ISO 13485 FOUNDATION CERTIFICATION

As per International Standards

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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

✔ Enrich with Industry best practices and case studies and present trends

✔ ISO 13485 Foundation course adhered with International Standards

✔ End-to-end support via phone, mail, and chat

✔ Convenient Weekday/Weekend ISO 13485 Foundation Training Course schedule

Importance of ISO 13485 Foundation Certification

✓ The ISO 13485:2016 standard is designed to assist businesses in maintaining the quality of medical devices. The standard specifies the requirements that organizations are required to follow while assisting medical device manufacturers. In addition, businesses that supply parts or services for manufacturing medical devices are necessitated to be certified with ISO 13485. Owning the ISO 13485 certification implies that an organization has enhanced its level of quality control for manufacturing medical devices. ISO 13485 Foundation Certification assists professionals to showcase their advanced skills in implementing MDQMS.

✓ Professionals certified with ISO 13485 Foundation indulge in developing a Medical Device Quality Management System as per the requirements. Businesses require the assistance of certified professionals while managing the MDQMS instilled within the organization. As a result, ISO 13485 Foundation Certification holders are highly sought-after.

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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

PHILIPS

AXCESS
FINACIAL PRODUCT MANAGEMENT

CLARIANT

AkerSolutions

WÜRTH

baycoat

DU PONT

DASHTI

GlobalSign

TriskeleLabs

مصرف الراجحي
Al Rajhi Bank

DHL

ARASCO   أراسـكو

ELIGIBILITY CRITERIA

✔ There are no eligibility criteria for attending ISO 13485 Foundation Training Course.

WHO SHOULD ATTEND

✔ Managers, technical experts, MDQMS team members, and any professional who wants to broaden the knowledge of the standard can take up the ISO 13485 Foundation Certification

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ISO 13485 Foundation Certification **Advantages**

CERTIFIES YOUR TALENT

HELPS BUILDING VALUES

GLOBAL RECOGNITION

PERFECT EXECUTION

BUILDS CUSTOMER LOYALTY

MORE EMPLOYABILITY OPTIONS

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Syllabus of 13485 Foundation Certification Training

Lesson 01 – Introduction to ISO 13485:2016
1. What is ISO 13485:2016?
2. Importance of ISO 13485 for an organization

Lesson 02 – An Overview of ISO 13485:2016 Requirements
1. General requirements
2. Documentation requirements
3. Management responsibility
4. Resources
5. Product realization
6. Infrastructure
7. Risk Management

Syllabus of 13485 Foundation Certification Training

Lesson 03 – Implementation Phases of the ISO 13485 Frameworks
1. Stages to implementation
2. Gap analysis
3. Process mapping

Lesson 04 – Conducting an ISO 13485 Certification Audit
1. Certification audits

Syllabus of 13485 Foundation Certification Training

Lesson 05 – The Relationship Between ISO 13485 and ISO 9001	
1.	Scope
2.	Focus
3.	Continual improvement
4.	Terminology
5.	Differences between the standards
6.	Similarities between ISO 13485 and ISO 9001

Format of 13485 Foundation Exam

Examination Format	
Exam Name	**ISO 13485 Foundation Exam**
Exam Format	Multiple Choice
Total Questions & Duration	30 Questions, 60 Minutes
Passing Score	70%
Exam Cost	Included in training fee

To get you fully prepared with the knowledge and skills for the ISO 13485 Foundation examination, a training session at Unichrone gives immense importance to mock questions at the end of every module and problem-solving exercises within the session. Prepared by certified ISO faculty, the practice tests are a true simulation of the ISO 13485 Foundation exam.

Contact Us

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