

Medical Device Industry FAQs

From our courses to industry regulations and more, here you'll find answers to our most asked questions, helping you make better decisions with insight you can trust.



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General FAQs

Q: What is ISO 13485:2016?

A: ISO 13485:2016 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements.

Related Course: ISO 13485:2016 Requirements E-Learning



Q: Why is risk management important in the medical device industry?

A: Risk management is crucial in the medical device industry to ensure the safety and effectiveness of medical devices. It involves identifying, evaluating, and mitigating

risks associated with medical devices throughout their lifecycle.

Related Course: ISO 14971:2019 Risk Management for Medical Devices Requirements On-demand Training Course

Q: What is the In Vitro Diagnostic Regulation (IVDR)?

A: The IVDR is a regulation of the European Union that sets out requirements for in vitro diagnostic medical devices to ensure they are safe and effective. It includes

higher and enhanced requirements for clinical evidence and post-market surveillance.

Related Course: Requirements of the In Vitro Diagnostic Regulation Training Course

Specific Training FAQs

Q: How can the ISO 13485:2016 Implementation Training Course help my organization?

A: This course provides comprehensive guidance on implementing ISO 13485:2016 requirements within your organization. It covers all aspects of the standard, from

planning and implementing to monitoring and continual improvement.

Related Course: ISO 13485:2016 Implementation Training Course

Q: What does the Medical Device Single Audit Program (MDSAP) entail?

A: The MDSAP allows for a single regulatory audit of a medical device manufacturer's quality management system that satisfies the requirements of multiple regulatory jurisdictions. It aims to reduce the overall number of audits and streamline regulatory processes.

Related Course: Medical Device Single Audit Program (MDSAP) Fundamentals and Readiness Training Course



Q: How do I transition from the Medical Device Directive (MDD) to the Medical Device Regulation (MDR)?

A: Transitioning from MDD to MDR involves updating your quality management system to comply with new MDR requirements. This includes changes in clinical evaluation,

technical documentation, and post-market surveillance.

Related Course: Medical Device Directive (MDD) to Medical Device Regulation (MDR) Transition Training Course

Q: What are the basics of medical device software?

A: Medical device software refers to any software system that is used as a medical device or in conjunction with a medical device. This includes software intended to diagnose, treat, or monitor patient

conditions, as well as software used to drive or control medical devices.

Related Course: Introduction to Medical Device Software Training Course

Q: What is involved in the post-market surveillance under the MDR and IVDR?

A: Post-market surveillance under the MDR and IVDR includes monitoring the performance and safety of medical devices after they are placed on the market. It requires systematic and proactive data collection to detect potential issues and ensure continued compliance.

Related Course: Post-market Surveillance and Vigilance under the Medical Device Regulation (MDR) and In Vitro Diagnostics Medical Devices Regulation (IVDR) Training Course



FAQs on Maintaining Compliance to the MDR

Q: What are the key requirements of the EU Medical Device Regulation (MDR) 2017/745?

A: The EU MDR 2017/745 outlines strict requirements for the safety and performance of medical devices, including rigorous clinical evaluation, comprehensive technical documentation, post-market

surveillance, and vigilance. It also places a strong emphasis on risk management throughout the product lifecycle.

Related Course: EU Medical Device Regulation (MDR) 2017/745 – QMS Auditor Training Course

Q: Why is maintaining compliance with the MDR important for medical device manufacturers?

A: Maintaining compliance with the MDR is crucial for ensuring the safety and effectiveness of medical devices in the European market. Non-compliance can result in significant consequences, including product recalls, bans, and reputational damage.

Related Course: EU Medical Device Regulation (MDR) 2017/745 – QMS Auditor Training Course

Q: What is the role of a Quality Management System (QMS) in MDR compliance?

A: A Quality Management System (QMS) provides a structured framework for managing and controlling medical device manufacturing processes. It ensures consistent product quality, compliance with regulatory requirements, and

continuous improvement. Under the MDR, a QMS must include processes for risk management, clinical evaluation, post-market surveillance, and vigilance.

Related Course: EU Medical Device Regulation (MDR) 2017/745 – QMS Auditor Training Course

Q: What are the responsibilities of a QMS auditor in the context of the MDR?

A: A QMS auditor is responsible for evaluating a manufacturer's quality management system to ensure it complies with the MDR requirements. This includes reviewing documentation, inspecting processes, and identifying non-conformities. The auditor

also provides opportunities for improvement and ensures that corrective actions are implemented effectively.

Related Course: EU Medical Device Regulation (MDR) 2017/745 – QMS Auditor Training Course

Q: How can our organization prepare for an MDR compliance audit?

A: To prepare for an MDR compliance audit, your organization should ensure that all QMS processes are well-documented and aligned with the MDR requirements. Conduct internal audits, provide training to staff on MDR provisions, and address

any identified non-conformities. It is also essential to maintain up-to-date technical documentation and ensure effective post-market surveillance practices are in place.

Related Course: EU Medical Device Regulation (MDR) 2017/745 – QMS Auditor Training Course

Q: What are common challenges faced during MDR compliance audits?

