

TRAINING BROCHURE

QMS ISO 9001:2015
Lead Auditor

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Introduction

The nature of internal quality audits is changing. In the past, they were done to examine compliance with standards. Now they are evolving to be more of an activity to improve the company's business processes.

ISO 9001 makes this clear through its requirements. Among other things, you now must examine whether the customer's requirements and expectations are really met by the company's products as well as if the system is effective and achieves results. This introduces a new approach to auditing, which places new demands on auditors.

IRCA certified

This course is certified by the International Register of Certificated Auditors, IRCA, in England. The course registration number with the IRCA is A18111.

Compared to a regular auditing course, this course has the added benefit of, once you have passed, entitling you to apply for registration as an auditor with IRCA. Please note that the course only provides you with the audit training you need. In addition to this, IRCA has other requirements – such as audit experience – for you to register.

Pre-requisites and rules

The IRCA has extensive requirements for auditing courses, and they apply to this course.

The participant should have some prior knowledge of the content, application, and implementation of the ISO 9000 series. If you do not, we recommend that you attend one of the courses "Internal audits - ISO 9001" or "ISO 9001 Basic Course".

The participant must be present for the entire duration of the course. Cell phones or similar devices interfere with the course and disturb other participants and must therefore remain switched off during the course. Exceptions for special needs can be made.

Examination and course certificates

Throughout the course, you will be continuously evaluated against the learning objectives. Both



performance in workshops and during the rest of the course are assessed. A participant who fails the continuous assessment must repeat the entire course again.

There is a comprehensive written test on the last day. A trainee who fails the written test but passes the continuous assessment is entitled to take a re-test, which must be taken within 12 months of the last day of the course to be approved by IRCA. Should the participant fail the retest, he/she will have to retake the entire course.

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If the participant passes both the continuous assessment and the final exam, a course certificate is issued. This is an important basis for applying for IRCA registration. Please note that IRCA only accepts qualifications that are no more than 3 years old. As a basis for an IRCA application, the diploma (Certificate of Successful Completion) has a limited validity of 3 years from the last day of the course.

In case of unsuccessful results, a certificate of attendance is issued.

The aim of the course

The aim of the course is to provide prospective second and third-party auditors with adequate audit training, by meeting the IRCA training objectives.

The training should ensure that participants who successfully complete the training have sufficient knowledge to perform second and third-party audits.

Through exposure to realistic situations, participants are prepared to lead audits of external companies.

IRCA training objectives

After completing the course, participants should be able to:

- Describe the purpose of quality systems and describe the 8 quality management principles.
 - Explain the purpose, content, and interrelationship of ISO 9000, ISO 9001, ISO 9004, and ISO 19011.
 - Interpret the requirements of ISO 9001 in an auditing context.
 - Describe the roles and responsibilities of auditors and audit managers.
 - Plan and conduct an audit in accordance with ISO 19011, demonstrating the ability to:
 - a) Plan and prepare effectively.
 - b) Gather objective evidence through effective interviews, observations, sampling, and record keeping.
 - c) Analyze and interpret information to determine compliance with requirements.
- Report the audit, including fact-based and value-added deviation reports.
 - Conduct follow-up activities, including evaluation of the effectiveness of corrective actions.

Who is it for?

Professionals who build and audit Quality Management Systems in companies and auditors of certification bodies attend this training. Individuals who are involved in supplier assessments and supplier development are also regular participants.

Assignment

About two weeks before the course, you will receive a homework assignment, which must be completed by the start of the course. The time it takes depends on your prior knowledge. A reasonably experienced participant should plan for 8-10 hours, spread out over a few days.

Training methodology

The course is structured around your work on solving cases. More than half of the course time is devoted to practical exercises in groups. In this way, we provide very extensive training in how to act in real-life situations. Additionally, you will be trained in interview methodology and presentation skills. For best result, we recommend that you repeat each day's activities outside of the scheduled time. The training is therefore carried out in boarding school format.

Do not expect to do anything else in the evenings. The time is needed for the cases and for the assignments for the exam. On the evening of the fourth day, there is a one-hour compulsory session where the results of a practice test are discussed individually with a lecturer.

The lecturers

The training is given by lecturers with cutting-edge knowledge, extensive experience, and good teaching skills. All lecturers have practical consulting and auditing experience and can provide examples from real-life situations. The lecturers are all IRCA-registered Lead Auditors.

