



Deming Certification Services Pvt Ltd
Studio 107,
Mehta Chambers, Navghar, Station Rd,
Vasai (W), Thane (Mumbai)
Telefax: +91 0250-2341170
Mob: +91 8369083940
+ 91 9322728183
sales@demingcert.com

Ref DCS /CO/ADM/2023-24/00

PRESENTS
Dtd: 09/010/2023

www.demingcert.com

CLASSROOM & DISTANCE LEARNING COURSE ISO 13485:2016 2 day internal auditor training

As is widely known, Deming Certification Services Pvt Ltd is conducting various technical courses inviting interested personnel/technocrats for enhancing & fine-tuning of the skill.

Deming Certification Services Pvt Ltd organizing Internal Auditor Classroom & online Training course for **ISO 13485:2016 2 day internal auditor training**

a) INTRODUCTION ON ISO 13485

The Standards Published By Iso Undergo Changes Periodically, To Reflect The Best-Suited Practices Over The Changing Times. Iso Series Of Standards For A Business Unit To Successfully Set Up An **ISO 13485:2016 2 day internal auditor training** Or Get Maximum Benefits From An Established Management System, Auditors Within The Organization Have To Be Trained To Assess The System Against For **ISO 13485:2016 2 day internal auditor training** Requirements. They Must Also Be Able To Assess Their Suppliers Required Management System To Support Own Quality Initiative. To Increase Professionalism, Quality Auditors Also Seek Formal Registration With The UKJAS (UK) One Of The Prerequisites For Such Registration Requires The Quality Auditors And Practitioners To Successfully Complete An UKJAS (UK) Approved Auditor Training.

b) OBJECTIVE OF THE COURSE ON ISO 13485

The objective of the course is to illustrate the importance of the Internal Auditors role, skills and competency in bearing the ultimate responsibility for the effective performance of the audit team. A practical and intensive course for Training quality professionals to External, Internal and manage third and second party audits of an for **ISO 13485:2016 2 day internal auditor training**



Course Describes How To Plan And Perform An Audit, Report Findings, Conduct Opening And Closing Meetings And Establish Follow-Up Action. You Will Understand By The End Of The Course How Regular Auditing By An Audit Team Directed By A Competent Internal Auditor Is The Foundation Of An Effective For **ISO 13485:2016 2 day internal auditor training** . On Completion Of The Course You Will Have The Necessary Skills And The Experience To Internal Audit And Manage Your Own Audits. The Learning Process Will Include A Series Of Tutorials, Exercises, Culminating In Both Practical And Written Examination. Delegates Will Be Supplied With A Bound Set Of Comprehensive Course Notes.

c) COURSE CONTENTS:

- Introduction For **ISO 13485:2016 2 day internal auditor training** Vocabulary & understanding definitions
- Introduction to For **ISO 13485:2016 2 day internal auditor training** Management System Requirements
- Need for Internal Quality Audits
- Auditing Techniques
- Conducting Internal Quality Audits
- Course Examination

DAY 1: INTRODUCTION TO ISO 13485:2016 AND AUDIT PLANNING

Session 1: Understanding ISO 13485

- Overview of ISO 13485:2016 and its significance in the medical device industry
- Key principles and requirements of the ISO 13485:2016 standard
- Understanding the quality management system (QMS) specific to medical devices

Session 2: Regulatory Framework for Medical Devices

- Overview of relevant regulations and standards (e.g., FDA, MDR, MDSAP)
- Understanding the role of ISO 13485:2016 in achieving regulatory compliance
- Implications of non-compliance and the importance of effective audits

Session 3: The Role of Internal Audits in ISO 13485

- Purpose and benefits of internal audits in the context of ISO 13485
- Roles and responsibilities of internal auditors in a QMS
- Overview of the audit lifecycle: Planning, execution, reporting, and follow-up

Session 4: Audit Planning for ISO 13485

- Defining the audit scope, objectives, and criteria based on ISO 13485:2016 requirements
- Developing an internal audit plan and checklist specific to the medical device industry
- Identifying key processes and areas of focus for the audit

Workshop: Creating an Audit Plan

- Hands-on exercise to develop an internal audit plan for an organization compliant with ISO 13485
- Organizing necessary resources, tools, and documentation for the audit

DAY 2: AUDIT EXECUTION, REPORTING, AND CONTINUOUS IMPROVEMENT

Session 1: Conducting the Internal Audit

- Techniques for effective evidence collection: Observations, interviews, and document reviews
- Evaluating compliance with ISO 13485:2016 requirements
- Identifying strengths, weaknesses, and nonconformities in the QMS

Session 2: Documenting and Classifying Audit Findings

- Types of audit findings: Major and minor nonconformities, observations, and opportunities for improvement
- Proper documentation of findings, including evidence collection and references
- Communicating findings effectively to management and relevant stakeholders

Session 3: Audit Reporting and Corrective Action Process

- Preparing a structured audit report: Key findings, conclusions, and recommendations
- Developing corrective and preventive action plans for identified nonconformities
- Follow-up processes to ensure the implementation and effectiveness of corrective actions

Session 4: Promoting Continuous Improvement in ISO 13485:2016 Compliance

- Strategies for fostering a culture of quality and continuous improvement in medical device manufacturing
- Preparing for external audits and ensuring readiness for certification
- Utilizing audit results to drive improvements in the QMS

Mock Audit Exercise and Final Q&A

- Practical mock audit exercise simulating an ISO 13485:2016 internal audit scenario
- Open Q&A session to clarify concepts, address challenges, and discuss best practices in auditing ISO 13485:2016 compliance

d) WHO SHOULD ATTEND:

