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CQI & IRCA Certified Course No. 2583 – provided by TÜV NORD CERT GmbH

PR369: MD-QMS ISO 13485:2016 Lead Auditor (Medical Device - Quality Management System)

Learning objectives

The aim of this course is to provide learners with the knowledge and skills required to perform first, second and third party audits of medical device quality management systems against ISO 13485 and applicable international regulatory standards in accordance with ISO 19011 and ISO/IEC 17021. All references to standards are to the current versions, unless stated otherwise. In detail the course will provide students with the basis for becoming a competent Lead Auditor by teaching amongst others the following knowledge and skills:

- Purpose and benefits of an MD-QMS
- Role of an auditor to plan, conduct, report and follow up a quality management system audit
- Plan, conduct, report and follow up an audit of an MD-QMS to establish conformity (or otherwise) with ISO 13485 via exercises and role play
- Generating Audit Findings
- Plan-Do-Check-Act cycle and its application to medical device framework
- Differences between first-party, second-party and third-party certification audit
- Benefits of third-party accredited certification
- Terminology defined in the standard
- Requirements for MD-QMS documented information
- Verify the effectiveness of the design and development process
- Verify the control of procedures and records and the effective documentation
- Verify the competence of MD-QMS personnel

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CQI | IRCA CERTIFIED COURSE

Successful completion of the course (including examination) will result in issuance of a certificate, which may be used to support an application to become registered as an IRCA auditor. Being certified as an IRCA auditor is a clear statement showing that you are a recognized, qualified and capable auditing professional.

Recommended prior knowledge
Knowledge of the requirements of ISO 13485 is recommended e.g. by completing an ISO 13485 foundation course. Additionally knowledge about the principles and concepts of the Plan, Do, Check, Act (PDCA) cycle, the relationship between ISO 13485 and applicable international regulatory requirements for medical devices, commonly used quality management terms and definitions within ISO 13485 and ISO 9000 as well as the knowledge about the process approach used in MD-QMS will support the successful completion of the examination. A working knowledge of risk-management principles related to the design of a medical device, for example ISO 14971, should be available.

Furthermore, a working knowledge of medical device regulatory process applicable to countries of course attendance is expected for proper discussions of examples during the course. Having the prior knowledge will support the successful completion of the course since it might be part of the final examination. Learners without sufficient prior knowledge might participate in a foundation course of the respective discipline first.

Group of participants
All those who require detailed knowledge of MD-QMS auditing processes are welcome: management system consultants, management involved in ISO 13485 implementation and maintenance, personnel working with regulatory authorities, personnel carrying out 1st, 2nd and 3rd party audits and all those who require a detailed knowledge of the MD-QMS audit process. The number of learners is limited to a maximum of 20 people – except courses in VILT format, where the limit is 10 participants.

Our know-how for your success
TÜV NORD CERT is an internationally recognized and reliable partner for testing and certification services. Our experts and auditors have in-depth knowledge and generally have a permanent position at TÜV NORD. This ensures independence and neutrality, as well as continuity in serving our customers. The benefit to you is clear: our auditors accompany and support the development of your company and provide you with objective feedback.

Are you interested?
Please send this filled-out document to your local training partner by e-mail to get specific details, like dates and pricing. We look forward to hearing from you.

☐ I am interested in your training course:
13485:2016 Lead Auditor

Sender (Please print name)

Company name

First name/Last name

Position

Street

Postcode/Place

Phone **Fax**

E-mail

☐ **I confirm that I have suitable basic knowledge of MD-QMS issues.**

The data is only transferred to third parties after the current valid data protection regulations have been taken into consideration. With my signature, I accept that my data can be forwarded to a local training partner to provide me with course-specific details, like dates and pricing.

Place/Date Stamp/Signature

Find your local contact:
tuev-nord.de/en/irca/contacts-and-locations/

Contact

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24-0557-04/23