

BLENDED (ONLINE + CLASSROOM) ISO 13485:2016 INTERNAL AUDITOR

COURSE OVERVIEW

Our CQI & IRCA Certified Blended ISO 13485:2016 Internal Auditor Course is ideal for anyone that has a basic understanding of Quality Management Systems (QMS) and the requirements of ISO 13485:2016 and needs to perform an internal audit of part of their QMS.

Course Format:	Blended (6hrs Online + 1-day Classroom)	Certification:	CQI & IRCA (No. 2286)
Blended Types:	Traditional or Virtual Classroom		
Duration:	16 hours		
Course Fee:	€595 per person		
Fee Includes:	Comprehensive Course Manual Phone & Email Support (Online Modules) Lunch & Refreshments (Public/Traditional Dates)		



COURSE CONTENT - ONLINE & SELF-PACED MODULES

Each Learner will first complete the following online & self-paced modules (in advance of their scheduled traditional or virtual classroom workshop):

Module 1 - Introduction to Quality Management Systems

- Overview of ISO 13485:2016
- Purpose & Benefits of ISO 13485:2016
- Structure of ISO 13485:2016
- Regulatory Requirements
- Key Terminology (ISO 13485:2016)
- Plan-Do-Check-Act Cycle
- ISO 13485 Process Requirements
- QMS Process Model
- Risk Based Thinking

Module 2 - Introduction to QMS Auditing

- ISO13485InternalAuditRequirements
- Introduction to ISO 19011:2018
- Key Terms & Definitions (ISO 19011)
- Internal Audit Program Management, Objectives & Risks
- Onsite & Remote Audits
- Principles of Auditing
- Audit Lifecycle
- Auditor Roles & Responsibilities
- Desired Auditor Behaviours

Module 3 - Initiation & Preparation

- Audit Planning
- Audit Objective, Scope & Criteria
- Selection of Audit Team & Leader
- Determination of Audit Feasibility
- Document Review
- Audit Preparation
- Audit Plan
- Audit Checklist

Module 4 - Conducting Audit Activities

- Opening Meeting
- Communication during the Audit
- Collecting & Verifying Information
- Generating Audit Findings
- Document Review

Module 5 - Report, Close and Follow up the Audit

- Non-Conformity Reporting
- Closing Meeting
- Audit Report
- Report Distribution
- Completing the Audit
- Audit Follow Up

BLENDED (ONLINE + CLASSROOM) ISO 13485:2016 INTERNAL AUDITOR

ASSESSMENT METHODOLOGY

To complete the course successfully, each Learner must:

Online & Self-Paced Modules

- Achieve an overall score of at least 70% in the online final assessment which will be available after all modules are completed (must be completed in advance of the classroom portion)

Traditional or Virtual Classroom Modules

- Fully attend and successfully complete the continuous assessments during all classroom-based modules

COURSE CONTENT - CLASSROOM MODULES

Traditional Classroom Times*

Day 1 - 8am - 6pm

Virtual Classroom Times*

Day 1 - 8:00am - 5:30pm

Once the online modules are completed, each Learner will attend a 1-day traditional or virtual classroom* workshop, where we will *put the theory into context* with highly interactive and engaging practical skills-based sessions that focus on:

- Initiating the Audit
- Conducting the Audit
- Preparing the Audit Report
- Conducting a Closing Meeting
- Following up the Audit Findings

**Subject to Change/By Assignment.*

FREE FOUNDATION COURSE INCLUDED

Each Learner can receive a *free license for* our Online & Self-Paced ISO 13485:2016 Foundation Course (worth €395). Completion of this course will ensure every Learner meets all of the prior learning requirements and is better prepared for the course!

Have a Question? Need a Quote?

Get in touch with our team today!

