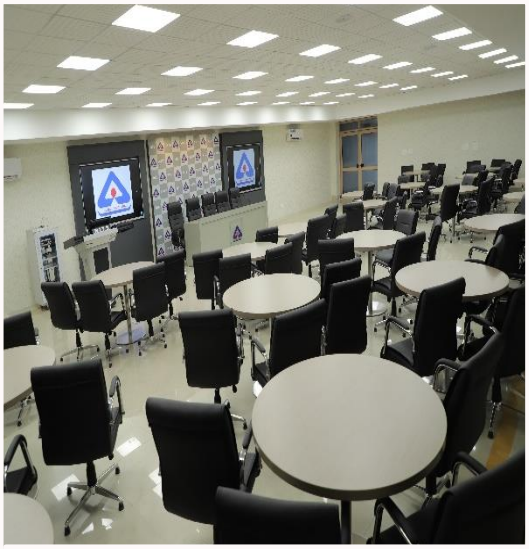
- **IS/ISO 13485:2016 -** ***Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes***
  Learn about the requirements of a quality management system tailored for medical devices, emphasizing regulatory compliance, product safety, and risk management. This will guide participants through the essential aspects of establishing and maintaining a QMS in line with global standards.
- **IS/ISO 14971:2019 -** ***Medical Devices - Application of Risk Management to Medical Devices***
  This covers the principles and processes for risk management in the development, production, and post-market phase of medical devices. Participants will explore risk identification, evaluation, control measures, and monitoring, ensuring they can apply these practices within their organizations.
- **IS/ISO/TR 24971:2020 -** ***Medical Devices - Guidance on the Application of ISO 14971***
  Gain detailed guidance on implementing risk management in compliance with ISO 14971. This includes explanations, and strategies to effectively address risk management requirements, enhancing participants' ability to manage device safety.
- **IS 18376:2023 (ISO/TR 20416:2020) -** ***Medical Devices - Post-Market Surveillance for Manufacturers***
  This emphasizes the importance of post-market surveillance as a critical component of the medical device lifecycle. Learn how to monitor product performance, address issues promptly, and maintain compliance with regulatory expectations.

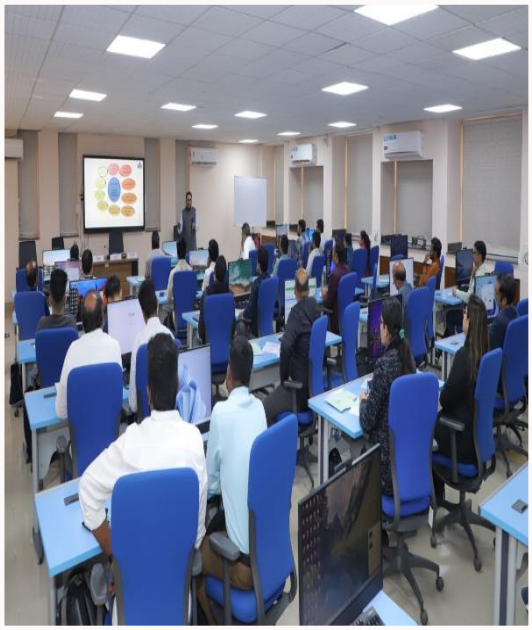
Learning Objectives

- Understand the requirements of ISO 13485 for establishing a robust Quality Management System.
- Implement risk management processes as per ISO 14971 to enhance device safety and compliance.
- Apply guidance from ISO/TR 24971 for practical risk management implementation.
- Conduct effective post-market surveillance activities in line with ISO/TR 20416.
- Enable professionals to ensure their medical devices are safe, effective, and compliant with regulatory standards throughout their lifecycle.

Training Methodology

- Classroom based with combination of lectures, presentations, videos, case studies and interactive workshops.





Fees

- **The course fee is Rs. 1500/- + 18%GST per participant.**
- Accommodation & transportation arrangement & charges have to be borne by the participant.
- **No training fees for Government Officials (Central/States/UTs) officially nominated by their department's heads.**

Who should attend?

This course is ideal for Quality Assurance and Regulatory Affairs Professionals, Medical Device Manufacturers and Designers, Risk Management and Compliance Officers, Healthcare Professionals involved in Medical Device Management, R&D and Product Development Engineers

Criteria for Selection

- Selection on First come First serve basis

Certification

- Certificate will be provided to all participants on completion of course

Venue

- The course will be held at NITS, Noida.
- Address: - National Institute of Training for Standardization, A - 20 & 21, Institutional Area,Sector-62, Noida - 201309

How to Apply?

• **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 memberotherwise "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.**
• **CHOOSE the course you want to apply for, fill in the required information and "PAY" therequisite fee.**

Contact

For any further queries, you may contact:

Ms. Ruchi Gautam
Course Coordinator
Mobile – 8004480245

Email: nits@bis.gov.in

Reach Us

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Bureau of Indian Standards
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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.				
6.				

Details of Payment (in Rupees)

Training Fees *	GST ##	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 progaramme 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 Fees :**

a) 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.
b) 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.
c) Hostel fees if any, paid in advance shall be returned in full.