Qserve®

.....the practical approach

Full Scope Regulatory Services
for Medical Device Compliance

Europe - Amsterdam (HQ) | **USA -** Boston - San Francisco | **China -** Nanjing

Contents

" Global reach, practical approach, experienced team"

Qserve Group

Qserve offers practical support to accelerate market approval. Our philosophy is to optimize and customize advice; our practical approach supports each individual company in the most efficient and cost-effective manner.

Qserve, as a global leading consultancy, provides a complete and global solution by offering a complete package of regulatory, quality and clinical services.

Global presence, local service.

Why choose Qserve?

- Strong international team with technical, regulatory, quality and clinical competence
- Ex EU Notified Body, FDA, and CFDA staff
- Medical Doctor on staff, in the Clinical Evaluation team
- Full Scope Regulatory Services for Medical Device Compliance
- Legal representation in China, Europe and United States
- Practical approach
- Native speakers in 9 languages
- ISO 9001 Certified
- Highly valued presenters
- Global presence, local service

Regulatory Compliance

Clinical Evaluation

Quality Assurance

Training

Global Registration

Auditing

Regulatory Compliance

Regulations vary depending on the medical device and market you wish to enter.

Are you looking for assistance in the regulatory field? Long term or short term? Project or task specific? Europe, United States, other markets? Our specialized teams will help you comply with all necessary regulations. We translate medical device regulations to regulatory strategy for your specific project to provide customized support.

Our customized services benefit both large, experienced medical device companies, as well as innovative, high-tech start-ups.

Whether it's resource or maintenance issues in an enterprising organization, or strategy, compliance and market approval challenges in an emerging firm, Qserve can craft a custom solution for your business.

Our Services

- **Regulatory Strategy** - Developing the optimal regulatory strategy
- **Notified Body Selection** - Support in selecting the best fit of manufacturer and notified body
- **Post-Market Activities** - Support to maintain compliance in the post market phase
- **GAP-Analysis** - identification of compliance gaps to all key RA/QA/CA standards, guidance documents and regulations
- **Product Registration** - Registration support in the USA, Europe, China and over 40 countries to date
- **Legal Representation** - Our local entities act as your independent legal representatives
- **Interim Management** - Temporary assistance for specific situations or hands-on expertise when you need it
- **Technical Dossier Set-Up** - Use Qserve to structure or update your dossier
- **Vigilance, MDRs and FSCAs** - Support in reporting incidents and field actions

Clinical Evaluation

Clinical Evaluation is the final validation of a medical device to confirm that the device performs as intended and can safely be used in patients in accordance with its instructions for use.

Worldwide regulations are focusing more and more on compliance, specifically of clinical data. Ensuring that your business maintains adequate and validated clinical data to support the performance and safety of your device and its connected claims, is crucial in today's market.

The experienced clinical team of Qserve provides hands-on support in all areas of your clinical strategy plan, including pre-market clinical strategies to present to regulatory bodies, as well as emphasized clinical follow up. If you value a practical approach, Qserve is the best partner to set-up your PMCFU protocol and organize all aspects of such a study.

Our Services

- **Pre-Market Clinical Strategy** - Clinical regulatory strategies to facilitate market approval
- **Post-Market Clinical Strategy** - Post-market strategies including Post Market Clinical Follow Up (PMCFU)
- **Clinical Auditing** - Verification that clinical investigations comply with the corresponding standards and protocols
- **Clinical Evaluation Report** - Full service for Europe (rev4 of MEDDEV 2.7.1), United States and China
- **Literature Review** - Assessment of clinical data that is relevant to your medical device
- **China Clinical** - Chinese Clinical Evaluation report based on CFDA guidelines
- **Clinical Investigation** - Full CRO and CRA services including clinical study management
- **Data Management & Statistics** - Clinical data analysis using a dedicated software system

Quality Assurance

A Quality Management System (QMS) has become mandatory to do business in the medical field.

Setting up and maintaining such a system can present challenges, especially if your business lacks experience in this area.

Qserve's consultants have worked as QA Managers in the medical device industry, and as auditors for regulatory bodies, thus turning their knowledge into a practical approach to set up your QMS structure.

Working as partners through each step of the process, we can build, implement and maintain a streamlined QMS together.

Our Services

- **Quality Strategy** - Setting up a strategy to align the Quality System with your business goals
- **QMS Implementation** - Setting up a detailed implementation plan covering activities and deliverables
- **Training Support** - Our on-the-job training of key-personnel will result in a successful QMS-implementation
- **GAP-Analysis** -The first step in gap analysis is assessing your existing compliance with its current requirements
- **Complaint Support** - Handling, analysis, processing complaints as part of post market surveillance and vigilance
- **Interim Management** - Use our quality experts for temporary management of your projects to add specific expertise and/or extra capacity to your team
- **CAPA Support** - We will help you maintain control of your corrective and preventive action processes to ensure regulatory compliance
- **Auditing Support** - Pre-Audit service to prepare your QMS for external inspections
- **QMS Maintenance** - Keeping your QMS up to date by analyzing and improving your processes to ensure compliancy with the latest developments

Training

Qserve offers medical device manufactures training on all regulatory levels, stay up to date and strengthen your team. A stimulating interactive training environment focused on all compliance areas of the medical device industry with pragmatic in-house training possibilities, based on your wishes.

Our practical approach makes our training a perfect fit for all companies that are looking for in-house training to changing worldwide regulations or to improve RA/QA/CA knowledge.

