ISO 13485 INTERNAL AUDITOR CERTIFICATION

As per International Standards



UNICHRONE



Unichrone Training Advantages

- ✓ 2 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 Internal Auditor course adhered with International Standards
- ✓ End-to-end support via phone, mail, and chat
- Convenient Weekday/Weekend ISO 13485 Internal Auditor Training Course schedule

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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



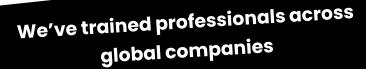
Handpicked Trainers



Global Presence



Online Training Option















































Importance of ISO 13485 Internal Auditor Certification Training

Professionals with ISO 13485 Internal Auditor Certificate play a crucial role in ensuring the organization complies with all standard requirements. They evaluate and enhance their adherence to regulatory requirements, lowering the possibility of non-compliance issues and regulatory penalties. This expertise enables them to secure lucrative jobs and increase their professional profile. Additionally, being certified in ISO 13485 is highly valuable and acknowledged globally.

ISO 13485 Internal Auditor Training teaches participants to plan and schedule an internal audit program for medical device quality management systems. It also imparts information on auditing methods, audit concepts, organizing, conducting, and reporting audits. Additionally, it discusses the main duties of an auditor as well as the structure and scope of the standard.

ELIGIBILITY CRITERIA

Aspirants need not meet any requirements to pursue ISO 13485 Internal Auditor Training Course. However, having prior knowledge of the ISO standard is beneficial.

WHO SHOULD ATTEND

Any professional who wants to advance his/her career in medical device quality management system can take up ISO 13485 Internal Auditor Course.

ISO 13485 INTERNAL AUDITOR CERTIFICATION Advantages



BUILDS CUSTOMER

LOYALTY









MORE EMPLOYABILITY OPTIONS



Lesson 01 - Introduction to ISO 13485:2016	
1.	Introduction
2.	What is ISO 13485:2016?
3.	Benefits of Implementing ISO 13485
4.	Applications of ISO 13485
5.	First Steps to ISO 13485:2016 Compliance
6.	What is a Medical Device?
7.	Purpose of a Quality Management System
8.	Importance of ISO 13485
9.	Basic Principles of ISO 13485
10.	Exercise

	Lesson 02 – ISO 13485 Clauses 1 and 2
1.	Clause 1 – Scope
2.	Clause 5 - Management Responsibilities
3.	Clause 6 - Resource Management
4.	Clause 2 - Normative References



Lesson 03 – ISO 13485 Clauses 3 and 4	
1.	Clause 3 - Terms and Definitions
2.	Clause 4 - Quality Management System
3.	Clause 4.1 General Requirements
4.	Clause 4.2 Document Requirements
5.	Exercise

Lesson 04 - Requirements and Quality Systems Requirements and Quality Systems Clause 5 - Management Responsibilities Clause 6 - Resource Management Clause 7 - Product Realization

Lesson 05 - Overview of ISO 13485:2016 Requirements	
1.	Requirements of ISO 13485:2016
2.	General Requirements
3.	Management Responsibility
4.	Resources
5.	Product Realization
6.	Infrastructure
7.	Risk Management
8.	Documentation Requirements

Lesson 06 - Implementation Phases of the ISO 13485 Frameworks Stages to Implementation Gap Analysis Process Mapping



	Lesson 07 – Conducting an ISO 13485 Certification Audit
1.	Certification Audits
2.	Exercise

Lesson 08 – Relationship Between ISO 13485 and ISO 9001 Scope Focus **Continual Improvement** Terminology Differences Between the Standards Similarities Between the Standards



Lesson 09 – Internal Auditing	
1.	Internal Auditing
2.	Internal Audit Objectives
3.	Auditing Skills
4.	Steps in Internal Auditing
5.	Planning, Preparation, and Management of Audits
6.	Internal Audit – PDCA Cycle
7.	Types of Audits
8.	Audit Techniques
9.	Exercise

	Lesson 10 – Internal Audit Plan
1.	Audit Plan
2.	Criteria



Lesson 11 – Audit Process	
Audit Process	
Conducting Process Audits	
Scope	
Criteria	
Reporting Audit Findings	

Lesson 12 - Internal Audit Evidence and Findings Internal Audit Evidence and Findings Classification **Closing Report** Nonconformities **Documented Procedure** Exercise



	Lesson 13 –Roles and Responsibilities
1.	Internal Auditor Responsibilities
2.	Closing Meetings

Lesson 14 — Resource Management and Product Realization 1. Provision of Resources 2. Infrastructure 3. Planning and Development of Products



Exam Format of ISO 13485 Internal Auditor Auditor Certification

Examination Format		
Exam Name	ISO 13485 Internal Auditor Exam	
Exam Format	Multiple Choice, Subjective- Online	
Total Questions & Duration	20 Questions, 2 Hours	
Passing Score	Minimum passing score of 70%	
Exam Cost	Included in training fee	

To get you fully prepared with the knowledge and skills for the ISO 13485 Internal Auditor, 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 Lead Auditor Exam.



support@unichrone.com



https://unichrone.com/

