

## Audits

**Qserve provides professional auditing support to medical device companies. With many years in the medical device industry, Qserve's qualified auditors have a wealth of auditing experience.**

In order to assess an organization for compliance to the appropriate regulations and standards, it is necessary to audit the various processes, their interfaces, functions, subcontractors, suppliers and distributors. Qserve's team of certified Lead Auditors for ISO 13485:2003, CMDCAS, QSR and ISO 9001:2000 can assist your organization with or can conduct such audits for you.

In the event your company is inspected by a Notified Body or the FDA or other Authority, Qserve can prepare you in advance and also attend the inspection, serving as a liaison between your company and the auditor. This can be especially useful when language may be a concern.

### Internal Audits

Internal audits are essential to your continuous improvement process and are obligatory for compliance with your product CE Marking, FDA and international regulatory compliance. Our program not only consists of advice and assistance with internal audits, but we also give higher level management advice to improve your Quality Management System and business process.

### Supplier Audits

Your supplier is an integral factor in your Quality Management System. Our program helps you with the implementation of your supplier quality audits and compliance to international regulations.

### Distributor Audits

Your distributor is an integral element in your Quality Management System. As a manufacturer you need to verify that your distributor has a quality system in place, which meets with your requirements and the regulatory responsibilities imposed upon you as manufacturer.

### FDA (MOCK) Audits

We assist your organization in preparation of FDA inspections, guiding you through the process by conducting FDA mock audits. By using "Quality System Inspection Techniques" (QSIT), Qserve auditors can pose as FDA inspectors and assess GMP, GLP, GCP and QSR processes within your company, testing internal systems and personnel in preparation for an FDA inspection. We can also provide you with techniques for the efficient organization of FDA audits and the management of multiple inspectors.

### Qserve's Auditing Deliverables include:

Audit Plan, audit report with all audit findings included, discussion of findings, recommendations for improvement and achieving compliance, follow-up of remedial actions, and CAPAs (Corrective and Preventive Actions)

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