A: Common challenges during MDR compliance audits include incomplete or outdated technical documentation, inadequate risk management processes, insufficient clinical evidence, and lack of effective post-market surveillance.

Organizations may also struggle with understanding and implementing the extensive requirements of the MDR.

Related Course: EU Medical Device Regulation (MDR) 2017/745 – QMS Auditor Training Course

Q: How does the MDR impact post-market surveillance and vigilance activities?

A: The MDR significantly enhances requirements for post-market surveillance and vigilance activities. Manufacturers must implement proactive and systematic processes to monitor the performance and safety of their devices, report adverse

events, and take corrective actions when necessary. This ensures continuous compliance and improvement of device safety and effectiveness.

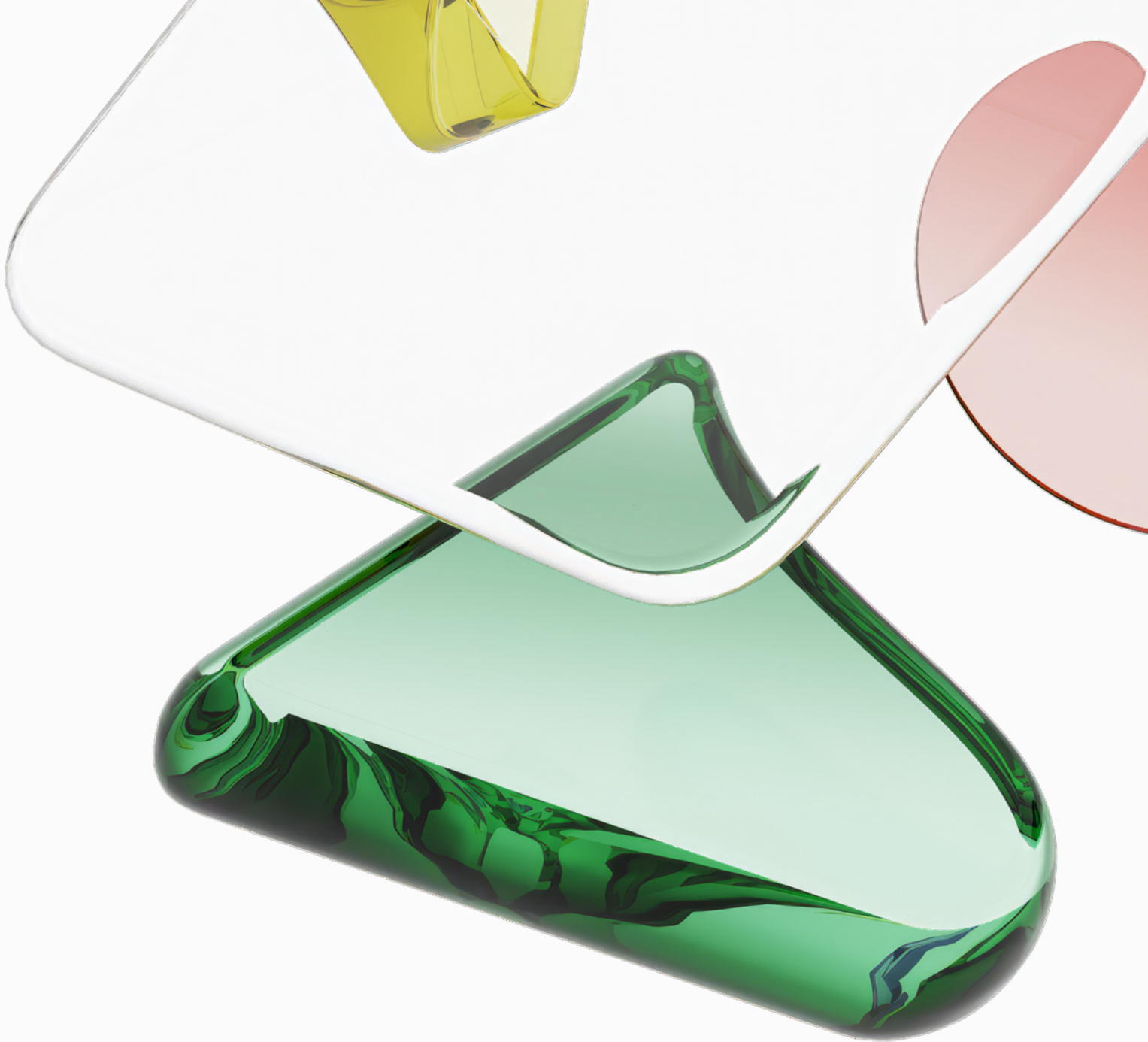
Related Course: EU Medical Device Regulation (MDR) 2017/745 – QMS Auditor Training Course

Q: How often should we conduct internal audits to maintain MDR compliance?

A: Internal audits should be conducted regularly, at least annually, or more frequently if significant changes occur within the organization or if previous audits identified non-conformities. Regular audits help to identify and address issues promptly, ensuring continuous compliance with the MDR.

Related Course: EU Medical Device Regulation (MDR) 2017/745 – QMS Auditor Training Course





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