


# ISO 13485:2016 Medical Devices Documentation


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 Course

 2 Dates available

 Certificate of Attendance

 Virtual learning

 8 Lessons

 Available online

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

Status: 16.03.2026. All current information can be found at <https://academy-ph.tuv.com/s/PH-C05-ISO13485-Doc-VC>

ISO 13485:2016 is the globally recognized standard for establishing a Quality Management System (QMS) dedicated to the medical devices industry. This training is designed to equip participants with a deep understanding of the standard's requirements, focusing on the creation, management, and control of documented information essential for meeting customer needs and regulatory compliance.

Embark on this essential training to master the documentation controls of ISO 13485:2016 and enhance the quality management of medical devices within your organization.

## Benefits

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

- **Enhanced Compliance:** Understand and implement the necessary practices to meet the standards of ISO 13485:2016.
- **Risk Reduction:** Learn to manage documentation effectively to avoid misunderstandings and losses in business operations.
- **Improved Efficiency:** Standardize operations and enhance the control of documents and records.
- **Knowledge Application:** Gain the ability to not only follow but also improve documentation processes within your organization.

# Target group

This course is tailored for professionals involved in the quality management and documentation of medical devices, including:

- Quality Assurance Managers
- Regulatory Affairs Specialists
- Document Controllers
- Process Engineers
- Compliance Officers

# 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

## **General Understanding of Management Systems**

- Purpose and Objective

## **Why Documentation is Critical**

- Role of Documents
- Using Documents to Control Process Outcomes

## **Document Management System Effectiveness**

- Structure and Compliance
- Naming Conventions and Documentation Standards

## **Detailed Examination of ISO 13485 Clauses**

- Clause 4: General Requirements and Documentation Information
- Clause 5: Implementation and Control of Documentation

## **Document Master List & Inventory**

## Document Workflow and Change Management

## Scope of ISO 10013:2021 Documentation Standard

## Normative References, Terms, and Definitions

### Annex A: Additional Insights

## Other information

For payment details and inquiries, please contact [academy@ph.tuv.com](mailto:academy@ph.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-Doc-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.

# Order form Page 1/3

I HEREBY BINDING REGISTRATION FOR THE FOLLOWING SEMINAR:

## ISO 13485:2016 Medical Devices Documentation

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

Please choose an appointment you would like to book:

- 07/03/2026 - 07/03/2026**, | Event number: PH-C05-ISO13485-Doc-VC-ISO 13485:2016 Medical Devices Documentation  
₹5,500.00 (Net price, plus VAT) ₹6,160.00 (Gross price, including VAT)
- 08/12/2026 - 08/12/2026**, | Event number: PH-C05-ISO13485-Doc-VC-ISO 13485:2016 Medical Devices Documentation  
₹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-Doc-VC>.

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

**E-mail:**  
[academy@phl.tuv.com](mailto:academy@phl.tuv.com)

**Phone:** +63 28128887

Please enter your order data on the next page.

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# Order form Page 2/3

- I am ordering as a consumer (private customer)
- I am ordering as a company / public authority (business customer)

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We use this data for order confirmation and invoicing.

Company name:

Position Title / Department (optional):

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Zip code:

City:

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Your internal purchase order number:

Your Tax VAT (optional):

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You can enter an internal purchase order number  
(SAP number)

## Your contact data

We use this data for order confirmation and invoicing.

Salutation:

First Name:

Last Name:

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Email Address:

Phone number:

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## 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:

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Email Address:

Phone number:

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Date of birth (optional):

Place of birth (optional):

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

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**Phone:** +63 28128887