POLISH CENTRE FOR
TESTING AND CERTIFICATION

TRAINING

Review of the In-vitro Diagnostic Regulation (IVDR) – Training Course

1 DAY **8 LESSON HOURS**

ONLINE **SYMBOL: O215**

Date according to open training schedule available on the website:
www.pcbc.gov.pl

WHY IS IT WORTH?

- A wide selection of topics
- Achieving the goal
- The best trainers
- 60 years on market
- Atrractive form

Polish Centre for Testing and Certification
469 Puławska Street, 02-844 Warsaw
Tel.: +48 22 46 45 200
pcbc@pcbc.gov.pl

ABOUT TRAINING

The course will focus on the practical explanation of new requirements so that MedDev companies could be able to smoothly organise and manage the final steps of the transition to align corporate strategies with new requirements and processes.

TRAINING PROGRAM

- Products and subject scope governed by the Regulation.
- Why did we come from the Directive to the Regulation – the scale of a change.
- Putting a device into service – obligations of market players.
- Key changes – what are the differences vs MDR?
- What's new?
- UDI, Performance evaluation, labelling requirements and a lot more.
- Vigilance and PMS obligations.
- Enforcement of the Regulation under Polish law and penal provisions.
- Timeline and transitional provisions .
- Discussions.

BENEFITS

- Understanding the regulatory requirements of IVDR and their impact on the business and products distribution chain.
- Understanding how to apply those requirements and use them to leverage a market position.
- Clarifying the new regulatory expectations.
- Putting across the consequences of non-compliance.

1 950 PLN

NET / PERSON

The price includes the organization of on-line training,
electronic training materials, and a paper-based participation certificate.

CERTIFICATION. TESTING. TRAINING.

Welcome to contact us!

Agnieszka Korczak
Kom.+48 691 192 671
email: akorczak@pcbc.gov.pl

Mariola Fijewska
Tel.+48 665 464 661
email:mfijewska@pcbc.gov.pl

Natalia Nowak
Tel.+48 669 474 742
email: nnowak@pcbc.gov.pl