Medical Device Quality and Regulation Course

From Theory to Practice in 5 Days

Syllabus, Rev.3

Course Overview:

This comprehensive 5-day course provides in-depth knowledge and practical skills on Medical Device Quality Management Systems and Regulatory Requirements. Participants will learn how to establish and maintain effective quality systems while ensuring compliance with key regulations in major markets.

Throughout the course, participants will engage in interactive discussions, case studies, and practical exercises to reinforce learning and develop skills in applying quality and regulatory requirements to real-world scenarios in the medical device industry.

#	Session	Topic
Day 1 Quality Management Systems (QMS) Fundamentals	**Session Kick-Off**	• Welcome & introductions • Course objectives, Structure and expectations
	Quality Management Systems (QMS) Fundamentals	• Introduction to Quality Culture • "Living" quality vs. merely following procedures • Building a culture of quality in medical device organizations
	Regulatory Compliance Concept Introduction	• MDSAP approach • EU MDR • FDA from QS 21 CFR 820 to QMSR
	Overview of ISO 13485:2016	• General requirements, Scope & Definitions • Clauses 1, 2 & 3 • PDCA & ISO 13485:2016 • Overview of Clause 4 Quality management system • Document and Record controls (DHF, DMR, DHR, QMS records) • Clause 5: Management responsibility, Resource management, Quality reviews • Clause 6 resource management
	Purchasing controls	• Purchasing controls and supplier management • Purchasing process, Purchasing information, Evaluation and selection of suppliers
	Production and process controls	• Production & service control, Process Verification and Validation, Measuring equipment, Acceptance activities
	Session Wrap-Up	• Feedback • Reflection for next session
Day 2	**Session Kick-Off**	• Day 1 Review
	Design and Development Process	• Design planning and development, Customer related processes, intended use, design input, design output • Design reviews

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Design Controls and Continuous Improvement		• Design verification and Product validation • Design changes
	Monitoring, Measurement, and Improvement	• Internal Auditing and Regulatory compliance • Nonconforming product handling • Feedback and complaint management • Corrective and Preventive Action (CAPA) system
	Linking it all together	• MDSAP, EU MDR, QS 21 CFR 820, QMSR
	Session Wrap-Up	• Course review & questions • Reflection & feedback
Day 3 **US FDA Regulatory Requirements Training**	**Session Kick-Off**	• Welcome & introductions
	Introduction **FDA Regulatory Framework**	• FDA's role and the Code of Federal Regulations (CFR) • US regulations for medical devices • FDA Scope and Code of Federal Regulation
	Premarket Pathways	• Regulatory pathways available for medical devices in the US • What Is a Regulated Medical Device? • How to practically use the various FDA tools and databases to determine the required regulatory route • Device Classification • FDA Pre-Market Notification [510(k)] • 513 (g) mechanism • De Novo Submission • Pre-Market Approval (PMA)
	FDA Quality System Regulation (QSR)	• Key differences between 21 CFR 820 and ISO 13485 • FDA QSR and Post-Submission Requirements • Post-market requirements • Device Registration and Listing
	Session Wrap-Up	• Course review & questions • Reflection & feedback
Day 4 **EU Regulatory Requirements Training**	**Session Kick-Off**	• Welcome & introductions
	Introduction	• Standard Conformity and Regulatory Compliance • MDD to MDR – Why?
	Transition from MDD to MDR	• Regulatory changes and transition timeline • Main changes overview
	EU Regulation Overview	• European Union (EU) Regulation • Regulatory changes and transition timeline • Main changes overview • Pathway to the EU Medical Device Market
	EU MDR Deep Dive	• Device classification system • QMS requirements under MDR – Obligations of the

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		Manufacturer • Technical documentation and conformity assessment routes • Economic operators • Person Responsible for Regulatory Compliance (PRRC) • Unique Device Identification (UDI) and EUDAMED • Post-market surveillance and vigilance requirements
	EU MDR In Practice	• Lessons Learned Supporting MDR Transition • Bonus session – Labeling, Translation, Brexit – UK
	Session Wrap-Up	• Course review & questions • Reflection & feedback
Day 5 **Risk Management Training**	**Session Kick-Off**	• Welcome & introductions
	Risk Management per ISO 14971:2019 Introduction	• ISO 14971:2019 Introduction: Overview, Terms and Process • General Requirements for Risk Management • Risk Management Process overview
	Risk Management Process	• Management Responsibilities and competence of personal • Risk management plan • Risk Analysis, Risk Evaluation, Risk Control • Evaluation of overall residual risk acceptability • Risk management review • Production and post-production activities
	Risk Management in Medical Device - Case Studies	• Case Studies and Exercise • Identify the links between ISO 14971:2019 and MDR 2017/745
	Risk Management in Medical Device Software	• Software Risk Management • Software risk control vs Risk controls implemented by software
	Risk Management Tools	• Techniques that support risk analysis Risk Analysis Tools Examples: Appendix B • dFMEA, pFMEA etc.; Risk Management vs FMEA • FTA – Fault Tree Analysis • ISO 14971:2019 - Medical devices — Application of risk management to medical devices 3rd edition – changes from ISO 14971:2007 (2012) • Overview of ISO 14971 :2019 Changes • Risk History and legal requirements reference between QMS risk Management, EU MDR, and ISO 14971 • V&V tests as risk control measures
	Session Wrap-Up	• Course review & questions • Reflection & feedback