ONLINE & SELF-PACED
EU IVDR 2017/746 PRACTITIONER

COURSE OVERVIEW

This Comprehensive Practitioner course provides an in-depth understanding on the key principles and practices required for the new In-Vitro Diagnostic Regulation (EU-IVDR) 2017/746. 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 Format: **Online & Self-Paced**

Duration: **18 hours**

Course Fee: **€1,115 incl. Certification Fees**

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

Certification: **Exemplar Global**

COURSE CONTENT - ONLINE & SELF-PACED MODULES

Module 1 - Introduction to the EU-IVDR

- Purpose & Structure of the IVDR
- Key Terminology
- IVDR v IVDD – Key Changes
- IVDR Timelines for Transition

Module 2 - Devices covered by the EU-IVDR

- What is an in-vitro medical device?
- Devices in scope & out of scope

Module 3 - Placing a Device on the Market

- Chapter II Terminology
- Articles 5-9
- Economic Operator & PRRC Responsibilities
- Articles 16-21

Module 4 - Device Classification

- Implementing Rules
- Classification Rules 1-7

Module 5 - Routes to Conformity

- Conformity Assessment Annexes IX, X, XI
- Article 48 Devices Categories & Groups
- Special Device Conformity
- Derogation from Conformity Assessment
- Notified Bodies

Module 6 - GSPR & Risk Management

- Overview of Annex I
- Chapter I General Requirements
- Chapter II Performance, Design & Manufacture
- Chapter III Device Information

Module 7 - Performance Evaluation & Performance Studies

- Article 56 & 57
- Performance Study Articles
- Annex XIII Part A & Part B
- Annex XIV
- Summary of Safety & Performance

Module 8 - Post Market Surveillance & Vigilance

- PMS Articles 78-81
- Vigilance Terminology & Reporting
- Trend Reporting
- Analysis of Serious Incidents & FSCA
- Data Analysis

Module 9 - Technical Documentation, UDI and Eudamed

- Annex II & III, UDI Terminology
- Annex VI, UDI Timelines
- EUDAMED Databases
- EUDAMED Timelines
- MDCG

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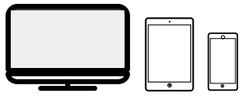
ASSESSMENT METHODOLOGY

To complete the course successfully, each Learner must:

- Achieve an overall score of at least 70% in three online final assessments which will be available after each phase of modules have been completed (3 Parts)

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.*

OUR EU IVDR EXPERT - ROD BEUZEVAL

Rod has worked in Pharmaceutical and Medical Device sectors for over 20 years and holds a degree in engineering.

His expertise lies in providing regulatory guidance to support new product development, worldwide registration and compliance activities. Rod is able to train large groups in the global regulatory requirements as well as QMS.

Rod has years of hands-on experience of industry standards and regulation such as ISO 13485, ISO 14971, ISO 10993, IEC 60601-1, IEC 62304, IEC 62366, MDD 93/42/EEC, 21CFR, CMDCAS (MDSAP) amongst others.

ABOUT MEDDEV SOLUTIONS - OUR IVDR 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. By providing their expertise on the IVDR, we combined that with our expertise in eLearning to create this industry-leading course.

Have a Question?
Need a Quote?

Get in touch with our team today!
Email: sales@complyguru.ie
Phone: (061) 529100 | (01) 2552888

COURSE SUMMARY

MEET OUR MANAGEMENT TEAM & IN-HOUSE EXPERTS

EOIN PHILIP KELLY

FOUNDER & CEO

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

He believes that there is a major gap in the world for a Learning Partner that can offer access to a growing library of industry-leading online & blended (online, classroom or virtual classroom) learning solutions that specifically focus on Quality, Regulatory Affairs & Compliance (ISO & Related Standards).

BREDA KEARNEY

QUALITY DIRECTOR

Breda leads the design of Comply Guru's internationally accredited CQI and IRCA & Exemplar Global Certified Online & Blended Training Programs.

She is a highly qualified Microbiologist with over 12 years' experience in Quality, Life Sciences & the Food Safety Industry.

Breda has both designed & delivered training to hundreds of Learners in various areas across ISO 9001, ISO 13485, ISO/FSSC 22000 & ISO/IEC 17025 – at Foundation, Internal Auditor & Lead Auditor level.

She is also an accomplished Consultant & Auditor who has helped a range of small, medium & large organizations in Ireland & the U.S. design, implement and improve their Management Systems.

WHAT OUR CUSTOMERS ARE SAYING

★ ★ ★ ★ ★

Excellent overview of EU MDR. Very informative presentation outlining the important changes to the EU MDD to EU MDR. Would recommend this course in the future to others.

Fiona

★ ★ ★ ★ ★

Comply Guru offer an excellent easy to navigate platform to complete online training. The EU MDR General Overview course provided exactly that giving insight into the changes for organisations and industry.

Jane

★ ★ ★ ★ ★

Very professional polished. Excellent video presentations. I liked the quizzes particularly the fact that the structure of the quizzes varied in nature. I also liked the fact that you could expand parts of the course this allows the learner to tailor the course to their own level of knowledge.

Angela

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

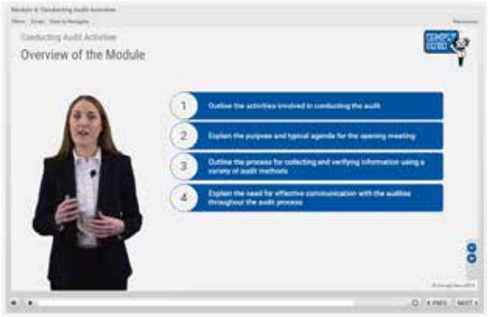
Throughout each Module, we have regular interactive knowledge checks to ensure that each Learner is absorbing the content as they progress through their chosen course

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

(061) 529100

E. sales@complyguru.ie

Through the LMS