



EU MDR

GENERAL OVERVIEW COURSE BROCHURE

IN PARTNERSHIP WITH



STANDARDS SIMPLIFIED

TRAINING TRANSFORMED

Comply Guru's Online EU Medical Device Regulation (MDR) Training Brochure

ABOUT THIS COURSE

This fully online course is ideal for anyone working in the Medical Device Industry looking for a general overview of the EU Medical Device Regulation (MDR) and wants to flexibility to learn at their own pace and in their own time.



Course Learning Time: **2 hours**

COURSE CONTENT

Module 0
Introduction

Module 1 - Introduction to
the EU MDR

History of MD Scandals
Purpose of the EU MDR
Structure of the EU MDR
Definitions
Medical Devices covered
by the EU MDR
Key Changes introduced
by the EU MDR
Timelines for Transition

Module 2 - Placing on
the Market

Overview of Articles 10, 11, 13-15
Role of the Manufacturer,
Authorised Representative,
Importer, Distributer and
Person Responsible for
Regulatory Compliance
Overview of articles 5, 19 & 20
Brief overview of Classification,
Conformity assessment,
EU declaration of conformity and
CE Marking

LEARNING OBJECTIVES

1. Explain the history, purpose and structure of the EU MDR
2. Describe the key changes to the EU MDR from the MDD
3. Identify the different roles and responsibilities associated with the EU-MDR
4. Outline the requirements for placing a medical device on the market

COURSE PRE-REQUISITES

It is recommended that each Learner as the following recommended prior knowledge:

- Working knowledge of medical device quality management systems and risk management

WHO SHOULD ATTEND

This course is suitable for anyone working in the medical device industry sector who is looking for a general overview course on the EU Medical Device Regulation (MDR).

ABOUT OUR PARTNER

Meddev Solutions are a team of QARA professionals, each with a minimum of 20 years' experience, working in the medical device industry for both manufacturers and Notified Bodies.

They routinely train and provide consultancy services to the top medical device manufacturers & due to their Notified Body experience, they are in an excellent position to ensure our courses deliver knowledge in a meaningful way, that will meet your needs and ensure compliance.

BENEFITS OF ONLINE LEARNING



Accessible to Everyone

Online courses can be taken anywhere and by anyone, at a time that suits them best (24/7/365).



Reduced Costs

Travelling to a classroom course can be really expensive as well as inconvenient. Online training can be completed anytime, anywhere, meaning that there are no travel expenses.



Environmentally Friendly

Online training is paperless and therefore protects the environment as there is no requirement to print training manuals or other course materials.

Less Time Away from Work or Home

Completing classroom training can mean losing valuable time away from home or work. With online training, you can complete your training where and when it suits you, from the same devices you use every day.

Self-Paced and Learner Driven

In a classroom, the pace of training is generally defined by the group. For some learners, this means the training can be too fast or too slow. With online training, each course can be completed at your own pace without the pressure or constraints of a group.

OUR EXPERT

Rod Beuzeval, Director of Meddev Solutions UK, has worked in Pharmaceutical and Medical Device sectors for over 20 years and holds a degree in engineering & has earned Global Regulatory Affairs Certification from the Regulatory Affairs Professional Society.

His expertise lies in providing regulatory guidance to support new product development, worldwide registration and compliance activities.

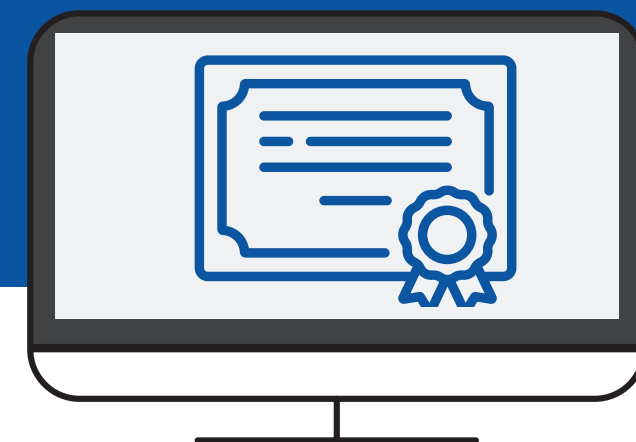


ASSESSMENT METHODOLOGY

Once all Modules are completed, each Learner will be able to access the final assessment. To complete the course successfully, each Learner must achieve an overall score of at least 70% in the final assessment.

