

# ONLINE & SELF-PACED RISK MANAGEMENT & ISO 14971:2019

## COURSE OVERVIEW

Our Online & Self-Paced Risk Management & ISO 14971:2019 Course is ideal for anyone that wants to gain a comprehensive overview of Risk Management based on ISO 14971:2019 - including the latest changes in the latest publication with practical examples throughout the course.

Course Format: **Online & Self-Paced**

Certification: **CQI, IRCA & Exemplar Global**

Duration: **8 hours**

Course Fee: **€495 incl. Certification Fees**

Fee Includes: **Course Access for 90 Days  
Phone & Email Support**



## COURSE CONTENT

### Module 1 - Introduction to Risk Management

- Purpose, History and Structure of ISO 14971
- Key Changes introduced by ISO 14971:2019
- Key Terminology
- Relationship with ISO 13485, MDR 2017/745, IVDR 2017/746 and 21 CFR part 820
- Risk Management and the Product Lifecycle

### Module 2 - Risk Management Planning

- Risk Management Process
- Risk Management Team
- Role of Top Management
- Risk Management Plan
- Risk Management File

### Module 3 - Risk Analysis & Evaluation

- Device Characterization
- Hazards and Hazardous Situations
- Risk Estimation
- Risk Evaluation

### Module 4 - Risk Control & Risk Management Techniques

- Risk Management Techniques – PHA, FTA, FMEA HAZOP
- Risk Control Analysis
- AFAP and ALARP
- Implementation of Risk Controls
- Residual Risk
- Benefit - Risk Analysis

### Module 5 - Risk Management Review

- Overall Residual Risk Evaluation
- Risk Management Review
- Production and Post-Production Activities

### Module 6 - ISO/TR 24971

- Purpose of ISO/TR 24971
- Structure of ISO/TR 24971
- Overview of Key Annexes

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## ASSESSMENT METHODOLOGY

To complete the course successfully, each Learner must achieve an overall score of at least 70% in the assessment. Each learner is limited to a maximum of 3 attempts per assessment.

## STANDARDS NEEDED

- **ISO 14971:2019** Medical Devices - Application of Risk Management to Medical Devices (Required & **not** included with the course)

## TECHNOLOGY REQUIREMENTS\*



For the best learning experience, we **strongly recommend** Google Chrome when completing the online & self-paced modules.

*\*A complete list of technology requirements is on our website.*



## CERTIFICATE OF COMPLETION

Successful completion of this course will entitle each Learner to receive a CQI, IRCA & Exemplar Global Recognised Certificate of Completion.

## COURSE FUNDING AVAILABLE



The Irish Medtech Skillnet actively supports the current and future training needs in the Medical Technology, Pharmaceutical, Biologics and Biopharma manufacturing industries in Ireland. They will be offering funding to companies based in Ireland who wish to complete this course!

### Contact Information

Michelle Reinecke-Quain

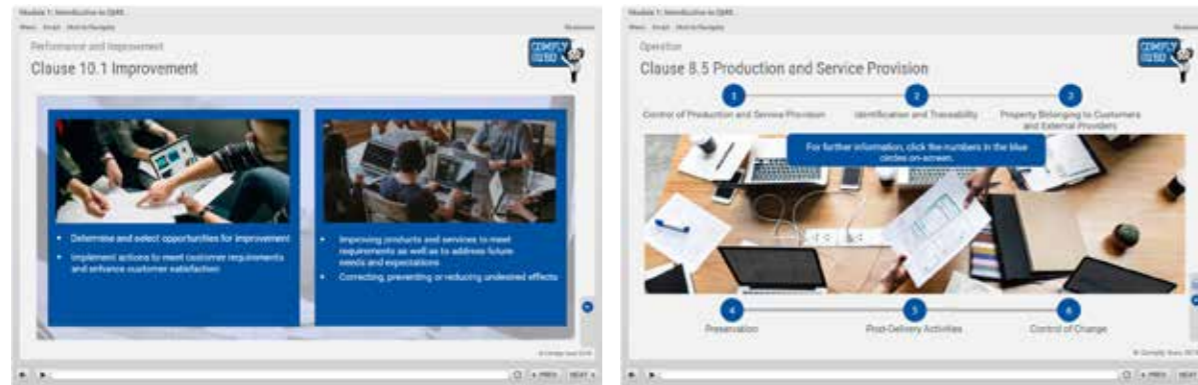
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# HOW YOU WILL LEARN WITH COMPLY GURU™'S ONLINE MODULES

