

ISO 14971 RISK MANAGEMENT FOR MEDICAL DEVICE CERTIFICATION

As per International Standards



UNICHROME

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 14971 Risk Management For Medical Device course adhered with International Standards
- ✓ End-to-end support via phone, mail, and chat
- ✓ Convenient Weekday/Weekend ISO 14971 Risk Management For Medical Device 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 14971 Risk Management For Medical Device Certification Training

- ✓ ISO 14971 standard focuses on the hazard identification feature of the medical device at every stage of its manufacturing and life cycle. It includes design, manufacture, and post-marketing surveillance. Through implementing the ISO 14971 framework, producers can estimate, examine, and control the risks. Thus, they protect people's and users' safety. This certification only certifies the products and not the organization itself. ISO 14971 Certified professionals demonstrate competence in applying this standard through certifications offered by recognized bodies.
- ✓ ISO 14971 Risk Management Certification Training offered by Unichrone opens the door for professionals to move up the career ladder. This creates employment space for well-trained individuals within the medical device industry. The program is led by industry professionals who have gained professional expertise and cover ISO 14971 in intimate detail. The gap between reiteration and understanding risk management concepts and methodologies is filled better. Participants are equipped not only with knowledge but also with a widespread understanding of it.

ELIGIBILITY CRITERIA

- ✓ Aspirants need not meet any requirements to pursue ISO 14971 Risk Management Certification Training Course. However, having prior knowledge of the ISO standard is beneficial.

WHO SHOULD ATTEND

- ✓ Any individual who wants to gain knowledge about Risk Management for Medical Devices can attend ISO 14971 Certification Training Course.

ISO 14971 RISK MANAGEMENT FOR MEDICAL DEVICE CERTIFICATION ADVANTAGES



CERTIFIES
YOUR TALENT



HELPS
BUILDING
VALUES



GLOBAL
RECOGNITION



PERFECT
EXECUTION



BUILDS
CUSTOMER
LOYALTY



MORE
EMPLOYABILITY
OPTIONS

Syllabus of ISO 14971 Risk Management For Medical Device Training

Lesson 01 – Introduction to ISO 14971

1.	Introduction
2.	Scope
3.	Terms and Definitions

Lesson 02 – General Requirements for Risk Management

1.	Risk Management Process
2.	Management Responsibilities
3.	Qualification of Personnel
4.	Risk Management Plan
5.	Risk Management File

Syllabus of ISO 14971 Risk Management For Medical Device Training

Lesson 03 – Risk Analysis

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|----|---|
| 1. | Risk Analysis Process |
| 2. | Intended Use and Reasonably Foreseeable Misuse |
| 3. | Identification of Characteristics Related to the Safety |
| 4. | Estimation of the Risk(s) for Each Hazardous Situation |

Lesson 04 – Risk Evaluation

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| 1. | Overview of Risk Evaluation |
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Syllabus of ISO 14971 Risk Management For Medical Device Training

Lesson 05 – Risk Control

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| 1. | Risk Reduction |
| 2. | Risk Control Option Analysis |
| 3. | Implementation of Risk Control Measure(s) |
| 4. | Residual Risk Evaluation |
| 5. | Risk/Benefit Analysis |
| 6. | Risks Arising from Risk Control Measures |
| 7. | Completeness of Risk Control |

Lesson 06 – Evaluation of Overall Residual Risk Acceptability

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| 1. | Risk Acceptability |
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Syllabus of ISO 14971 Risk Management For Medical Device Training

Lesson 07 – Risk Management Review

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| 1. | Risk Management |
| 2. | Effective Management of Risk |

Lesson 08 – Production and Post-Production Activities

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|----|------------------------|
| 1. | General |
| 2. | Information Collection |
| 3. | Information Review |
| 4. | Actions |

Exam Format of ISO 14971 Risk Management For Medical Device Certification

Examination Format	
Exam Name	ISO 14971 Risk Management For Medical Device Exam
Exam Format	Multiple Choice
Total Questions & Duration	30 Questions, 1 Hour
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 14971, 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 14971 Risk Management For Medical Device Exam.

Contact Us

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