

## ISO 13485 Foundation Training



Unichrone



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# About Unichrone

We are a professional training institute with an extensive portfolio of professional certification courses. Our training programs are meant for those who want to expand their horizons by acquiring professional certifications across the spectrum. We train small- and medium-sized organizations all around the world, including in USA, Canada, Australia, UK, Ireland and Germany.



Guaranteed Quality



Handpicked Trainers



Global Presence



Online Training Option

We've trained professionals across global companies



# Unichrone Training Advantages

- 1 Day Interactive Instructor –led Online Classroom or Group Training
- Course study materials designed by subject matter experts
- Mock Tests to prepare in a best way
- Highly qualified, expert & accredited trainers with vast experience
- Get Course Completion Certificate
- Interactive session with Case Studies
- Enrich with Industry best practices and Real Life Examples
- ISO 13485 Foundation Training Course adhered with International Standards
- End-to-end support via phone, mail, and chat

# ISO 13485 Foundation Certification Advantages




# Why should you attend?

ISO 13485 is designed to be used by organizations involved in the design, production, installation and servicing of medical devices and related services. It can also be used by internal and external parties, such as certification bodies, to help them with their auditing processes.

Below are the benefits of ISO 13485 benefits;

1. Improve your company's credibility and image
2. Improve customer satisfaction
3. Improve your processes
4. Improve decision-making
5. Create a culture of continual improvement
6. Better employee engagement

A close-up photograph of a document with a survey question. The text on the document reads "Are you eligible?" followed by two empty checkboxes. Below the checkboxes, the words "Yes" and "No" are printed. A silver pen is resting on the document, pointing towards the checkboxes. The background is a blurred yellow and blue gradient.

Are you eligible?

Yes

No

# ISO 13485 Foundation Training Course Agenda

Duration: **1 Day**

**Module 1** Introduction to ISO 13485:2016 Basic terminology and definitions of Quality Management Systems

**Module 2** Importance of ISO 13485 for an organisation

**Module 3** An Overview of ISO 13485:2016 Requirement

**Module 4** General requirements & Documentation requirements

**Module 5** Management responsibility, Resources

**Module 6** Product realisation, Infrastructure, Risk Management

**Module 7** Implementation Phases of the ISO 13485 Frameworks

**Module 8** Stages to implementation, Gap Analysis, Process mapping

**Module 9** Conducting an ISO 13485 Certification Audit

**Module 10** The relationship between ISO 13485 and ISO 9001

## **Examination**

**30 questions**

**Multiple Choice**

**60 mins Duration**

**50% Passing Mark**

**Closed Book**

# Contact Us

Email :  
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<https://unichrone.com>