Email: training@complyguru.ie

Phone: (061) 529100

BLENDDED (ONLINE + CLASSROOM) ISO 13485:2016 INTERNAL AUDITOR

ENTRY REQUIREMENTS

CQI & IRCA *recommend* that each Learner have the following prior knowledge before completing this course:

- The Plan, Do, Check, Act (PDCA) Cycle
- The core elements of a management system and the interrelationship between top management responsibility, policy, objectives, planning, implementation, measurement, review and continual improvement.
- Knowledge of the requirements of ISO 13485 and the commonly used quality management terms and definitions

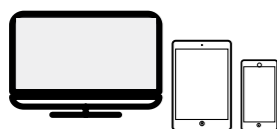
Important Note: Successful completion of Comply Guru's Online & Self-Paced ISO 13485:2016 Foundation (QMS) Course (FD125) or equivalent will mean you meet the above prior learning requirements.



CERTIFICATE OF ACHIEVEMENT

Successful completion of this course will entitle each Learner to receive a CQI & IRCA Recognised Certificate of Achievement.

TECHNOLOGY REQUIREMENTS*



The online modules may be accessed by desktop, tablet, or mobile device. Please ensure a minimum internet connection of at least 1 megabit per second (Mb/s).

For the best learning experience, we **strongly recommend** Google Chrome (the latest version where possible) when completing the online & self-paced modules.

*A complete and up-to-date list of technology requirements is available on our website.

Have a Question? Need a Quote?

Get in touch with our team today!

Email: training@complyguru.ie

Phone: (061) 529100

WHAT OUR CUSTOMERS ARE SAYING



The content of course was comprehensive and well structured. The online modules were self-paced and being accessible at any time was handy. The classroom portion of the course delivered virtually via Zoom worked well the tutor had an in-depth knowledge of the auditing process and was able to give real life examples from her own auditing experience. Feedback on the assessments was constructive and useful the additional class giving an overview of the individual clauses of ISO13485 prior to the classroom day was beneficial.

Stephen



I was very impressed by the well-organised and structured course. It is divided into a self-managed and a classroom training session that provides you with a good understanding of the ISO 13485:2016 and good knowledge on how to prepare and conduct an Internal Audits. The one day course via Zoom was in a group based environment with a very competent tutor. The assessments provide a good feeling of how an internal audit as an Auditor would look like. All in all an extremely good experience and I am looking forward to doing more courses with Comply Guru.

Miriam



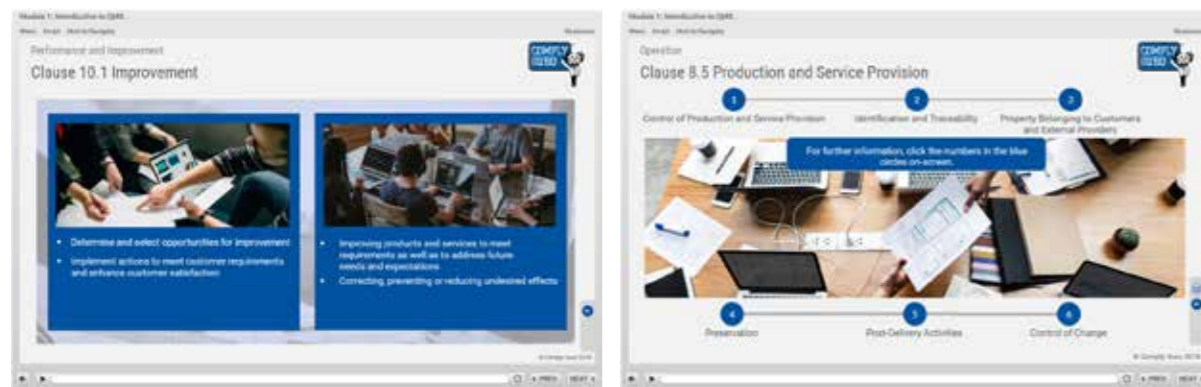
The Course was very well prepared and I really enjoyed it.

