



# دورة شهادة ISO 13485 لإتقان نظام إدارة جودة الأجهزة الطبية



## دورة شهادة ISO 13485 لإتقان نظام إدارة جودة الأجهزة الطبية

المرجع: 103600269\_29861 التاريخ: 05 - 09 Jan 2027 الموقع: دبي - Road Zayed Sheikh Marriott by Inn Residence  
الرسوم: Euro 6500

### Course Overview

ISO 13485 certification is a globally recognized standard for quality management systems in medical devices. This course offers a comprehensive understanding of ISO 13485 compliance, regulatory requirements, and best practices.

Participants will learn how to implement ISO 13485 to ensure their organizations meet regulatory demands and enhance product safety. The training covers key topics including differences between ISO 13485 and FDA 21 CFR 820, risk management, documentation, and audit processes.

### Target Audience

- Quality Managers responsible
- Regulatory Affairs Specialists
- ISO 13485 Consultants
- Medical Device Engineers
- Internal & Lead Auditors
- Manufacturing & Production Managers

### Targeted Organizational Departments

- Quality Assurance & Control
- Regulatory Compliance
- Manufacturing & Production
- Research & Development
- Supply Chain & Procurement

### Targeted Industries

- Medical Device Manufacturing
- Pharmaceuticals & Biotechnology
- Healthcare & Hospitals
- Regulatory & Certification Bodies
- Testing & Calibration Laboratories



## Course Offerings

By the end of this course, participants will be able to:

- Understand ISO 13485 standard requirements and its role in medical device quality assurance •
- Implement ISO 13485 best practices to enhance product safety •
- Conduct internal audits using the ISO 13485 audit checklist •
- Differentiate between ISO 13485 vs FDA 21 CFR 820 compliance requirements •
- Develop and manage ISO 13485 documentation requirements •
- Gain insights into ISO 13485 accreditation and certification steps •
- Become an ISO 13485 lead auditor or ISO 13485 lead implementer •

## Training Methodology

- Case Studies: Real-world examples of ISO 13485 compliance failures & successes •
- Workshops & Exercises: Hands-on ISO 13485 certification training activities •
- Group Discussions: Peer-to-peer knowledge exchange on ISO 13485 QMS training •
- Mock Audits: Practice applying ISO 13485 audit training techniques •

## Course Toolbox

- ISO 13485 implementation guide & templates •
- ISO 13485 compliance checklist for internal audits •
- ISO 13485 regulatory requirements reference guide •
- ISO 13485 certification exam prep materials •

## Course Agenda

### Day 1: Introduction to ISO 13485 & Regulatory Framework

- Overview of ISO 13485 certification and its importance in the medical devices industry Topic 1: •
- Understanding the medical devices quality management system QMS Topic 2: •
- Key regulatory requirements and compliance standards for ISO 13485 Topic 3: •
- ISO 13485 vs FDA 21 CFR 820: Key differences and alignment strategies Topic 4: •
- ISO 13485 documentation requirements: Essential records and reports Topic 5: •
- ISO 13485 certification process: Step-by-step guide to implementation Topic 6: •
- Key takeaways, Q&A, and discussion on regulatory challenges Reflection & Review: •



## Day 2: Implementation of ISO 13485 Quality Management System

- ISO 13485 standard requirements: Understanding the structure and clauses Topic 1: •
- Developing an ISO 13485 implementation guide for organizations Topic 2: •
- Risk management and preventive measures in ISO 13485 compliance Topic 3: •
- Internal audits and ISO 13485 compliance checklist for effective monitoring Topic 4: •
- Managing ISO 13485 accreditation and certification requirements Topic 5: •
- Integrating ISO 13485 with other quality standards for seamless compliance Topic 6: •
- Group activity and discussion on implementation challenges Reflection & Review: •

## Day 3: ISO 13485 Lead Auditor & Internal Audit Processes

- Understanding the role of an ISO 13485 lead auditor and internal auditor Topic 1: •
- Preparing an ISO 13485 audit checklist for internal and external audits Topic 2: •
- Conducting ISO 13485 audit training: Key skills and techniques Topic 3: •
- Handling non-conformities and corrective action processes Topic 4: •
- Reporting and documentation of audit findings in ISO 13485 compliance Topic 5: •
- ISO 13485 certification exam preparation and mock assessment Topic 6: •
- Interactive session on audit best practices and case studies Reflection & Review: •

## Day 4: Advanced ISO 13485 Implementation & Process Optimization

- Best practices for ISO 13485 QMS training and workforce development Topic 1: •
- Supplier management and control in ISO 13485 compliance Topic 2: •
- Enhancing medical device quality assurance through continuous improvement Topic 3: •
- ISO 13485 lead implementer strategies for effective QMS deployment Topic 4: •
- Documentation and record-keeping requirements for regulatory audits Topic 5: •
- Addressing ISO 13485 certification cost and budget considerations Topic 6: •
- Discussion on real-world implementation success stories Reflection & Review: •

## Day 5: Certification Exam & Practical Application

- Final preparation for the ISO 13485 certification exam Topic 1: •
- Conducting a full-scale internal audit simulation Topic 2: •
- Common mistakes and challenges in ISO 13485 implementation Topic 3: •
- ISO 13485 consulting services and career opportunities Topic 4: •
- Developing a roadmap for ISO 13485 accreditation and long-term compliance Topic 5: •
- Continuous improvement and maintaining compliance post-certification Topic 6: •
- Course wrap-up, certification guidance, and Q&A Reflection & Review: •

## FAQ

- What specific qualifications or prerequisites are needed for participants before enrolling in the course? •

No prior certification is required, but experience in medical device quality assurance or ISO 13485 compliance is recommended.

