Quality Management Systems, ISO 13485

Qserve offers ISO 13485:2003, “Medical devices – Quality management systems” services to help manufacturers to access the market. This Quality System Management (QMS) Standard is designed specifically for medical device companies.

Whatever the class of device, complexity of your organization or the legal jurisdiction in which you operate, Qserve’s team of experts and certified Lead Auditors can implement and maintain ISO 13485 for your company. Qserve’s quality management system services fully meet European, Canadian and Australian requirements and comply with FDA Quality Systems Regulations (QSR). We offer a fully customized service ensuring cost-effective and timely implementation of your Quality Management System. Time to market is crucial!

During implementation of your QMS, Qserve offers high quality on-the-job training, and assistance with internal audit programs and the management review process. If required, we can supply both interim Quality Assurance Managers and senior management services, saving you the expense of hiring personnel before they are required. If your QMS is already in place, we can assess it for compliance and provide assistance in implementing any modifications that may be necessary.

Qserve offers a full range of services including:

- GAP analysis (a first assessment to verify what is needed)
- Implementation of Quality Management System EN ISO 13485, FDA 21 CRF 820 Quality Systems Regulations (QSR) and Canadian CMDCAS
- Advice on and assistance with your quality management organization
- Advice on and assistance with preparing your quality manual and umbrella procedures
- Compilation of documentation and help with the certification process (third party audit)
- Validation services: Installation Validation (IQ), Operational Validation (OQ) and Performance Validations (PQ) in relation to products, design control, and other processes such as purchasing, logistic and production
- Maintenance of quality management systems in compliance with applicable standards (EN ISO 13485, QSR/FDA and CAN/CSA 13485, and International Regulations)
- Assistance with or writing supplier/subcontractor contracts
- Assistance with internal, supplier/sub-contractor and distributor audits
- Experienced consultants who work closely with you to ensure a timely and on budget implementation of the QMS

Qserve’s many years of experience as Lead Auditors in the medical device industry and our excellent relationships with Regulatory Authorities worldwide, will ensure for your company, a fully compliant, comprehensive and first-class Quality Management System, on time and on budget!

If you would like more information or a free consultation and price quotation, please contact us.