III. QUALITY SYSTEM UNDER EN ISO 13485, US FDA QSR - GMP

Medical device manufacturers must establish their quality systems in compliance with the appropriate regulations and standards. Failure to do so can result in poor product quality, loss of certification or lack of process improvement. Our services assist Medical device companies to establish, update, and maintain Quality Management System including GMP (Good Manufacturing Practice) in compliance with the local regulation, FDA Quality System Regulation (FDA QSR), European Device Directives, ISO 13485, and Canadian Medical Device Regulations (CMDR).

The purpose is to enable you to establish and implement an effective tailored QMS system including GMP requirements:

- ☐ **Overview of the standard and the implications to your company.**
- ☐ **Benefits of adopting the standard and regulatory requirements.**
- ☐ **Why the process approach makes sense.**
- ☐ **Setting objectives and defining responsibilities.**
- ☐ **Who needs to be involved within the company.**
- ☐ **The responsibility of senior management.**
- ☐ **Role of design and development, purchasing, production, record keeping, customer communications.**
- ☐ **Maintaining effectiveness of the quality system, how and why.**
- ☐ **Process validation, monitoring and traceability, control of measurement devices and data analysis.**

Our services include:

A. EN ISO 13485 Training for Medical Device Companies

This ISO 13485 training is conducted on-sites. The training session tailored to the needs of your organization.

B. EN ISO 13485 Auditing for Medical Device Companies

Full or partial internal audit - ISO and FDA QSR (GMP). We provide internal auditing services which allow for an independent review of your full quality system.

C. EN ISO 13485 Quality System Implementation Consulting and maintenance

Gap analysis, design solution (custom made system), standard operating procedures, implementation, training, verification of effectiveness, and follow up.

References

EN ISO 13485, U.S. FDA Quality System Regulations (21 CFR PART 820), EU Medical Device Directive (MDD 93/42/EEC) and new EU MDR , Canada Medical Device Regulations (SOR/98-282), local regulation.