Medical Device Quality and Regulation Course

Syllabus, Rev.2

Day 1- QMS Introduction and Process Approach	
Module	Topics
Session Kick-Off	• Introductions • Course objectives and expectations
Culture for Quality & Quality System According to ISO 13485:2016 and 21 CFR 820	• General requirements, Scope & Definitions • Document and Record controls (DHF, DMR, DHR, QMS records) • Management responsibility, Resource management, Quality reviews
Purchasing controls	• Purchasing process, Purchasing information, Evaluation and selection of suppliers • Statistical acceptance sampling inspection principles (Attributes)
Production controls	• Production & service control, Process Verification and Validation, Measuring equipment, Acceptance activities • Statistical Techniques • Process capability and statistical process control (SPC) concepts
Session Wrap-Up	• Feedback • Reflection for next session

Day 2- QMS Introduction and Process Approach	
Module	Topics
Session Kick-Off	• Reflections from last session
Design controls	• Design planning and development, Customer related processes, intended use, design input, design output • Design reviews • Design verification and Product validation • Design changes
Monitoring and Feedback	• Nonconforming product, Feedback & Complaint handling, Corrective and Preventive Action (CAPA) • Internal audit & MDSAP concepts
Session Wrap-Up	• Feedback

Day 3 – EU Regulation	
Module	Topics
Session Kick-Off	• Reflections from the last session, Introduction • Learning objectives
Introduction	• Standard Conformity and Regulatory Compliance • MDD to MDR – Why?
EU Regulation Overview	• European Union (EU) Regulation • Regulatory Change • Transition timeline • Main Changes overview • Pathway to the EU Medical Device Market
EU MDR	• Classifications + exercise • QMS requirements under the MDR • Technical files • Conformity Assessment routs • Economic Operators • PRRC • UDI • EUDAMED • Post Market Surveillance, Clinical Data, Vigilance • Lessons Learned Supporting MDR Transition • Bonus session – Labeling, Translation, Brexit – UK
Session Wrap-Up	• Feedback • Reflection for the next session
Home exercise	• Home exercise

Day 4 – US Regulation	
Module	Topics
Session Kick-Off	• Reflections from the last session, Introduction • Learning objectives
Introduction	• US regulations for medical devices and the role of the FDA • FDA Scope and Code of Federal Regulation
US Regulation Overview	• 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
US FDA regulatory pathway	• Device Classification • FDA Pre-Market Notification [510(k)] • 513 (g) mechanism • De Novo Submission • Pre-Market Approval (PMA) • FDA QSR and Post-Submission Requirements • Device Registration and Listing
Session Wrap-Up	• Feedback

Day 5 – Risk Management Training	
Module	Topics
Risk Management per ISO 14971:2019 Introduction	• Risk History and legal requirements reference between QMS risk Management, EU MDR, and ISO 14971 • 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 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 • TR 24971:2019
Risk Management in Medical Device - Case Studies	• Case Studies and Exercise • Identify the links between ISO 14971:2019 and MDR 2017/745
Session Wrap-Up	• Feedback