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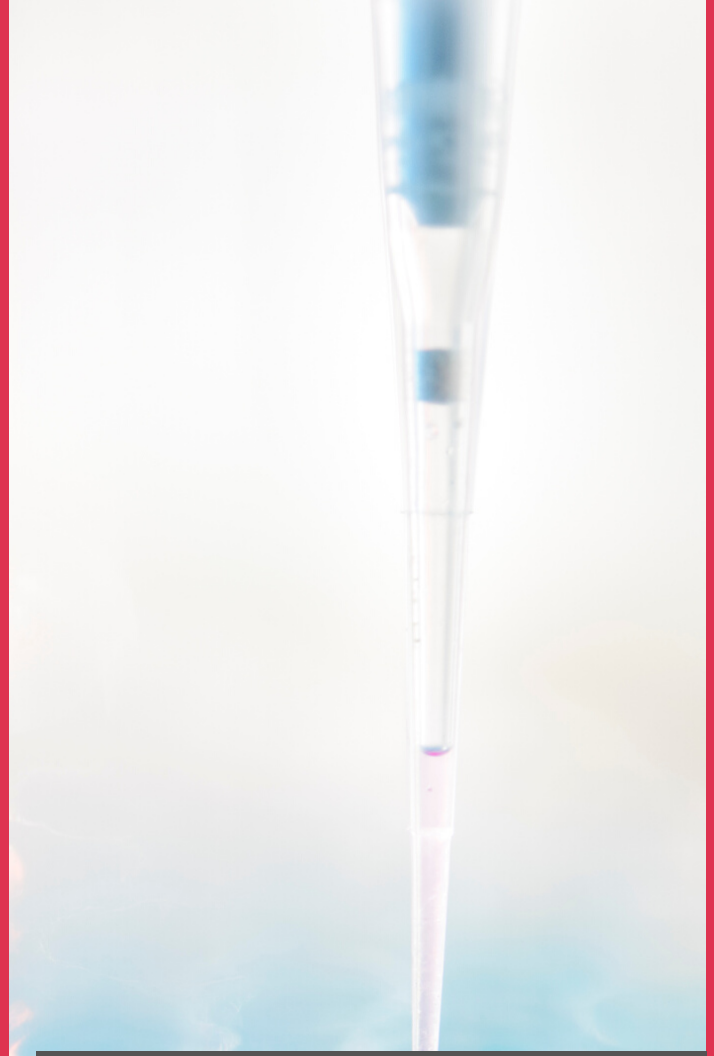
Successful Medical Device & IVD Post Market Surveillance and Vigilance Reporting

Live Online Course



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

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 Notified Body

Best strategies for successful PMS

- Evaluating PMS strategies: reactive or proactive?
- Importance of clinical evaluation and documentation
- Monitoring competitors
- Monitoring scientific and technological development
- Ensuring against product recall

Vigilance

- How does vigilance fit into PMS
- What are the legal requirements for vigilance?
- Discovering how this may vary between Competent Authorities
- Defining the vigilance process: What to report and when

Agenda: Day One

Clarifying vigilance reporting and exemptions

- Determining what does and does not need reporting
- Handling indirect harm
- Managing cases of use error/abnormal use
- Trend and periodic reporting

Agenda: Day Two

The dark side of PMS

- Understanding what triggers remedial action
- Corrective action (CAPA and FSCA)
- Notified Body verification of PMS implementation
- Negotiating with Competent Authorities

Electronic reporting in medical devices and IVDs

- An overview of the guidance for electronic repoting
- How do these differ between Competent Authorities?
- How is electronic reporting enforced?
- Demonstration of electronic reporting systems online