Successful completion of this course will entitle the Learner to a certificate of completion.

Each learner is limited to a maximum of 3 attempts.



ACCESSING THE COURSE



This course may be accessed by desktop, tablet, or mobile device. For the optimum learning experience, please ensure a minimum internet connection of at least 1 megabit per second (Mb/s).

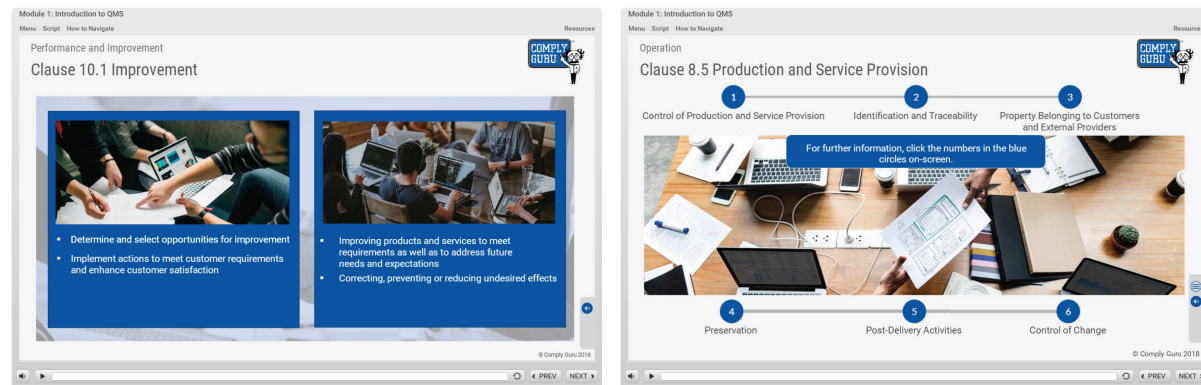
Although the course has been tested in all major browsers, we have found for the best learning experience we recommend Google Chrome (the latest version where possible).

1. Cookies should be enabled, for our logins to work.
2. JavaScript should be enabled.
3. Popup blockers can cause problems on some browsers from time to time, so if the Learner can add LearnUpon to their popup blocker exception list that would be preferable.

