



Deming Certification Services Pvt Ltd
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Ref DCS /CO/ADM/2023-24/00

PRESENTS
Dtd: 09/10/2023

CLASSROOM & DISTANCE LEARNING COURSE
ISO 13485:2016 Medical devices — Quality management systems
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 Medical Devices — Quality Management Systems 2 day internal auditor training**

a) Introduction of ISO 13485:2016

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 MEDICAL DEVICES — QUALITY MANAGEMENT SYSTEMS 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 MEDICAL DEVICES — QUALITY MANAGEMENT SYSTEMS 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 of ISO 13485:2016

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 MEDICAL DEVICES — QUALITY MANAGEMENT SYSTEMS 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 Medical Devices — Quality Management Systems 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 Medical Devices — Quality Management Systems 2 day internal auditor training** Vocabulary & understanding definitions
- Introduction to For **ISO 13485:2016 Medical Devices — Quality Management Systems 2 day internal auditor training** Management System Requirements
- Need for Internal Quality Audits
- Auditing Techniques
- Conducting Internal Quality Audits
- Course Examination

For detail of contents refer our website at www.Demingcert.com

d) WHO SHOULD ATTEND:

- 1) All Employees Whose Work Responsibility Directly Affects For **ISO 13485:2016 Medical Devices — Quality Management Systems 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 Medical Devices — Quality Management Systems 2 day internal auditor training 2 day internal auditor training**
- 3) Management Representatives Responsible For Effective Implementation And Execution Of **ISO 13485:2016 Medical Devices — Quality Management Systems 2 day internal auditor training**

• Day 1: ISO 13485:2016 & Internal Auditing Fundamentals

1. Introduction to Medical Device Quality Management Systems
2. Overview and Structure of ISO 13485:2016
3. Key Differences Between ISO 9001 and ISO 13485
4. Regulatory and Quality Requirements for Medical Devices
5. Quality Management System Requirements
6. Management Responsibility and Quality Objectives
7. Resource Management and Competence
8. Product Realization and Process Controls
9. Risk Management Principles for Medical Devices
10. Documentation and Record Control
11. Nonconformity, Corrective Action, and Preventive Action
12. Introduction to Internal Audit Principles
13. Audit Planning and Audit Programme
14. Preparation of Audit Checklists

15. Practical Case Study and Interactive Exercises

• **Day 2: Conducting & Reporting ISO 13485 Internal Audits**

1. Audit Preparation and Opening Meeting
2. Process-Based Auditing Approach
3. Collecting and Verifying Objective Evidence
4. Interviewing Techniques for Auditors
5. Auditing Medical Device Processes
6. Identification and Classification of Nonconformities
7. Root Cause Analysis and Corrective Action Evaluation
8. Audit Findings and Audit Evidence
9. Preparation of Internal Audit Reports
10. Closing Meeting and Follow-up Audits
11. Audit Effectiveness and Continual Improvement
12. Practical Internal Audit Simulation
13. Group Exercise: Audit Checklist and Report Preparation
14. Final Assessment and Feedback
15. Certificate Distribution

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 MEDICAL DEVICES — QUALITY MANAGEMENT SYSTEMS
2 day internal auditor training
[Timings: 10.00 am to 6.00 pm]

FEES:

ISO 13485:2016 MEDICAL DEVICES — QUALITY MANAGEMENT SYSTEMS
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”**

AXIS Bank

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.

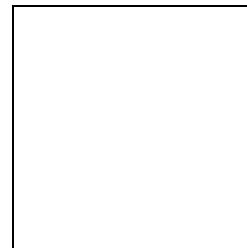
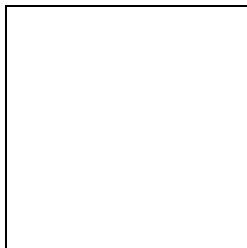
Please send your nomination of the delegated immediately as limited seats are available. Seats are filled on first cum first serve basis.

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.