Invitation to Lead Auditor Training

Mediteq is proud to host an extensive and highly interactive Lead Auditor Training course for ISO 13485:2016 in Gothenburg area in September 2023.

The course is IRCA certified and Fergal King from the IRCA approved training partner Irish Quality Centre (IQC) will be our main trainer during the five days.

Helen Sandelin from Mediteq will be co-trainer on this course. This gives an opportunity to have a bi-lingual course program, where the course material and main sessions are in English, but with the possibility to ask questions and have discussions in Swedish. The written IRCA exam will be available in English and Swedish.

You are welcome to participate if you have knowledge in ISO 13485:2016 and have multiple experience of ISO Medical Device audits as either an auditor or auditee. The more experience you have from working with QMS and auditing, the better skills you will gain from the course.

Time: 11 – 15 September 2023, at 8 – 17 o'clock

Place: Mediteq's office at Jonsereds Fabriker, Gothenburg area

Price: 32 500 SEK (excl. VAT) with 10% discount for Mediteq Forum members

Examination: The course is finalized with a written IRCA exam

Presence: You are expected to participate in scheduled training from 8 to 17 for 5 days and do tasks individually or in groups in the evenings

Preparation: Preparation tasks are expected before the course

Sign-up form: Registration

Welcome to contact us at utbildning@mediteq.se

Mediteq is a team of consultants who helps and guides you in the regulatory landscape of requirements for medical device development, market access and CE-marking. We always have clear goals, an open mindset and a long-term perspective in our deliverables.

Mediteq Svenkebo AB
Kanalstråket 1
S-433 76 Jonsered

+ 46 31 774 25 00
contact@mediteq.se
www.mediteq.se

Included in the course

Training, course manuals and course documentation, IRCA levy fee, course certificates, examination, and conference meals for 5 days including 'förmiddagsfika', lunch and 'eftermiddagsfika'. The course material and main sessions are in English, but with the possibility to ask questions and have certain discussions in Swedish. The final written IRCA exam will be available in English and Swedish.

Target audience

Auditors and internal auditors at manufacturers, contract manufacturers, suppliers, Notified Bodies and Competent Authorities as well as quality managers, regulatory managers, QMS managers and quality personnel in the medical device industry.

Required knowledge

You need to have knowledge about ISO 13485:2016 and have multiple experience of ISO Medical Device audits as either an auditor or auditee to participate in the training. There are preparation tasks to be performed before start of the course as well as homework during the course.

Course concept

During the course days you are expected to participate in scheduled training from 8 to 17 and should be able to do tasks individually or in groups in the evenings.

The training is performed in a group of up to 9 persons.

Accelerated learning is used throughout the five days. The course is highly interactive, with a live audit carried out during day 4. Other days consists mostly of case studies, individual and team exercises, and 1-to-1 discussions on many different scenarios.

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Course Objectives:

- Describe the purpose of a quality management system and explain the 7 principles of quality management
- Explain the purpose, content and interrelationship of ISO 13485, ISO 9000, GMP's, ISO 9001 and ISO 19011
- Interpret requirements of ISO 13485 and GMP's in the audit context
- Manage an audit programme
- Understand the different types of audits
- Describe the roles and responsibilities of auditors and lead auditors
- Plan and conduct an audit in accordance with ISO 19011 and demonstrating ability to;
    - Plan and prepare effectively
    - Gather objective evidence, through effective interviewing, observation, sampling and note taking
    - Analyse and interpret information in order to determine conformance with requirements
    - Report the audit, including writing valid, factual and value-adding non-conformity reports
    - Undertake audit follow-up activities, including evaluating the effectiveness of corrective action
    - Professionally liaise with external auditors

During the course, the participants will acquire knowledge and skills in auditing. Auditing, like any other acquired skill, requires practice and the best place to practice and extend your experience is during actual audits.

The tutors

Fergal King from IQC has been auditing for more than 25 years and 17 within the medical device industry and has been a Lead Auditor Trainer at IQC since 2018. IQC's success rate on the course is over 95%.

Helen Sandelin from Mediteq has within the medical device industry for 20 years and as a Lead Auditor since 2010.

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Live audit opportunity

We are happy to give the participants a live audit experience during this training. It will be performed at a medical device manufacturer within the Gothenburg Area on Thursday 14th of September.

Course approval and examination

This course is internationally approved by IRCA (www.irca.org).

There is continuous assessment throughout the course and a 2-hour written examination at the end. To successfully complete the course, participants are required to pass both the written examination and the continuous assessment.

IQC Irish Quality Centre

CQI | IRCA
APPROVED TRAINING PARTNER

Conference center

We will spend the training days at Mediteq's office at Jonsereds Fabriker, with beautiful views and surroundings. You get here easily by car or by a short ride with commuter train from Gothenburg central station to Jonsered's Station and a following 2 minutes' walk.

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Accomodation

We recommend accommodation at any of the hotels or other accommodations around Gothenburg's Central Station, such as Clarion Hotel Post, First Hotel G, Hotel Opera, Radisson, or Hotel Eggers.

Payment conditions

You will be invoiced a registration fee of 5 000 SEK to be paid within 10 days after your registration. Full payment for the course will be invoiced for payment 1st of September 2023.

Cancellation conditions

Registration is legally binding. When cancellation less than 4 weeks before the start of the training, 50% of the training fee will be invoiced. When cancellation less than 2 weeks before the start of the training, full training fee will be invoiced. Written cancellation is required to utbildning@mediteq.se and needs to be confirmed by Mediteq.

Mediteq has the right to cancel the training due too few participants or under other circumstances out of Mediteq's control up to 10 working days before the training. Mediteq is not responsible for any expenses associated with a cancelled training, such as travels or accommodation.

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