How long is each day's session, and what is the total course duration? •

Each session lasts 4-5 hours, with breaks and interactive discussions. The total course spans five days, approximately 20-25 hours.

What is the cost of obtaining ISO 13485 certification, and what factors affect it? •

The ISO 13485 certification cost varies based on factors such as training provider fees, company size, and accreditation body charges. Contact us for detailed pricing.

## How This Course is Different from Other ISO 13485 Training Courses

This ISO 13485 certification training goes beyond standard courses by offering:

- Real-world case studies on ISO 13485 compliance
- Hands-on exercises and mock audits for skill development
- Training for roles like ISO 13485 lead auditor and internal auditor
- Flexible online learning options

With expert trainers and a structured curriculum, this course prepares professionals for ISO 13485 accreditation and medical device industry certification.



## فئات الدورات التدريبية



HR TRAINING & DEVELOPMENT

دورات إدارة و تطوير الموارد البشرية



دورات إدارة و تحليل البيانات ودورات علم البيانات



دورات إدارة الجودة وتطوير العمليات



الدورات التدريبية في مجال البيئة والاستدامة



دورات التسويق وإدارة علاقات العملاء وإدارة المبيعات



دورات التدريب القانوني والمشتريات والتعاقدات



دورات الاتصال الجماهيري و السياسات والعلاقات العامة



دورات النظم السيبراني ودورات تقنية المعلومات



دورات الصيانة ودورات المجالات الهندسية المتنوعة



دورات الصحة والسلامة والأمن المهني



دورات السكرتارية و إدارة المكاتب



دورات الحوكمة وإدارة المخاطر والامتثال



## فئات الدورات التدريبية



دورات معتمدة بشهادة CPD



دورات في مجالات القيادة والإدارة



دورات المهارات الشخصية وتطوير الذات



دورات المحاسبة و التمويل و دورات الإدارة  
الهائية



دورات مكتب إدارة المشاريع وإدارة المشاريع  
الرشيقية



دورات معتمدة من قبل هيئات دولية

## مدن التدريب



اسطنبول - تركيا



أمستردام - هولندا



أكرا - غانا



أثينا - اليونان



الرياض - المملكة العربية السعودية



الدوحة - قطر



الدار البيضاء - المغرب



الجبيل - المملكة العربية السعودية



باريس - فرنسا



المنامة - مملكة البحرين



الكويت - الكويت



القاهرة - مصر



براغ - جمهورية التشيك



بانكوك - تايلند



بالي - جمهورية إندونيسيا



باكو - أذربيجان

## مدن التدريب



جاكرتا - جمهورية اندونيسيا



تبليسي - جورجيا



بوكيت - تايلاند



برشلونة - إسبانيا



روما - إيطاليا



دبي - الإمارات العربية المتحدة



جوهانسبرغ - جنوب إفريقيا



جنيف - سويسرا



شهر الشيخ - قطر



سيول - كوريا الجنوبية



سان دييغو - الولايات المتحدة الأمريكية



زنجبار - تنزانيا



طوكيو - اليابان



طشقند - أوزبكستان



طرابزون - تركيا



شيكاغو - الولايات المتحدة الأمريكية

## مدن التدريب



كوالالمبور - ماليزيا



فيينا - النمسا



عن بعد - منصة زووم



عمان - المهلكة الدرعية الهاشمية



ماربيا - اسبانيا



لندن - المملكة المتحدة



لانكاوي - ماليزيا



كيب تاون - جنوب إفريقيا



ميلان - إيطاليا



مونترنو - سويسرا



مسقط - سلطنة عمان



مدريد - إسبانيا



نيس - فرنسا



نيروبي - كينيا



ميونخ - ألمانيا

# WHO WE ARE

Agile Leaders is a renowned training center with a team of experienced experts in vocational training and development. With 20 years of industry experience, we are committed to helping executives and managers replace traditional practices with more effective and agile approaches.

## OUR VISION

We aspire to be the top choice training provider for organizations seeking to embrace agile business practices. As we progress towards our vision, our focus becomes increasingly customer-centric and agile.

## OUR MISSION

We are dedicated to developing value-adding, customer-centric agile training courses that deliver a clear return on investment. Guided by our core agile values, we ensure our training is actionable and impactful.

## WHAT DO WE OFFER

At Agile Leaders, we offer agile, bite-sized training courses that provide a real-life return on investment. Our courses focus on enhancing knowledge, improving skills, and changing attitudes. We achieve this through engaging and interactive training techniques, including Q&As, live discussions, games, and puzzles.



**AGILE LEADERS**  
Training Center

## CONTACT US

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