Medical Device Regulations: USA Seminar

The US is the world's leading medical device market, with a unique regulatory framework. Navigating the US 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 US.

This seminar focuses on the practical application of regulatory tools and pathways available through the US FDA, 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:

- Learn about US regulations for medical devices, and the role of the FDA
- Learn how to practically use the various FDA tools and databases to determine the required regulatory route and how to navigate the FDA website to find more relevant information for specific devices
- Understand the various regulatory pathways available for medical devices in the US
- Understand the importance of ISO 13485 Quality Management System (QMS)
- Learn about the obligations of the Manufacturers and UDI

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
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