ISO 13485:2016 Medical devices QMS - Internal Auditor

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Seminar | 2 Dates available | Certificate of Attendance

Classroom training | 16 Lessons

Seminar Number: IDN-A9-PUB

Status: 26.09.2024. All current information can be found at https://academy-id.tuv.com/s/IDN-A9-PUB

Auditing the **ISO 13485:2016** quality management system for medical devices is the subject of this training. You'll gain the knowledge to efficiently plan and execute audits, checking for adherence to quality and safety regulations. Patient safety and regulatory compliance depend on the work of internal auditors to ensure that medical devices continue to meet or exceed industry standards.

And participants will learn how to identify non-conformities and evaluate the effectiveness of corrective actions, and will gain the knowledge and skills needed to effectively audit a medical device company's QMS. This training is ideal for quality managers, internal auditors, and those looking to expand their knowledge in the medical device industry.

Benefits

- Understanding of the principles and requirements of ISO 13485:2016 QMS standards for medical devices, which will help in ensuring compliance within your organization.
- Learning the process and techniques for conducting effective internal audits, which will help identify non-conformities and evaluate the effectiveness of corrective actions.
- Gaining knowledge and skills in auditing a medical device company's QMS which will help to improve the overall quality and compliance of the organization.
- Providing a platform to network and exchange ideas with other professionals in the medical device industry, which will help to improve the understanding and implementation of ISO 13485:2016 QMS standards.
- Improving the career prospects for participants by demonstrating knowledge and skills in auditing and compliance with ISO 13485:2016 QMS standards.

Target group

- Overview of ISO 13485:2016 QMS standard for medical devices, including the principles and requirements of the standard.
- The process of conducting internal audits, including the steps involved, the roles and responsibilities of the auditor, and the use of checklists and other audit tools.
- Techniques for identifying and evaluating non-conformities, and evaluating the effectiveness of corrective actions.
- Methods for reporting and documenting internal audit results, and following up on corrective actions.
- Best practices for maintaining and improving the QMS, and maintaining compliance with the standard.
- Overview of regulatory requirements and industry standards related to medical devices
- Case studies and real-life examples to illustrate the application of the standard in the medical device industry.

Requirements

No Prerequisites required. Anyone can complete this course.

Training outline

- Overview of ISO 13485:2016 QMS standard for medical devices, including the principles and requirements of the standard.
- The process of conducting internal audits, including the steps involved, the roles and responsibilities of the auditor, and the use of checklists and other audit tools.
- Techniques for identifying and evaluating non-conformities, and evaluating the effectiveness of corrective actions.
- Methods for reporting and documenting internal audit results, and following up on corrective actions.
- Best practices for maintaining and improving the QMS, and maintaining compliance with the standard.
- Overview of regulatory requirements and industry standards related to medical devices
- Case studies and real-life examples to illustrate the application of the standard in the medical device industry.

Other information

Face-to-Face Training / Classroom Terms and Conditions:

1. Laws and Regulations: This training follows the applicable laws of the country where it takes place.

2. Equipment and Internet: Participants need a computer or mobile device with reliable internet for training. The company is not responsible for technical issues with participants' equipment or internet.

3. Attendance and Completion: Participants must attend all sessions and complete coursework to receive a certificate.

4. Cancellation or Rescheduling: The company may cancel or reschedule training due to unforeseen circumstances. Participants will be notified promptly.

5. Conduct: Participants must behave ethically and professionally. Disruptive behavior, harassment, or discrimination will result in removal from training.

6. Intellectual Property: Training materials are owned by the company and may not be shared or reproduced without written permission.

7. Recording: Participants cannot record sessions without prior consent from the company.

8. Feedback and Evaluation: Participant feedback may be used for training improvement. Personal information won't be disclosed without consent.

9. Payment and Refunds: Full payment is required before training starts. Refunds are granted if the company cancels or with written notice within a specified timeframe.

10. Agreement: By registering, participants agree to the company's terms and conditions.

Event overview and booking

Book your desired date now directly online at https://academy-id.tuv.com/s/IDN-A9-PUB and benefit from these advantages:

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ISO 13485:2016 Medical devices QMS - Internal Auditor

Seminar Number: IDN-A9-PUB

Please choose an appointment you would like to book:

☐ **28/10/2024 - 29/10/2024**, Daerah Khusus Ibukota Jakarta | Event number: IDN-A9-PUB- ISO 13485:2016 Medical devices QMS - Internal Auditor
Rp 3.500.000,00 (Net price, plus VAT) Rp 3.885.000,00 (Gross price, including VAT)

☐ **19/12/2024 - 20/12/2024**, Daerah Khusus Ibukota Jakarta | Event number: IDN-A9-PUB- ISO 13485:2016 Medical devices QMS - Internal Auditor
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All further information about the dates can be found at https://academy-id.tuv.com/s/IDN-A9-PUB.

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