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Successful Medical Device & IVD Post Market Surveillance and Vigilance Reporting

Live Online Course
27-29 July 2021



MEET THE TRAINER

MIKA REINIKAINEN

Mika has a Master's degree in Law from the University of Nice and later gained a Master's in Business Administration from the Wharton School.

He has more than 30 years of experience managing European medical regulatory affairs in industry, as a healthcare legal counsel and as a regulatory consultant. He has also been involved directly in the development of the Medical Devices Directives and of technical standards since the 1990s.

He founded the medical device consulting company Abnovo Ltd in 2007 to provide a wide variety of networked services to the medical device industry worldwide.

He is currently a member of various medical device expert working groups of the European Commission and is Chairman of the European Association of Authorised Representatives (EAAR).

Agenda: Day One

Introduction

- The new regulations
- Implementation timeline

An overview of Post-Market Surveillance (PMS)

- Understanding the place of PMS in overall compliance
- What are the legal obligations for PMS?
- Key concepts: Benefit/risk and state of the art monitoring
- PMS and Risk Management
- Understanding the role of the Competent Authority and the Notified Body

Vigilance

- How does vigilance fit into PMS
- What are the legal requirements for vigilance?
- Different types of adverse incidents
- Investigation of incidents
- Reporting of incidents
- Corrective action
- Practical vigilance case

Agenda: Day One

Market surveillance and regulatory risk

- Competent authorities
- Notified Bodies
- Competition

Agenda: Day Two

Setting up a PMS system

- Practical case: leveraging the manufacturer's resources
- PMS documentation
- Data management and the use of the Internet
- Practical case: searching for information

The dark side of PMS

- Historic device failures
- Dealing with enforcement action
- Practical case: crisis management

PMS and Vigilance: An international perspective

- IMDRF
- Brexit

Future of PMS

- Globalisation
- Impact of technological development



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