

# ONLINE & SELF-PACED MDSAP FOUNDATION TRAINING

## COURSE OVERVIEW

This Introduction to MDSAP Course aims to provide learners with the knowledge required to understand the IMDRF Medical Device Single Audit Program (MDSAP) for medical device quality management based on ISO 13485:2016 & international regulatory bodies medical device regulations.

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

Duration: **8 hours**

Course Fee: **€495 per person**

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

Certification: **Exemplar Global**



## COURSE CONTENT

### Module 1 Introduction to MDSAP

- What is MDSAP?
- Purpose and benefits of MDSAP
- Role of IMDRF in development of MDSAP
- Relationship with ISO 13485:2016 and regulatory requirements
- MDSAP Guidance Documents

### Module 2 MDSAP Audit

- MDSAP Structure
- Audit Sequence
- MDSAP Audit Cycle
- Special and Unannounced Audits
- Audit Time and Duration
- Introduction to MDSAP NC Grading

### Module 3 MDSAP Chapter 1 and 2

- Introduction to Chapter 1 and 2
- Chapter 1 Management Tasks 1-11
- Additional Country Specific Requirements
- Chapter 2 Tasks 1-3
- Additional Country Specific Requirements

### Module 4 MDSAP Chapter 3 and 4

- Introduction to Chapter 3 and 4
- Chapter 3 Tasks 1-16
- Additional Country Specific Requirements
- Chapter 4 Tasks 1-2
- Additional Country Specific Requirements

### Module 5 MDSAP Chapter 5

- Introduction to Chapter 5
- Project selection and planning
- Design and development inputs
- Verification, validation, clinical evaluation
- Design change, review and transfer
- Software design and development

### Module 6 MDSAP Chapter 6

- Introduction to Chapter 6
- Tasks 1-9 including country specific requirements
- Tasks 10-19 including country specific requirements
- Tasks 20-29 including country specific requirements

### Module 7 MDSAP Chapter 7 and Annexes

- Introduction to Chapter 7
- Tasks 1-6 including country specific requirements
- Tasks 7-12 including country specific requirements
- Annex 1 and Annex 2
- Annex 3 Adverse Events and Advisory Notices Reporting
- Annex 4 Written Agreements

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## ASSESSMENT METHODOLOGY

To complete the course successfully, each Learner must:

- Achieve an overall score of at least 70% in the final online assessment (MCQ-based)

## 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.*



## CERTIFICATE OF COMPLETION

Successful completion of this course will entitle each Learner to receive an Exemplar Global Certified Certificate of Completion.

## DO YOU HAVE A QUESTION FOR US?

If you have a question, get in touch with our team today!

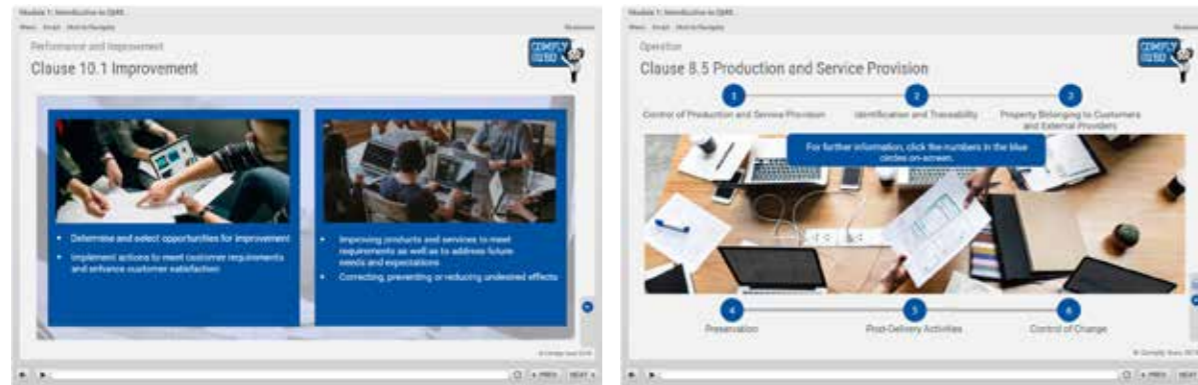
Email: [training@complyguru.ie](mailto:training@complyguru.ie)

Phone: +353 (61) 529100

# 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



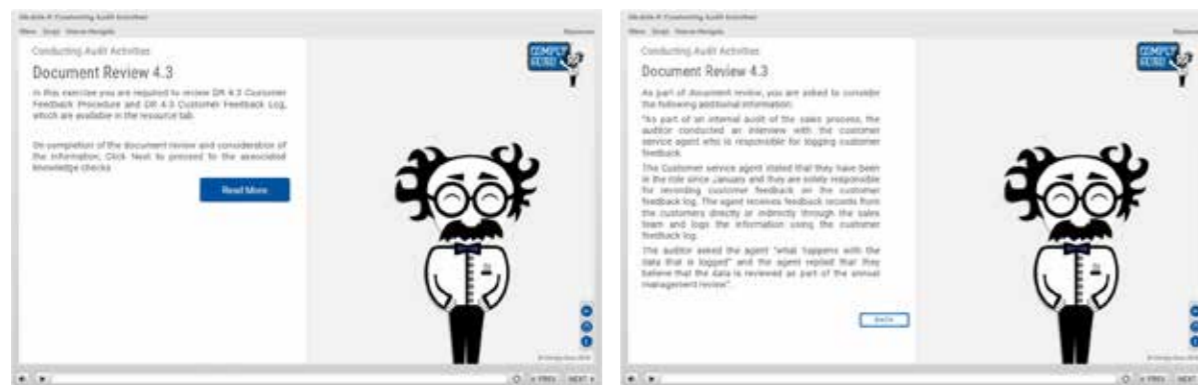
## 2. REGULAR INTERACTIVE KNOWLEDGE CHECKS

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



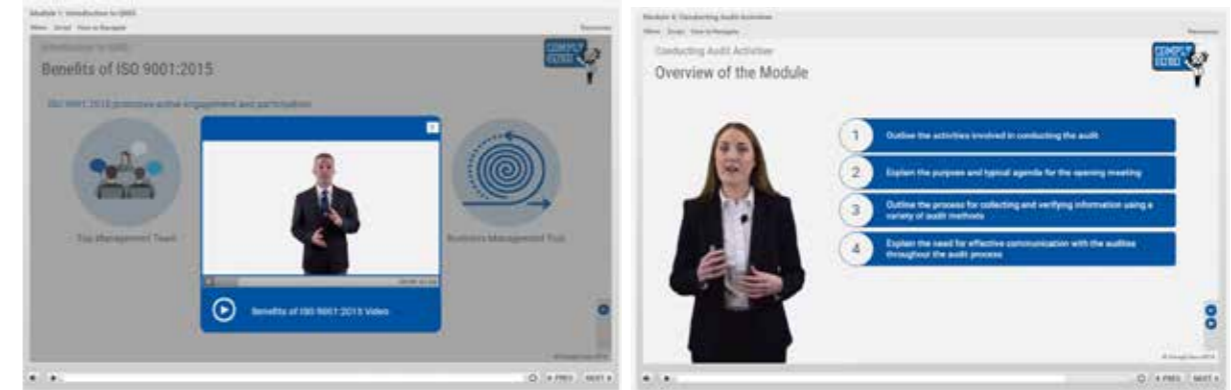
## 3. REAL LIFE SCENARIOS AND PRACTICAL EXAMPLES

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!



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Through the LMS

