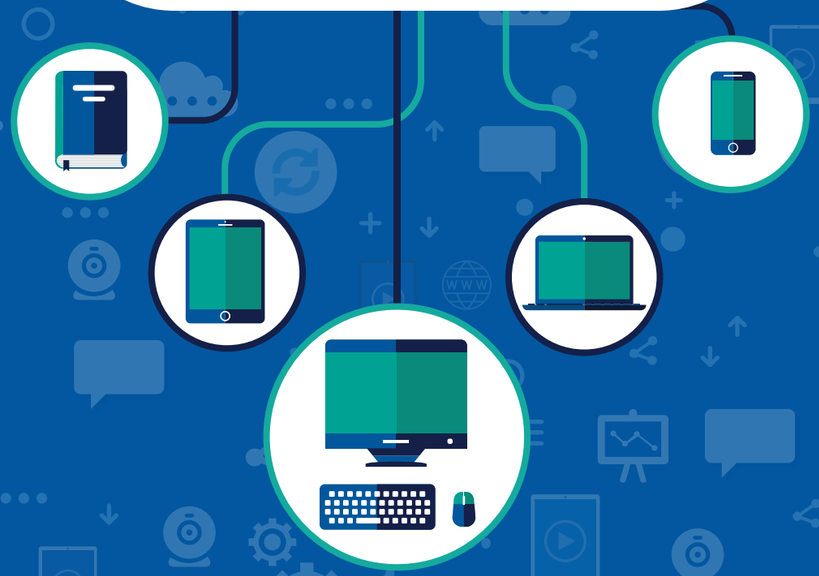
# EU MDR

## IN-DEPTH FOUNDATION COURSE BROCHURE

IN PARTNERSHIP WITH

MEDDEV SOLUTIONS



STANDARDS SIMPLIFIED

TRAINING TRANSFORMED



# ABOUT THIS COURSE

This fully online, self-paced course can take you comprehensively through the regulation, not just from an industry perspective, but also from a Notified Body perspective, which means you get the benefit of understanding what both sides are looking for. This course will focus on the overview & application - it isn't just a simple 'read and understand,' it is a **practical 'how to' guide**, which you can actually use immediately.

Course Learning Time: **16 hours**

## COURSE OVERVIEW

Module 0 - Course Introduction

Module 1 - Introduction to the EU-MDR

Module 2 - Medical Devices covered by the EU-MDR

Module 3 - Placing a Device on the Market

Module 4 - Device Classification

Module 5 - Routes to Conformity

Module 6 - GSPR & Risk Management

Module 7 - Clinical Evaluation

Module 8 - Technical Documentation

Module 9 - Post Market Surveillance & Vigilance

**Detailed Breakdown Available on our Website.**

## LEARNING OBJECTIVES

1. Explain the history, purpose and structure of the EU-MDR, and the key terminology used throughout the regulation
2. Identify the types of devices covered by the EU-MDR and the rules for classifying these devices
3. Describe the obligations of the economic operators and the PRRC
4. Describe the General Safety & Performance Requirements and the key features of a risk management system based on ISO 14971
5. Describe the contents of the Technical Documentation and the requirements for Post Market Surveillance, Vigilance and Clinical Data
6. Explain the Unique Device Identifier requirements and the relationship with Eudamed

## WHO SHOULD ATTEND

The course is aimed at anyone working in the medical device industry sector who is responsible for or involved in the implantation or maintenance of a Medical Device QMS including not limited to:

- QA Professionals
- Quality Engineers
- Research & Design Engineers
- Internal Auditors
- Quality Managers
- Manufacturing Engineers
- Regulatory Professionals

## RECOMMENDED PRIOR KNOWLEDGE

Working knowledge of medical device quality management systems and risk management is recommended prior to completing this course.

# 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).

### 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.

### 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.

### 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.

### Environmentally Friendly

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



## 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 earnt 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

There are two final assessments (Part 2 & 1 as part of this course). To complete the course successfully, each Learner must achieve an overall score of at least 70% in each 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 strongly 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 Leaner can add LearnUpon to their popup blocker exception list that would be preferable.

