

# ISO 13485 INTERNAL AUDITOR CERTIFICATION

As per International Standards



**UNICHROME**

# 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



# 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



AkerSolutions



# 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



CERTIFIES  
YOUR TALENT



HELPS  
BUILDING  
VALUES



GLOBAL  
RECOGNITION



PERFECT  
EXECUTION



BUILDS  
CUSTOMER  
LOYALTY



MORE  
EMPLOYABILITY  
OPTIONS

# Syllabus of ISO 13485 Internal Auditor Certification Training

## 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

# Syllabus of ISO 13485 Internal Auditor Certification Training

## 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

1.	Requirements and Quality Systems
2.	Clause 5 - Management Responsibilities
3.	Clause 6 - Resource Management
4.	Clause 7 - Product Realization



# Syllabus of ISO 13485 Internal Auditor Certification Training

## 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

1.	Stages to Implementation
2.	Gap Analysis
3.	Process Mapping

# Syllabus of ISO 13485 Internal Auditor Certification Training

## Lesson 07 – Conducting an ISO 13485 Certification Audit

- |    |                      |
|----|----------------------|
| 1. | Certification Audits |
| 2. | Exercise             |

## Lesson 08 – Relationship Between ISO 13485 and ISO 9001

- |    |                                    |
|----|------------------------------------|
| 1. | Scope                              |
| 2. | Focus                              |
| 3. | Continual Improvement              |
| 4. | Terminology                        |
| 5. | Differences Between the Standards  |
| 6. | Similarities Between the Standards |

# Syllabus of ISO 13485 Internal Auditor Certification Training

## 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

# Syllabus of ISO 13485 Internal Auditor Certification Training

## Lesson 11 – Audit Process

1.	Audit Process
2.	Conducting Process Audits
3.	Scope
4.	Criteria
5.	Reporting Audit Findings

## Lesson 12 – Internal Audit Evidence and Findings

1.	Internal Audit Evidence and Findings
2.	Classification
3.	Closing Report
4.	Nonconformities
5.	Documented Procedure
6.	Exercise

# Syllabus of ISO 13485 Internal Auditor Certification Training

## Lesson 13 – Roles and Responsibilities

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|----|-----------------------------------|
| 1. | Internal Auditor Responsibilities |
| 2. | Closing Meetings                  |

## Lesson 14 – Resource Management and Product Realization

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|----|--------------------------------------|
| 1. | Provision of Resources               |
| 2. | Infrastructure                       |
| 3. | Planning and Development of Products |

## Exam Format of ISO 13485 Internal Auditor Auditor Certification

Examination Format	
<b>Exam Name</b>	<b>ISO 13485 Internal Auditor Exam</b>
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.

# Contact Us

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<https://unichrone.com/>