Karolina

HOW YOU WILL LEARN WITH COMPLY GURU™ ONLINE MODULES

1. HIGHLY ENGAGING, VISUAL LEARNING

All of our courses have leading edge instructional & graphic design to offer a learning content that is highly engaging and visual for an effective learning experience



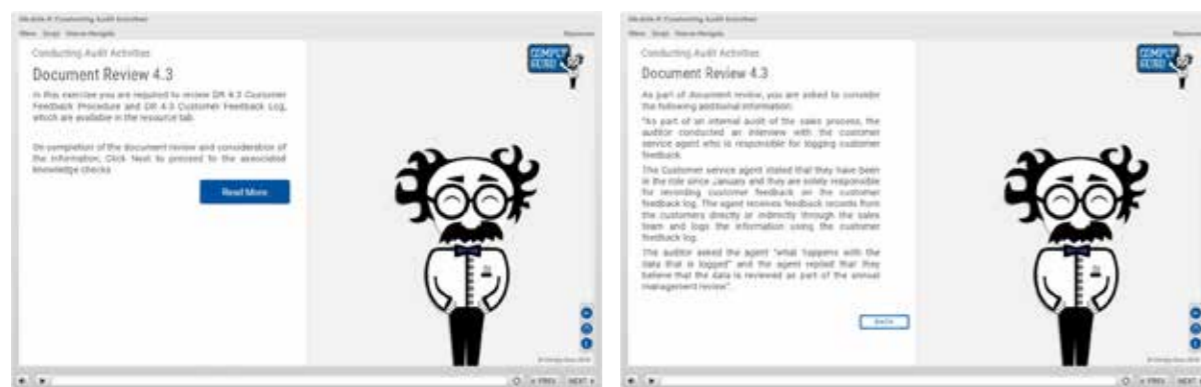
2. REGULAR INTERACTIVE KNOWLEDGE CHECKS

Throughout each Module, we have regular interactive knowledge checks to ensure that each Learner is absorbing the content as they progress through their chosen course



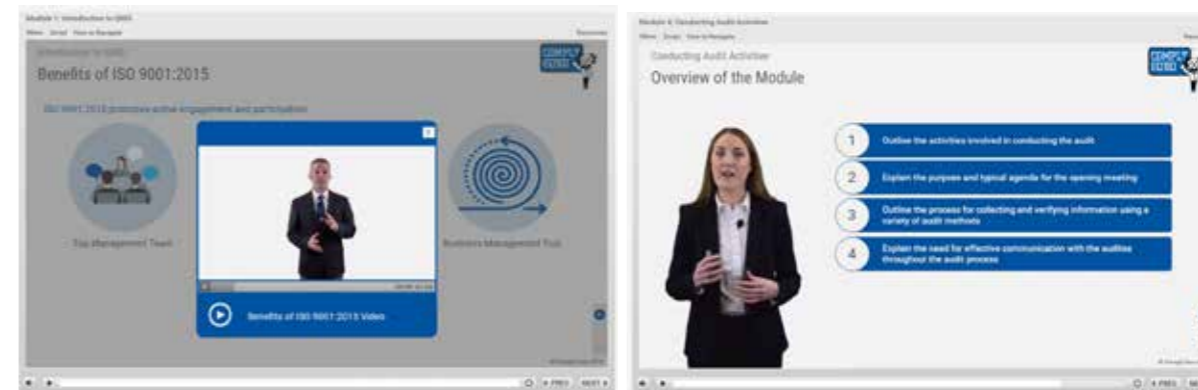
3. REAL LIFE SCENARIOS AND PRACTICAL EXAMPLES

An important part of learning is to ensure we provide real life scenarios and practical examples so Learners understand how the content relates to the real world.



4. EXPERT VIDEOS

Each course includes professional videos where our Subject Matter Experts will explain key concepts & topics to help each Learner master the learning content.



5. Excellent Customer Support

Should any Learner need support during their training, our team will be willing & available to assist by phone or email or within the Learning Management System, by clicking the mail icon while taking one of our courses. Just get in touch!



(061) 529100



E. training@complyguru.ie



Through the LMS