# HOW YOU WILL LEARN WITH COMPLY GURU™

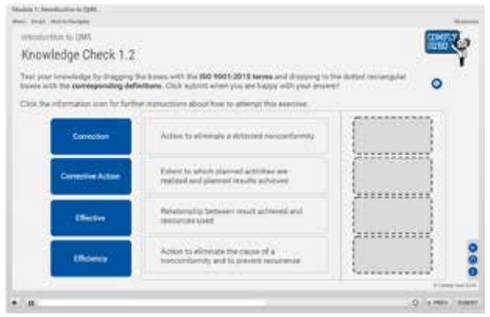
## 1. HIGHLY ENGAGING, VISUAL LEARNING

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

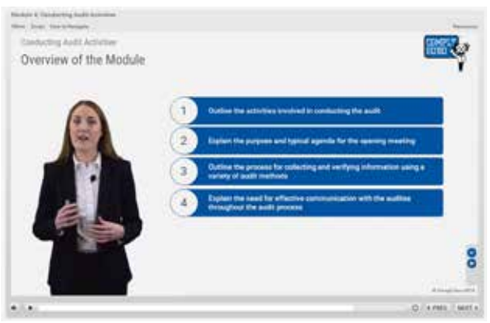




Comply Guru's Online EU Medical Device Regulation (MDR) In-Depth Foundation Training Brochure

## 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.

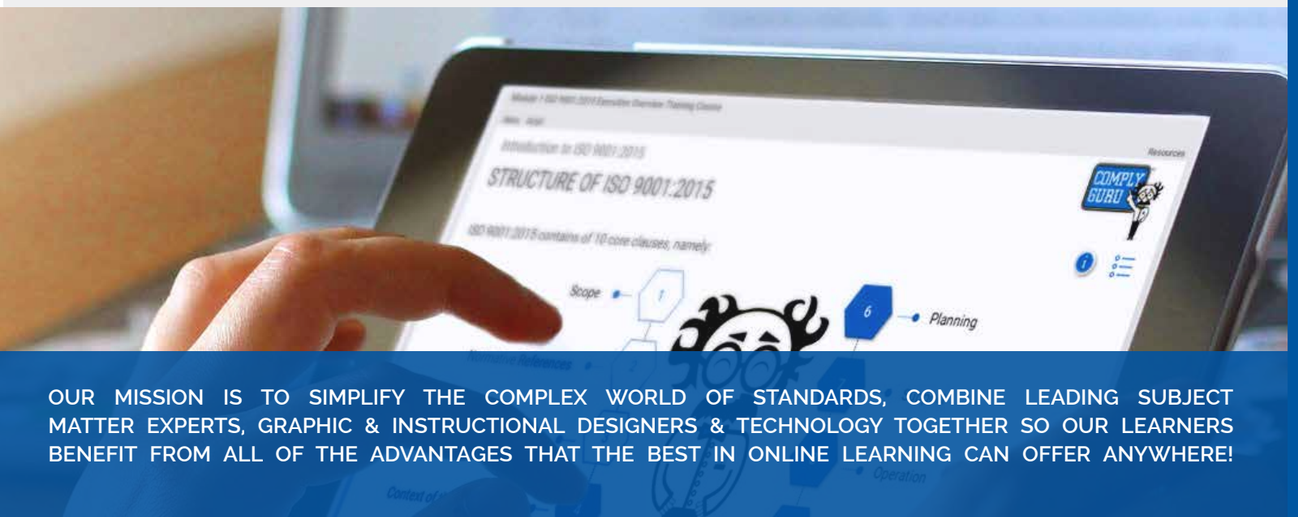
### Breda Kearney - Quality Director

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.

# 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.




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!

COMPLY GURU™
Standards Simplified
Training Transformed

# GET IN TOUCH

**For more information on Comply Guru or any of our services, please contact us at:**

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