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Contents

Introduction

- Program.
- Introduction.

Background

- Background to audits.
- Quality management principles.

Interpreting ISO 9001

- Terminology.
- The ISO 9000 series.
- Content of ISO 9001.

Audit of ...

- Documentation of a quality system.
- Quality policy.
- Management review.
- Design and projects.
- Production of goods.

General information about audits

- Quality audits.
- Third-party certification.
- The audit process.

Conducting an audit

- Planning and preparation.
- Opening meeting.
- Conducting the audit.
- Guides.
- The auditor and the auditee.
- Documentation, closure meeting and follow-up.
- Common quality tools.

Others

- Qualification of auditors.

Homework assignment

- Homework assignment.

Standard

- ISO 9001:2015.

Cases

- What is important?
- Getting familiar with ISO 9001.
- Summarizing requirement elements.

- Document review.
- Preparation of the audit.
- Preparation of checklists.
- Conducting the audit, parts 1-4.
- Quiz walk.
- Observation reports.
- Summary in words.
- Corrective action and follow-up.

Program

Day 1

09.00–19.30

- Introduction, overview of the program, objectives of the course.
- Why audits are done, basic concepts.
- *Coffee*
- Audit of: Main process map and process management.
- Case 1: What is important?
- *Lunch*
- Review of case 1.
- Revision of: Documentation.
- Case 2-1: Interpreting ISO 9001.
- *Coffee*
- Review of case study 2-1.
- Revision of: Management responsibilities.
- Case 2-2: Interpreting ISO 9001.
- *"Fruit break"*
- Review of Case 2-1.
- Revision of: Design, purchasing and production.
- Case 2-3: Interpreting ISO 9001.
- *Dinner*
- Private studies.

Day 2

09.00–19.30

- Looking back at the previous day.
- Review of Cases 2-3.
- Revision of: Measurement, analysis, and improvement.
- Case 2-4: Interpreting ISO 9001.
- *Coffee*
- Review of Cases 2-4.
- Quality audits, third party certification.
- Audit process: Audit program, preparation, document review.
- *Lunch*
- Continued. Audit process: Audit program, preparation, document review.
- Case 3: Document review.

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- Review of case study 3.
- *Coffee*
- Case 4: Preparation of the audit.
- Review of case 4.
- “Fruit break”
- Checklists.
- Case 5: Preparation of checklists.
- Summary of day 2, private studies.
- *Dinner*

Day 3

08.00–17.00

- Looking back at the previous day.
- Review of Case 5.
- Opening meeting, execution of audit.
- *Coffee*
- Case 6: Conducting the audit Part 1: Preparation.
- Case 6: Conducting the audit Part 2: Interviewing.
- *Lunch*
- Case 6, cont.: Conducting an audit Part 2: Interviewing.
- Joint discussion on interviews.
- Case 7: Quiz walk.
- *Coffee*
- Documentation of the audit, observation reports.
- Case 8: Observation reports.
- “Fruit break”
- Review of Case 8.
- Summary of day 3, private studies.
- *Dinner*

Day 4

08.00–17.00

- Looking back at the previous day.
- The auditor and the auditee.
- Closing meeting.
- Case 6: Conducting the audit Part 3: Summing up.
- *Coffee*
- Case 6, cont., Part 3.
- Case 6: Conducting the audit Part 4: Closing meeting.
- *Lunch*
- Case 6, cont.: Conducting the audit Part 4: Closing meeting.
- Joint discussion.
- Case 9: Summary in words.
- *Coffee*
- Review of case 9.
- Practice test.

- Summary of day 4.
- *Dinner*
- Private studies.
In the evening: a 1-hour mandatory individual review of the practice test (45 min alone, 15 min with lecturer).

Day 5

08.00–17.00

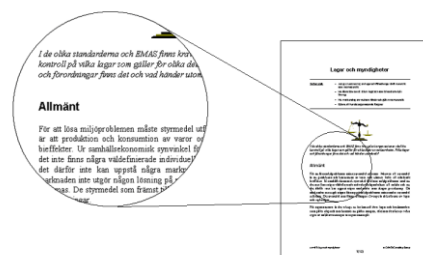
- Looking back at the previous day.
- Corrective actions and follow-up.
- Case 10: Corrective actions and follow-up.
- *Coffee*
- Review of case 10.
- Certification and registration of auditors.
- Repetition of the course.
- Evaluation of the course.
- *Lunch*
- Test.
- Coffee and conclusion.

