Medical Devices Quality System Requirements

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

** Total of 16 academic hours.*