Medical Devices Regulatory Requirements and ISO 13485:2003

Module 1 – EU, US and Canadian Regulation – Path for approval of Medical devices (2 hours)

1. EU Directive of Medical Devices – path for approval, role of Notified Body
2. US – FDA submission requirements
3. Canadian Medical Devices Regulations – “alike” but different

Module 2 – ISO 13485:2003 specifics and CFR QSR 820 (2 hours)

1. ISO 13485 and ISO 9001 – main differences
2. Design Control – principles, methods, documentation
3. Risk Management
4. Cleanness, sterilization of products
5. Traceability
6. Documents and Records retention

Module 3 – “Regulatory” processes in Quality System (1 hour)

1. Essential Requirements, applicable standards identification, evidence of safety and effectiveness
2. Vigilance and Recall
3. Medical Device Reporting (Mandatory Problem Reporting)
4. Post Marketing Surveillance
5. Notified Body and Competent Authorities Notification
6. Labeling requirements and translation requirements