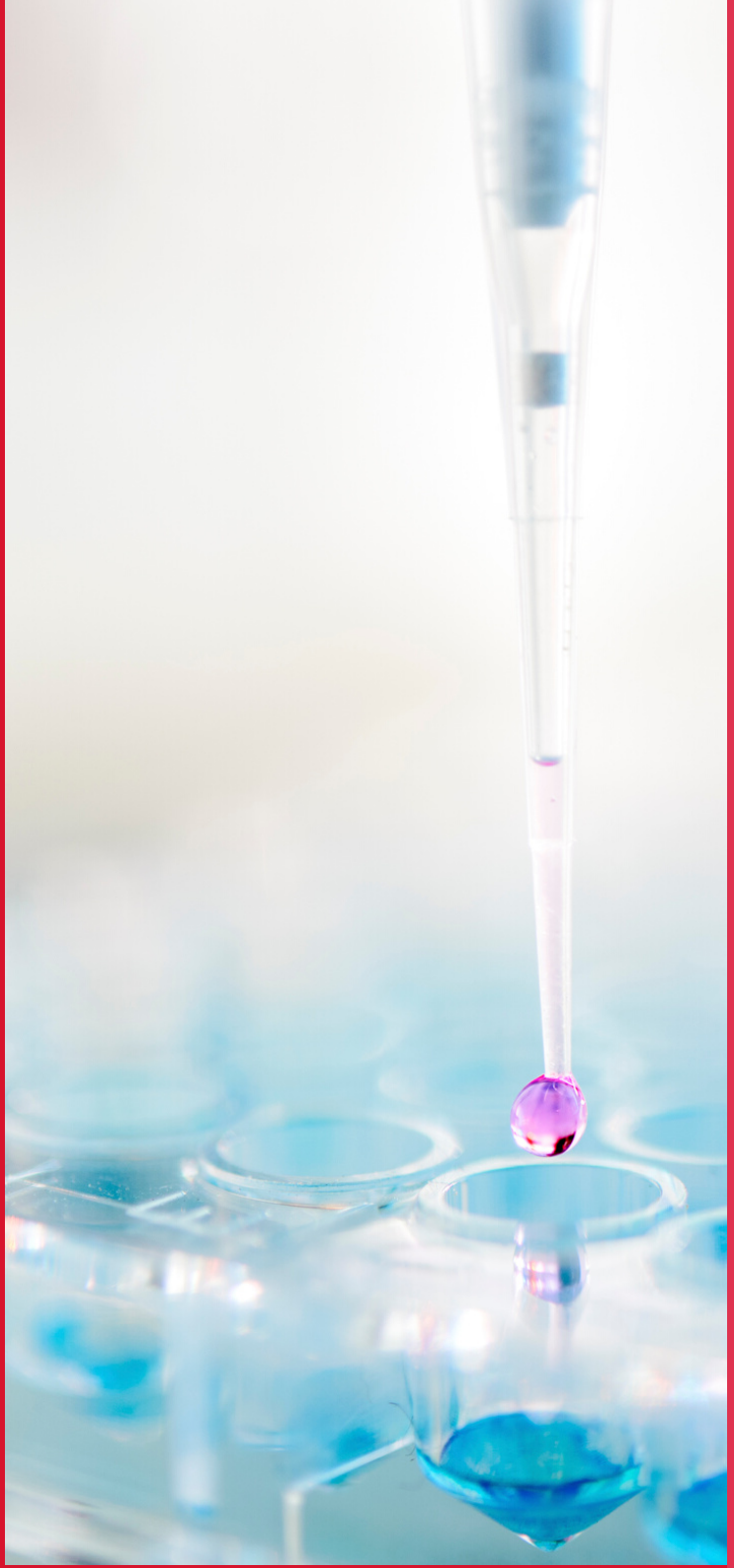
PMS and Vigilance: An international perspective

- New developments in PMS around the world
- Understanding the impact of these developments on industry
- How do these compare to EU regulations
- What is expected
- Timelines

Agenda: Day Two

Emerging requirements for PMS

- Overview of regulatory developments: Impacts on industry
- Other expected changes
- The global electronic enviroment
- Impact of technological development



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