

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



## Importance of ISO 13485 Lead Implementer Certification

- ✓ The ISO 13485:2016 standard is applicable to businesses that produce medical devices and related services. ISO 13485 Lead Implementer credential certifies that an individual possesses all the skillset required to implement a Medical Device Quality Management System in conformance with the standard. Individuals pursuing ISO 13485 Lead Implementer course are said to have a command over the implementation techniques and practices that are currently followed in the industry.
- ✓ ISO 13485 Lead Implementer Certification Training is designed for individuals who are pursuing a career in the medical device industry. The training sessions enable professionals to master the skills of applying the ISO 13485 standard and meeting its requirements. Individuals further gain the ability to design, monitor, and manage a Medical Device Quality Management System to comply with the ISO 13485 standard.

# 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      CLARIANT

AkerSolutions      WÜRTH      baycoat

DUPONT      DASHTI      GlobalSign

Triskele Labs      مصرف الراجحي Al Rajhi Bank      DHL

ARASCO      أراسكو

## ELIGIBILITY CRITERIA

- ✓ There are no eligibility criteria for attending ISO 13485 Lead Implementer 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 Implementer Certification

# ISO 13485 Lead Implementer Certification Advantages



CERTIFIES  
YOUR TALENT



HELPS  
BUILDING  
VALUES



GLOBAL  
RECOGNITION



PERFECT  
EXECUTION



BUILDS  
CUSTOMER  
LOYALTY



MORE  
EMPLOYABILITY  
OPTIONS

# Syllabus of 13485 Lead Implementer 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 Lead Implementer 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
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# Syllabus of 13485 Lead Implementer 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 Implementer Certification Training

## Lesson 07 – Internal Audit Plan

<b>1.</b>	The audit plan
<b>2.</b>	Criteria

## Lesson 08 – The Audit Process

<b>1.</b>	Conducting process audits
<b>2.</b>	Internal audit scope and criteria
<b>3.</b>	Reporting audit findings

# Syllabus of 13485 Lead Implementer Certification Training

## Lesson 09 – Internal Audit Evidence and Findings

<b>1.</b>	Classification
<b>2.</b>	The closing report
<b>3.</b>	Nonconformities
<b>4.</b>	Documented procedure

## Lesson 10 – Roles and Responsibilities

<b>1.</b>	Internal Auditor responsibilities
<b>2.</b>	Closing meeting
<b>3.</b>	Management responsibilities

# Syllabus of 13485 Lead Implementer Certification Training

## Lesson 11– Resource Management and Product Realisation

1.	Provision of resources
2.	Infrastructure
3.	Planning and development of products

## Lesson 12– ISO 13485 and Quality Management Systems

1.	ISO 13485 and Quality Management Systems
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## Lesson 13– Principles of Quality Management System

1.	Customer and regulatory focus
2.	Leadership
3.	Involvement
4.	The process approach
5.	Common tools
6.	Decision making
7.	Supplier management
8.	System management
9.	Continuous improvement

## Lesson 14– Fundamentals of Quality Management Systems

1.	Fundamentals of QMS
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# Syllabus of 13485 Lead Implementer Certification Training

## Lesson 15– Requirements and Quality Systems

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|----|----------------------------------|
| 1. | Requirements and quality systems |
|----|----------------------------------|

## Lesson 16– Measurement Analysis and Improvement

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|----|---|
| 1. | Monitoring and measurement                  |
| 2. | Control of non-conforming products          |
| 3. | The performance of the QMS                  |
| 4. | Analysis of data                            |
| 5. | Improvement of quality                      |
| 6. | Corrective action                           |
| 7. | Preventive action                           |
| 8. | Identification of improvement opportunities |

## Lesson 17– Risk Management

- |    |  |
|----|--|
| 1. | Risk management principles                 |
| 2. | The risk management process                |
| 3. | Risk lifecycle                             |
| 4. | Risk management tools                      |
| 5. | Risk management culture                    |
| 6. | Assessments and control of risk management |

## Format of 13485 Lead Implementer Exam

Examination Format	
Exam Name	ISO 13485 Lead Implementer Exam
Exam Format	Multiple Choice
Total Questions & Duration	100 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 Implementer 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 Implementer exam.

# Contact Us

[support@unichrone.com](mailto:support@unichrone.com)



<https://unichrone.com/>

