Pharmakon

Introduction to ISO 13485

This comprehensive course provides a strong foundation for understanding the Quality Management System for medical devices and ISO 13485.
It will give you insights into the key requirements for establishing and maintaining compliant systems and processes.

Through a step-by-step approach, you will expertly be guided through the standards, with a primary focus on ISO 13485.

Additionally, you will gain an overview of essential standards and regulations, including MDSAP, EU MDR, and QSR.

Furthermore, the course will provide you with insight and understanding of the structure of effective Quality Management Systems, as well as the key requirements needed for establishing and maintaining a compliant system and processes.

You will also be presented (high level) with critical elements of the quality management system, such as design control (product development), manufacturing, validation, management responsibilities, handling of resources, internal audits, change control, post-market surveillance, and CAPA management, to gain an overall understanding of the backbone of the QMS system.

To sum up: after the course you will effectively be able to contribute to compliant systems, elevate the decision-making, and play a pivotal role in your organisation's operational excellence. You will be able to navigate complex standards, ensure compliance, and become catalysts for quality enhancement in the dynamic medical device industry.

The course language is English.

At the course you will meet:

Naram El-Shamary, Managing Partner, ImproveMatic – Quality by Simplicity

Course facts

FORMAT
2 days

PRICE THIS YEAR
16.100 DKK excl. VAT, Pris inkl. overnatning

Sign-up dates

Hillerød

18. apr. — **19. apr.**
2024

Do you have questions about this course?

Kontakt
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Target group

The course is ideal for:
• Professionals within Quality Assurance
• Professionals with Q-related tasks, such as Manufacturing, R&D, Procurement, Distributions & services
• Professionals entering the Medical Device industry.

Your benefits

• You will develop skills to navigate ISO 13485 effectively. This means you will know where to look in the standard and how to apply its principles to practical situations
• You will be able to apply the knowledge gained from the course to enhance compliance within their own processes. This could lead to improved processes, reduced errors, and better decision-making within their work environment
• You will gain a solid understanding of ISO 13485 and Quality Management Systems for medical devices. This knowledge will empower them to contribute effectively to their organization's compliance efforts and overall operational excellence.

Your company's benefits

• Your employee will be better equipped to work effectively in regulated industries due to their enhanced understanding of ISO 13485 and QMS
• Your organisations will benefit from enhanced compliance with international standards and regulations, reducing the risk of non-compliance issues

• Your employees improved understanding of ISO 13485 and QMS can lead to the identification of non-compliance and process gaps, ultimately leading to cost savings. A stronger focus on Good Manufacturing Practices (GMP) mindset and better decision-making can improve overall efficiency.

Course agenda

The course duration is 2 days and accommodation are included.

The course covers the following topics, among other:

• Overview of standards
• Overview of regulations
• Purpose of Quality Management System
• Structure and backbone of Quality Management System
• Management Responsibility & Resources management
• Document Control
• Product Realization, including Design & Development, Risk Management, purchasing & supplier control, Production, identification, and traceability.
• Measurement, analysis, and improvement, including PMS, Vigilance complaint handling etc.

The course consists of informative lectures and interactive sessions, allowing participants to engage with the content and collaborate with fellow learners. This interactive approach will enhance understanding and enable participants to apply their knowledge directly.

The course is based on the speakers' own practical and real-life cases from the Medical Device industry.

Sign up online at
www.pharmakon.dk