



ISO 13485:2016 Medical Devices Awareness

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 Seminar

 2 Dates available

 Certificate of Attendance

 Virtual learning

 8 Lessons

 Available online

Seminar Number: PH-C05-ISO13485-Aw-VC

Status: 15.04.2026. All current information can be found at <https://academy-ph.tuv.com/s/PH-C05-ISO13485-Aw-VC>

ISO 13485:2016 Medical Device Quality Management System Awareness Training provides a foundational introduction to the internationally recognized standards that govern the quality management systems specific to the medical devices industry. This training focuses on the importance of aligning organizational processes with best practices outlined in **ISO 13485:2016** to ensure safety, compliance, and efficiency in the medical device sector.

The program is delivered using a combination of instructor-led lectures, case study and exercises on practical implementation of the concepts discussed within the training. The topics presented below define the areas of focus under the program.

Benefits

At the end of the training, participants should be able to:

- **Regulatory Insight:** Gain a deep understanding of the requirements necessary for compliance with medical device regulations.
- **Quality Improvement:** Learn the best practices for quality management throughout the product lifecycle.
- **Risk Reduction:** Implement robust risk management processes to mitigate potential issues.
- **Operational Efficiency:** Drive efficiency gains and cost savings through improved processes and operations.
- **Supply Chain Excellence:** Enhance supplier monitoring and product consistency for continuous improvement.

Target group

This training is designed for individuals and teams involved in any stage of the medical device lifecycle, including:

- New Employees in the Medical Device Industry
- Quality Assurance Personnel
- Regulatory Affairs Managers
- R&D Professionals
- Supply Chain Managers

Requirements

To fully benefit from this training, participants should have:

- A foundational understanding of **ISO 9001:2015 Quality Management Systems**.
- Some experience auditing practices is recommended but not mandatory.

No advanced technical skills are required, making this training accessible to anyone looking to enhance their auditing capabilities within the ISO 13485:2016 environment.

Training outline

- Introduction to Quality Management Systems
 - Global Approach to Quality
 - Definition of Quality
 - Quality Philosophies
- QMS criteria for business practices
 - The Structure of Quality
 - PDCA / Deming Cycle
 - ISO Quality Management Framework
- Clause 1: Scope
 - Applicability
 - Lifecycle of Product
- Clause 2: Normative references
 - Reference Documents used (ISO standards)
- Clause 3: Terms and definitions
 - Acronyms & Abbreviations used in the documentation

- Clause 4: Quality Management System
 - General
 - Documentation

Other information

For payment details and inquiries, please contact academy@phl.tuv.com. Our team will guide you through the payment process and answer any questions about schedules, content, or logistics.

ADDITIONAL INFORMATION

- Training fees include materials and a certificate.
- Unless stated otherwise, fees are subject to **12% VAT**.
- A **50% down payment** is required before the first day of training. The balance is due on or before the last day.
- We accept various payment methods; please reach out for instructions.
- **For Classroom Trainings, there will be an additional ₱ 1,000 for ancillary costs.**

CANCELLATION POLICY

- TÜV Rheinland Philippines reserves the right to postpone or cancel public courses due to valid reasons.
- Unless cancelled by TÜV Rheinland Philippines, all fees are non-refundable once registration is confirmed.
- Cancellations made five days or fewer before the training date are non-refundable; full fees will be charged.
- You may nominate a substitute delegate at no extra cost. Please provide their details at least three business days beforehand.

Event overview and booking

Book your desired date now directly online at <https://academy-ph.tuv.com/s/PH-C05-ISO13485-Aw-VC> and benefit from these advantages:

- Fast booking process
- Personal customer account
- Simultaneous booking for several participants.

Alternatively, you can use the order form to order via fax or e-mail.

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I HEREBY BINDING REGISTRATION FOR THE FOLLOWING SEMINAR:

ISO 13485:2016 Medical Devices Awareness

Seminar Number: PH-C05-ISO13485-Aw-VC

Please choose an appointment you would like to book:

- 07/02/2026 - 07/02/2026**, | Event number: PH-C05-ISO13485-Aw-VC-ISO 13485:2016 Medical Devices Awareness
₹5,500.00 (Net price, plus VAT) ₹6,160.00 (Gross price, including VAT)
- 08/11/2026 - 08/11/2026**, | Event number: PH-C05-ISO13485-Aw-VC-ISO 13485:2016 Medical Devices Awareness
₹5,500.00 (Net price, plus VAT) ₹6,160.00 (Gross price, including VAT)

All further information about the dates can be found at <https://academy-ph.tuv.com/s/PH-C05-ISO13485-Aw-VC>.

Please send us **all pages** of the form by fax or email to order the above seminar.

E-mail:
academy@phl.tuv.com

Phone: +63 28128887

Please enter your order data on the next page.

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Position Title / Department (optional):

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Zip code:

City:

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Your Tax VAT (optional):

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First Name:

Last Name:

Email Address:

Phone number:

Participant information

I will participate in the seminar myself (contact details as indicated above)

The following person is to participate in the seminar:

Complete only if you are not attending yourself, but another person is.

Salutation:

First Name:

Last Name:

Email Address:

Phone number:

Date of birth (optional):

Place of birth (optional):

Payment method: Invoice

For consumers, the cancellation policy applies, which you can find under the attached terms and conditions.

I hereby accept the following general terms and conditions of the organizer (<https://academy-ph.tuv.com/terms>).

Location, date

Signature

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