Course certificate

A certificate of attendance will be issued for participation on all days of the course.

Course material

The course material consists of a course binder in which the different lectures are documented in detail. It is detailed enough to be used as a reference book in daily work.



Our goal is to always offer the best training material on the market.

Course fee

The price per participant is specified in the training calendar. The price includes full course documentation, lunch, and morning and afternoon coffee.

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Our training methodology

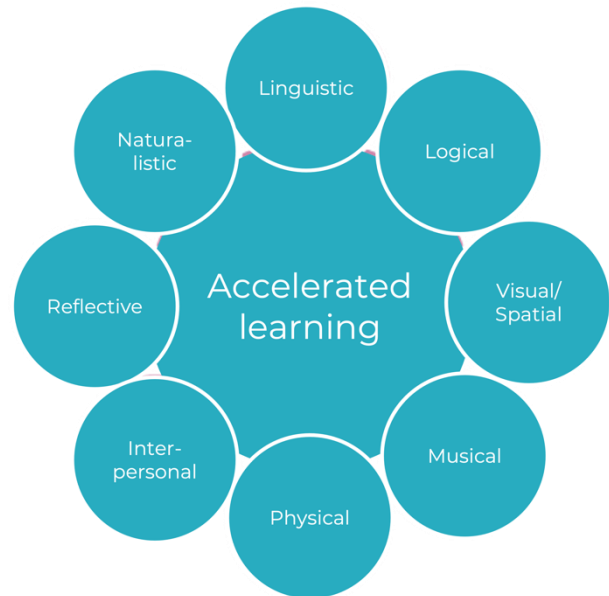
We run both open and in-house training courses. Knowledge is the basis for fact-based decisions and a prerequisite for engaging management and staff. Knowledge is part of our approach to changing behavior. Simply providing information is seldom enough to make people act differently.



The staircase model for information transfer and processing of values and attitudes

We complement the information with methods to address the values and attitudes of the participants. Through well-thought-out workshops, we go through all stages of the learning process. In in-house training, we often use the staircase model (see picture above) with training in the company's own operations and follow-up.

To further customize the training, company visits and consultations with our experienced consultants often precede in-house training. Part of our strength is that we can offer a complete solution for each company's training needs, from operator level to senior management. Our training courses are based on best practices from practical work in companies, where the lecturer provides many real-life examples. This is combined with a theoretical foundation.



The Accelerated Learning methodology, which involves stimulating learning with all the senses, is widely applied. The training group should consist of a maximum of 20 people, which gives the lecturer the opportunity to activate all participants in discussions. By alternating theory with activities and workshops, participants are given the opportunity to apply what they learned, which facilitates learning.

Contact us for more information:

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CANEA – lasting success

There are three key factors for a successful change process: Competence to create and drive the change. IT systems that control and support it properly. And relevant know-how among your employees to maintain it over time. We are unique in bringing these three factors together in an integrated offering. This is a key reason why we have been able to deliver great results to hundreds of customers over the past 20 years.



CANEA Management – making your organization better

Our experience from numerous assignments shows that there are valuable opportunities for improvement in every organization. To meet increasingly stringent requirements, it is important to develop your own operations.

We have extensive experience with what works. This is gathered in our own method library, which forms the core of our knowledge and experience management. Based on each client's situation, an adaptation is made so that both the whole and the details work.

Our consultants understand both the whole and the details of an organization's environment, function, and management. Additionally, they have well-developed analytical mindsets and the ability to motivate. Teaching skills are also a given since we place great emphasis on knowledge transfer.

CANEA ONE – an integrated software suite

CANEA ONE is a comprehensive software suite for effective business management. The system enables control, implementation, monitoring and improvement of the business thanks to a fully integrated management of strategies, projects, processes, cases and documents.



CANEA Document

A document management system that creates order. Ideally managing an integrated management system.



CANEA Workflow

A case management system that allows you to design, deploy and monitor all types of workflows in a single solution.



CANEA Project

A comprehensive and easy-to-use project, portfolio, and resource management system supporting all aspects of project activities.



CANEA Process

An effective solution for modeling, communicating, collaborating, and improving business processes.



CANEA Strategy

Enables strategy activation through smart features such as goal decomposition, communication, and visualization.