- 1) All Employees Whose Work Responsibility Directly Affects For **ISO 13485:2016 2 day internal auditor training** Those Individuals Willing To Take Up External Auditing As A Future Profession By Becoming An Independent Auditor.
- 2) Those Who Intend To Enroll Themselves To UKJAS (UK & IND) Registration Schemes Of For **ISO 13485:2016 2 day internal auditor training**
- 3) Management Representatives Responsible For Effective Implementation And Execution Of **ISO 13485:2016 2 day internal auditor training**

e) FACILITIES:

All facility for delegates covering lecture hall, tea and lunch will be arranged by Client or if you are attending the course at Deming Certification Services. Deming Certification institute will arrange the above facility.

f) COURSE DETAILS:

Detail program of every days Training course will be sent / given on the first day to the delegates on registration.

g) DURATION:

ISO 13485:2016 2 day internal auditor training
[Timings: 10.00 am to 6.00 pm]

FEES:

ISO 13485:2016 2 day internal auditor training
Is Rs 8,500 +18%GST

Payment should be made by Cheque / DD in favor of **“Deming Certification Services Pvt Ltd, Mumbai”**

BANKERS DETILS FOR EFT/ECS/RTGS/NEFT PAYMENT

Sr. No.	Name	Details
1.	Name of Beneficiary	DEMING CERTIFICATION SERVICES PVT LTD
2.	Name of Bank	Indian Overseas Bank
3.	Bank Branch	Vasai Diwanman Branch, Vishal Nagar VASAI(W)-401202
4.	Bank Branch Code	0001295
5.	Account No	129502000000889
6.	RTGS/NEFT / IFSC Code	IOBA 0001295
7.	Account Type	CURRENT
8.	MICR code	400086009
9.	SWIFT code	IOBAINBB089
10.	Email Id	info@demingcert.com
11.	PAN No.	AVZPS7816G
12.	GST No.	27AVZPS7816G1ZN

We hereby declare that the particulars given above are correct and complete.
Thanking You

Step for Admission:

1. Select the course, you want.
2. Choose Classroom/Distance Learning
3. Pay the fees by ECS/RTGS/NEFT to our Indian Overseas Bank
4. Send transaction ID/Deposit Slip along with duly filled Registration form
5. Get Confirmation of your admission by email. Admission is based on first cum first serve basis.
6. Currently Classroom Training is only available at Mumbai and your office premises/factory, if there are more than 4 participants in the same city/factory. For outside student, Guest house facility is available of Rs 300/per day in Mumbai depends on seat availability; otherwise all ranges of hotels are available near to our institute.
7. Other cities student, who doesn't want to come Mumbai, can opt for Distance Learning Mode. Syllabus is the same. You will be given course material by email and we will recommend some books, which you can buy. Three month time will be allowed to study the course material and for any doubts and faculty interaction can be done one to one on
Skype is: Deming Certification and whatsapp video call on +91 7979801035 on Sunday between 5.00 to 8 pm. If you want Training online we can share presentation on www.googlemeet.com with live presentation. You can attend from any cities around the world.

h) **VENUE:**
Client Office
Or
Deming Certification Services Pvt Ltd
107/108, Mehta Chambers, Station Road
Vasai (W), Thane (Mumbai)-401202
Email: info@demingcert.com
Tel: +91 8369083940/+91 9322728183

i) NOMINATIONS:

You may send in your nominations to the course co-coordinator, Deming Certification Services Pvt .Ltd, on the Registration form at the following address along with the fees.

Ranjeet Prasad

+91 8369083940

107/108, Mehta Chambers, Station Road

Vasai (W), Thane (Mumbai)-401202

Email: info@demingcert.com

Tel: +91 0250-2341170

www.demingcert.com

Fees once paid will not be refunded, however it could be adjusted against the next course for the same financial year.

Please send your nomination of the delegated immediately as limited seats are available. Seats are filled on first cum first serve basis.

j) TERMS & CONDITIONS:

- I. Deming Certification Services Pvt Ltd general terms and conditions will be applicable for qualification of personnel.
- II. Minimum candidates per batch should be 04 Number and Maximum should be 25 per batch. **10% discount will be offered for** 04 Number and Maximum should be 25 per batch
- III. Delegate Fees shall be send in advance through cheque / DD in favor of **“Deming Certification Services Pvt Ltd”** payable at Mumbai.
- IV. Deming Certification Services Pvt Ltd will charge Service tax as applicable.
- V. Travel & Subsistence by 3rd AC train or economy class airfare will be charged for faculties on actual to be borne by client in case of course will be conducted in-house at client premises.



REGISTRATION FORM

PERSONAL DATA

Name in Full: _____ (In
Capital Only) Surname Name Father's/Spouse's Name

Name of the Firm & Address.....

Phone No: (With STD Code): Sex:

Mobile No: E-mail:

Date of Birth: Qualification:

Training Course:

Place: (Signature)

Date: Name:

PAYMENT MADE BY: Cheque No / Demand Draft No..... Date

Drawn on Bank:

Cheque / Demand Draft Should be drawn in favor of **Deming Certification Services Pvt Ltd** payable at Mumbai, Maharashtra, India.

Note : Fees once paid will not be refunded, however this will be carried forward for the next course during the same financial year

Deming Certification Services Pvt Ltd, 107 Mehta Chambers, Station Road, Vasai (W)
Mumbai-401 202, Tel : +91 0250- 2341170 Ext. 206 Email: info@demingcert.com

Other Offices : New Delhi, Ludhiana, Baroda, Jaipur, Udaipur, Ahmedabad, Nasik, Pune, Indore, Nagpur, Daman, Kolhapur, Bangalore, Belgaum, Hyderabad, Chennai, Kolkata.