HOW YOU WILL LEARN WITH COMPLY GURU™

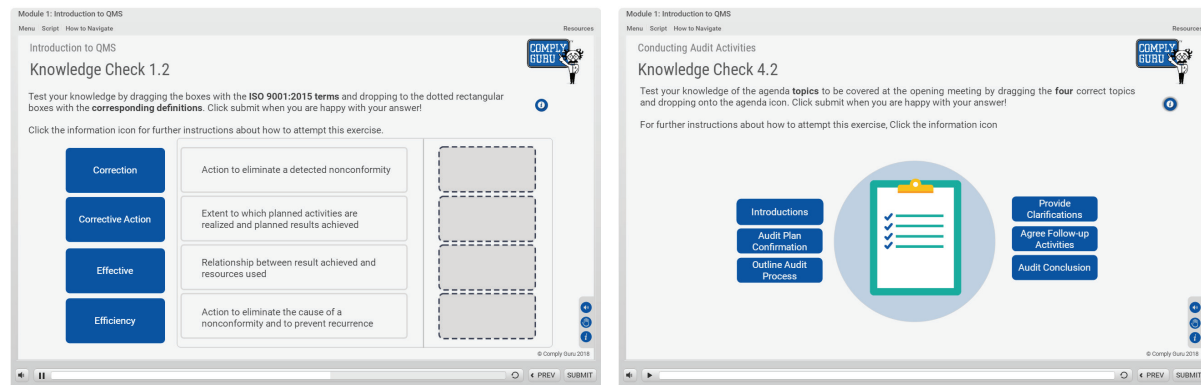
1. HIGHLY ENGAGING, VISUAL LEARNING

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



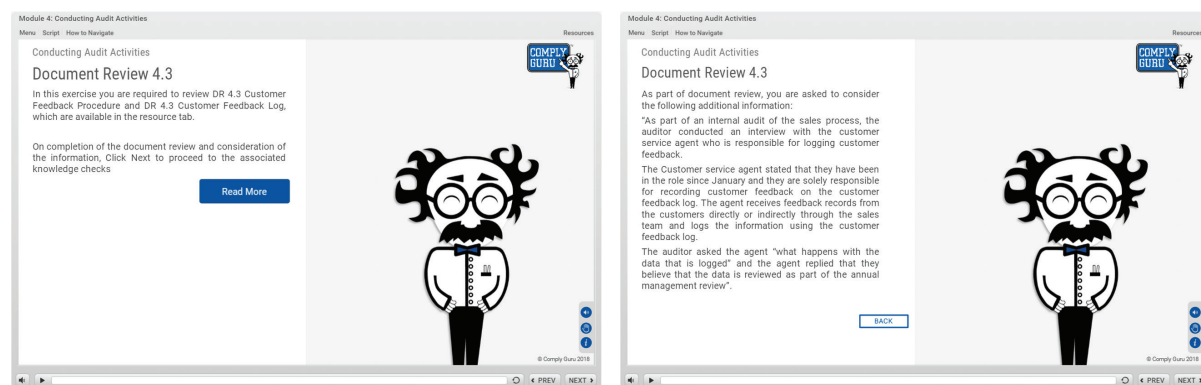
2. REGULAR INTERACTIVE KNOWLEDGE CHECKS

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



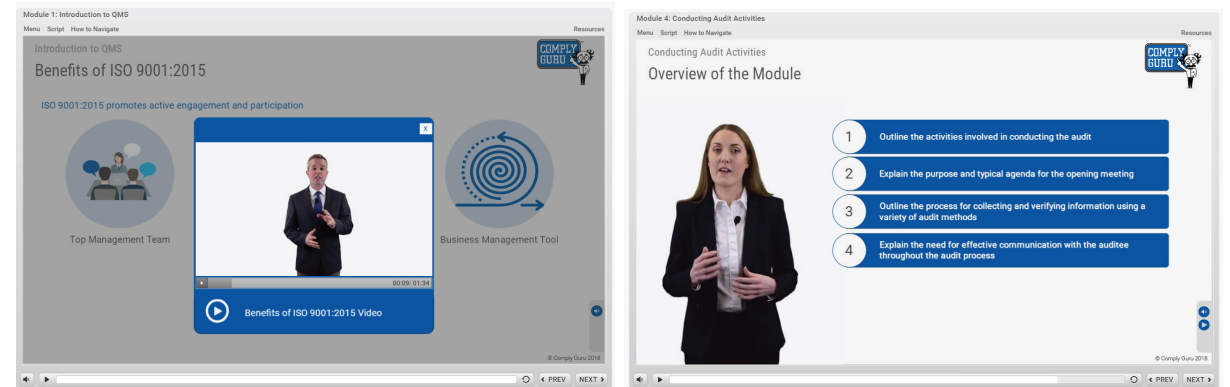
3. REAL LIFE SCENARIOS AND PRACTICAL EXAMPLES

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 Mangement System, by clicking the mail icon while taking one of our courses. Just get in touch!



Ph. Call Us



E. sales@complyguru.com



Through the LMS



OUR COMPANY

Comply Guru™ offers industry-leading online & blended training solutions to enable its Learners to get the knowledge and skills they need, from the same systems and devices they use every day – and minimize the invaluable time that can be lost in a classroom, travelling or away from home/work!

MEET THE TEAM

Eoin Philip Kelly
Founder & CEO

Eoin founded Comply Guru & executively manages the day-to-day running of the company. He previously spent the last 12.5 years as a Director, President & Chief Operations Officer in a leading consulting & training provider, including over 6 years based in Chicago, IL.



Breda Kearney
Quality Director

Breda joined in January 2019. She has over 10 years' experience in the Quality and Food Safety Industry. Breda oversees the development of our online course library and is responsible for managing our Quality Management System.



OUR MISSION IS TO SIMPLIFY THE COMPLEX WORLD OF STANDARDS, COMBINE LEADING SUBJECT MATTER EXPERTS, GRAPHIC & INSTRUCTIONAL DESIGNERS & TECHNOLOGY TOGETHER SO OUR LEARNERS BENEFIT FROM ALL OF THE ADVANTAGES THAT THE BEST IN ONLINE LEARNING CAN OFFER ANYWHERE!

GET IN TOUCH

For more information on Comply Guru or any of our services,
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