Polskie Centrum Badań i Certyfikacji S.A.

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

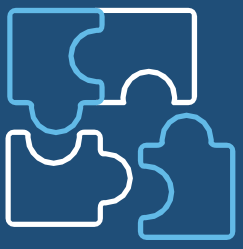
## 1 DAY | 8 LESSON HOURS
## ONLINE| SYMBOL: O215
## DATE OF TRAINING: 14TH OCTOBER 2022


A wide selection of topics


Achieving the goal


The best trainers


60 years on market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# Training program:

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

# Benefits:

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.

We will discuss what companies can expect from the Polish regulators as the transitional terms draw to a close, as well as clarify areas of uncertainty such as implementing acts.

Key benefits of the course:

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

## 1 350 PLN NET / PERSON

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

## Zapraszamy do kontaktu!


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