TUV India Training Academy

Webinar on Application of Risk Management to Medical Devices as per ISO 14971:2019

Date : 16th June 2020, Time: 3.30pm to 5.30pm

Course Objectives

- Provide a basic understanding of Risk Management Approach in Medical Devices

Course Features

ISO 14971:2019 specifies a process for a manufacturer to identify the hazards associated with medical devices, including in vitro diagnostic (IVD) medical devices, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls.
The requirements of ISO 14971:2019 are applicable to all stages of the life-cycle of a medical device.

Who should attend ?

- Design Professionals in Medical Devices Field
- QA Professionals in Medical Devices Field
- Risk Management Professionals
- Core Team Members of Medical Devices – QMS Team
- Internal Auditors of Medical Devices QMS
- External Auditors of medical Devices QMS.
- Students having interests in Medical Devices

Course Contents

- Basic Definitions
- Risk Management Plan
- Reference Standards
- Product Design Lifecycle and Phases
- Product Description
- Responsibilities and Authorities
- Hazard Identification and Risk Analysis
- Risk Evaluation, Risk Classification and Acceptance Criteria
- Risk Treatment, Residual Risk and Further Mitigation Plan
- Risk Benefit Analysis
- Production and Post-Production Information Monitoring
- Risk Management Report

Issue of Certificate

Softcopy certificate of successful attendance shall be issued to all the delegates who attend entire duration of the course.

Duration : 120 Minutes (2 Hours)

Registration Fee : Rs. 1,250 + 18 % GST Per Participant

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Registered & Head Office-

801, Raheja Plaza I, LBS Marg, Ghatkopar (W), Mumbai 400 086
Email: trainingindia@tuv-nord.com Tel: +91-22-66477000
Website: www.tuv-nord.com/in
Toll Free: 1800-209-0902

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