Medical Device Regulations: Europe Seminar

The EU is the world's leading medical device market, with a unique regulatory framework. Navigating the EU regulatory landscapes is an essential skill for anyone interested in working in regulatory affairs or anyone looking to bring a device to market in the EU.

This seminar focuses on the practical application of regulatory tools and pathways available through the EU, using real-world examples and exercises to help you understand the regulations and how to comply with them effectively.

How will I benefit?

The real benefit is that the seminar will save you time by understanding regulation in simple terms and practical examples:

- Understand European Union regulatory affairs for marketing a medical device in the EU and Understand the timelines for the transition of the MDR 2017/745
- Help you prioritize work to prepare for the MDR 2017/745 timelines
- Learn about the obligations of the Manufacturers and Economic Operators, EUDAMED, Post Marketing Surveillance, and Vigilance
- Classification of medical devices and Conformity assessment routes
- Review the General Safety and Performance Requirements (GSPRs) for devices and the role of standards to demonstrate compliance
- Understand the implications of Brexit on the MDR 2017/745

Target Audience

- Junior Quality/ Regulatory Affairs professionals
- QA Engineers with medical device experience
- Medical device project team members
- Medical Device Engineers
- Entrepreneurs or small and medium start-up companies intend to develop a new medical device.
- Marketing teams within the medical device industry

Link to Syllabus

Certification seminar

For more information

lital@gsap.co.il 052-3610566