"Invest in knowledge, train your staff"

A selection of our training offer:

- **Medical Device Regulation** - Learn from Qserve's EU-MDR top experts the ins and outs of the new European Medical Device Regulation
- **Risk Management ISO14971** - Grasp the process and importance of risk management throughout the life cycle of a device, including how to meet the deviations in the EN ISO 14971
- **CAPA & Complaints** - Learn how to write, manage and close complaints / CAPA's, including performing suitable root cause analysis
- **Internal Auditing** - Our experts all have many years of "real" experience in their own particular areas of the Medical Device Industry, ensuring your company a high quality training session
- **Medical Software** - Learn (more) about software requirements and risk assessment in regards to software verification
- **Clinical Evaluations** - Gain an understanding of how to write, define, and maintain clinical evaluation reports and procedures. We are experts for rev4 MEDDEV 2.7.1.
- **ISO13485/QSR21CFR820** - Get (more) insight into the scope of international QMS standards like the new ISO13485:2016
- **Electrical Safety: IEC60601** - Gain awareness of the electrical safety and essential performance compliance processes

Global Registration

Where would you like to go?

We understand you wish to market your medical devices in multiple countries. We can help to determine which countries will be most suitable on the basis of your current certification. Our international team, local offices and professional alliances support market access.

Europe

Our local team and legal entity can support you with both the CE certification, the ISO13485 certification and the local database requirements.

MDR requirements are on top of our expertise list and we claim to be the best regulatory partner for this area.

Our local entity can also act as your European Authorized Representative (EAR).

China

Our local team and legal entity are in close contact with our European and American offices.

We combine local expertise with transparent communication. Full scope of services, ranging from set up of Chinese product requirements, communication with test houses, preparing technical files, clinical evaluation and clinical studies in Chinese hospitals.

Our office acts as independent legal representative.

United States

Our local team and legal entity can guide you through all the different routings to market access in the United States like 510(k) and the de novo process.

Also all companies intending to market their devices in the United States must register and Quality System Regulations (QSR) compliance is a must in most cases.

Our local entity can act as your US Agent including listing and registration services.

"Use Qserve's global network to market your medical device"

Latin America

The Latin American countries are getting more harmonized but every country still requires a separate product registration and local expertise is tight.

Qserve has an in-house Brazilian expert and professional alliances in various countries offering registration support and independent legal representation.

Australia & Canada

Two English speaking countries which regulatory systems are strongly connected to the European regulations which makes market access generally easier when possessing your European CE and ISO13485 certification. Qserve offers regulatory support in both countries and independent legal representation in Australia.

Middle-East & Africa

A strongly developing area when it comes to medical device regulatory, so local monitoring is necessary to stay up to date and to stay compliant.

Regulatory support and legal representation possible in various countries.

South-East Asia

In this sub-region of Asia are many interesting markets like Thailand, Singapore, Malaysia and Indonesia. Some of the countries already have strong developed regulatory systems, other only a basic setting based on products that require an import license. Qserve's local representatives guide you through and offer quick communication, local knowledge and legal representation services.

East Asia

Besides China and Hong Kong, Qserve also offers her local market access services in countries like Japan, Taiwan and South Korea using local professional partners that are experienced and service oriented. We offer a strong combination of an international strategy with local expertise, easy communication and independent legal representation.

Russia

In Russia you have to start all over again. Prepare yourself for bureaucracy, testing, shipping of product samples, eventual clinical trials and translations of all your documentation. Enlighten the registration process using Qserve as your project manager guiding you through the process, facilitating all testing and coordinating translations.

Auditing

Ensure quality and compliance before the official audit.

Qserve provides mock audits, document reviews, practical solutions, checklists and internal audit programs to ensure your compliance.

Follow the trend of other manufacturers, who outsource their supplier management and internal audits. Use Qserve's local presence to verify your suppliers efficiently.

We are prepared, are you?

"Qserve has a unique auditing style which provides a high level of engagement and professionalism that encourages critical thinking"

Our Services

- **Internal Audit** - Qserve has a dedicated team that can perform your internal audits to set the base line or on a structural basis to teach you how to do it yourself
- **Mock FDA Inspection** - With our mock FDA-inspection we guide you step-by-step through the process before the FDA visits you
- **Clinical Investigation Audit** - Verify that the execution of the clinical investigation complies with proper standards and protocols
- **Supplier / Subcontractor** - Qserve has a dedicated team that can perform your supplier audits to set the base line or on a structural basis to teach you how to do it yourself
- **CE Pre-Audit** - With our CE pre- audit, we walk you through the audit process before the notified body comes to you
- **Brazilian GMP Audit** - Our Brazilian expert can execute a pre- audit and review your documentation before ANVISA visits you
- **Witness Audit** - Qserve offers on-site support during regulatory audits and inspections
- **Due Diligence Audit** - If you are considering a merger or acquisition a due diligence audit is risk reduction
- **Unannounced Audit** - Notified bodies can perform unannounced audits. Prepare yourself with Qserve's experienced notified body auditors

About Qserve

Our mission is to support all medical device manufacturers with a practical approach, translating existing regulations to understandable requirements. We serve to guide manufacturers in gaining and maintaining compliance for their safe and qualitative medical devices in the most streamlined way possible.

"Qserve's global team combines their regulatory knowledge and experience in the medical device industry, sharing more than 500 years' worth of combined expertise in the medical field. This allows us to assist manufacturers in marketing thousands of devices worldwide.

This unique combination of regulatory knowledge and device experience is highly valued among our clients.

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Global Medical Device Regulatory Compliance Consultants

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www.qservegroup.com