

# ISO 13485 LEAD AUDITOR CERTIFICATION

As per International Standards



## UNICHROME

# Unichrone Training **Advantages**

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



## Importance of ISO 13485 Lead Auditor Certification

- ✓ ISO 13485 Lead Auditor Certification entitles professionals to gain a comprehensive understanding of MDQMS. Businesses implementing the ISO 13485 standard need to conduct frequent audits of the Medical Device Quality Management System to stay up-to-date. The international standard is revised according to the changes in the industry. Organizations conduct MDQMS audits frequently, ensuring all the requirements are met. Certified ISO 13485 Lead Auditors assist such businesses in preparing for the audit, leading the audit, performing the audit, and drafting reports of the findings.
- ✓ Candidates enrolling for the ISO 13485 Lead Auditor Training course gain a deeper understanding of the Medical Device Quality Management System. The course covers the approach, brief of the ISO standard, MDQMS, and auditing procedures. Professionals attending ISO 13485 Lead Auditor Certification Training get to enhance their auditing capabilities through case studies and real-life examples.

# 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**


## ELIGIBILITY CRITERIA

- ✓ There are no eligibility criteria for attending ISO 13485 Lead Auditor Training Course. However, prior knowledge of ISO 13485 standard through ISO 13485 Foundation Certification is suggested for aspiring individuals.

## 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 Lead Auditor Certification

# ISO 13485 Lead Auditor Certification Advantages



CERTIFIES  
YOUR TALENT



HELPS  
BUILDING  
VALUES



GLOBAL  
RECOGNITION



PERFECT  
EXECUTION



BUILDS  
CUSTOMER  
LOYALTY



MORE  
EMPLOYABILITY  
OPTIONS

# Syllabus of 13485 Lead Auditor Certification Training

## Lesson 01 – Introduction

<b>1.</b>	What is ISO 13485:2016?
<b>2.</b>	Importance of ISO 13485 for an organization

## Lesson 02 – Overview of ISO 13485:2016 Requirements

<b>1.</b>	General requirements
<b>2.</b>	Documentation requirements
<b>3.</b>	Management responsibility
<b>4.</b>	Resources
<b>5.</b>	Product realization
<b>6.</b>	Infrastructure
<b>7.</b>	Risk management

# Syllabus of 13485 Lead Auditor Certification Training

## Lesson 03 – Implementation Phases of the ISO 13485 Frameworks

1.	Stages to implementation
2.	Gap analysis
3.	Process mapping

## Lesson 04 – Conducting ISO 13485 Certification Audit

1.	Certification audits
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# Syllabus of 13485 Lead Auditor 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

## Lesson 06 – Internal Auditing

1.	Internal audit objectives
2.	Auditing skills
3.	Internal audit objectives
4.	Records and follow-ups
5.	Using correct procedures in reference to the 9001:2015 standard

# Syllabus of 13485 Lead Auditor Certification Training

## Lesson 07 – Procedures

1.	Definition of scope, objectives, and policies of a QMS
2.	Analyzing implementation methodologies
3.	Methods to operate a QMS efficiently
4.	Planning, selecting and reviewing the implementation process
5.	Different ways to detect problems
6.	Roles and responsibilities of a Lead Implementer and quality team

## Lesson 08 – Implementation process based on ISO 9001

1.	Report reconciliation and documentation
2.	How to maintain QMS structure through compliance policies
3.	Sequential operation process
4.	Measurement, monitoring and controlling of errors

# Syllabus of 13485 Lead Auditor Certification Training

## Lesson 09 – Lead Auditor Training

<b>1.</b>	Roles and responsibilities of a lead auditor
<b>2.</b>	Lead Auditor requirements, scope, and procedures
<b>3.</b>	Report preparation, findings, reconciliation, and conclusions

## Lesson 10 – On-site lead auditor techniques

<b>1.</b>	Team selection and planning
<b>2.</b>	Interactive meetings
<b>3.</b>	Opening meeting
<b>4.</b>	Daily discussion meetings
<b>5.</b>	Closing meeting
<b>6.</b>	Objective of an Audit Report
<b>7.</b>	Presentation of reports
<b>8.</b>	Techniques and processes of an audit

# Syllabus of 13485 Lead Auditor Certification Training

## Lesson 11- Closure of Audit

<b>1.</b>	Prevention of errors
<b>2.</b>	Rectifying errors efficiently
<b>3.</b>	Reviewing audit strategies and plans
<b>4.</b>	Follow ups

## Lesson 12 – Methods of Collecting Information

<b>1.</b>	Visual observation
<b>2.</b>	Examination of records
<b>3.</b>	Employee interviews

## Format of 13485 Lead Auditor Exam

Examination Format	
Exam Name	ISO 13485 Lead Auditor Exam
Exam Format	Multiple Choice
Total Questions & Duration	20 Questions, 120 Minutes
Passing Score	70%
Exam Cost	Included in training fee

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

# Contact Us

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<https://unichrone.com/>