## 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



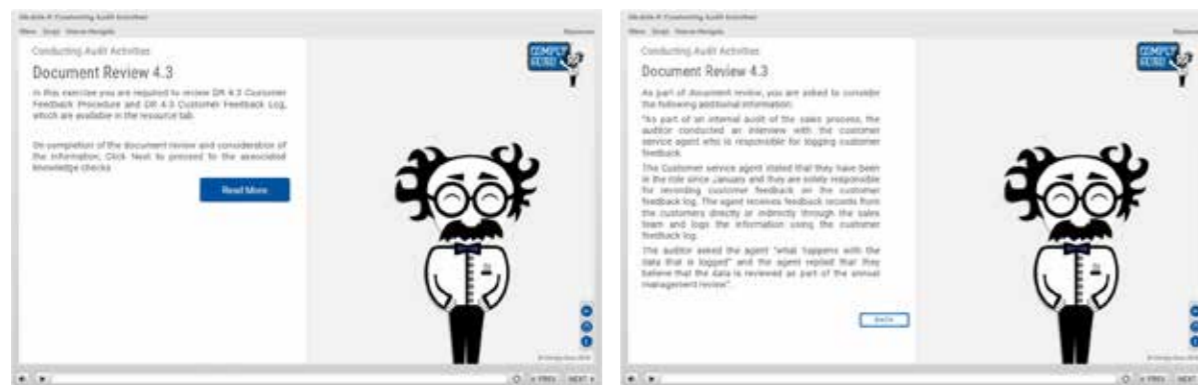
## 2. REGULAR INTERACTIVE KNOWLEDGE CHECKS

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



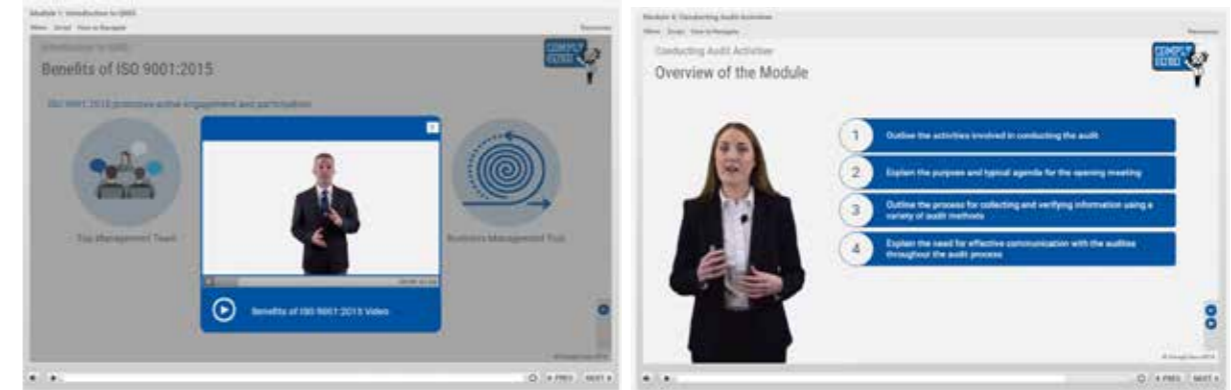
## 3. REAL LIFE SCENARIOS AND PRACTICAL EXAMPLES

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



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Through the LMS

