

US Agent and Official Correspondent Services

With our years of experience in the medical device industry and our excellent relationship with Regulatory Authorities worldwide, Qserve is pleased to offer US Agent and Official Correspondent services via Qserve America Inc.

US Agent

By law foreign medical device manufacturers wishing to sell their products in the US are required to retain a US Agent with a physical address within the USA. More than just an address, as your US Agent, Qserve will assist your company in ensuring your organization and its products are properly registered with the FDA. We act as a liaison between your company and the FDA, responding to questions concerning your products, assisting you and the FDA to schedule inspections and helping you resolve problems or delays. This can be especially helpful if issues arise with FDA and US Customs regarding the initial importation of your product(s) into the US.

Why should you appoint Qserve as your US Agent?

We ensure that all the regulatory needs of our clients are handled professionally, confidentially and promptly.

- We are a well known FDA US Agent representative in the industry with a proven track record in assisting medical device companies worldwide.
- With offices in Europe and the US, we can provide coordinated regulatory and quality planning, from design and development through market launch, including regulatory documentation and filings.

Official Correspondent

An Official Correspondent is someone within your organization, who is specifically responsible for communicating with FDA. While the FDA does not require a foreign manufacturer to assign the responsibilities of the Official Correspondent to their US Agent, the FDA prefers to work with US representatives for reasons of language and time zone differences. The FDA will contact the Official Correspondent whenever the Agency has a question about your company or its product. Qserve understands the needs of the FDA and can help prevent misunderstandings that can delay or stop your products from being imported and sold in the US. To provide better service and as part of our on-going commitment to our US Agent clients, at your request we will also serve as your Official Correspondent at no extra charge.

Qserve can also undertake:

- Preparation and/or review of Establishment Registration and Device Listing Forms. This service is also provided at no additional charge provided you use Qserve as your US Agent.
- Adverse event reporting according to the US Medical Device Reporting regulations; all US Agent clients are charged at a reduced rate for each complaint evaluation.

With 25+ years of experience interacting with the FDA, Qserve has a unique understanding of FDA requirements and a wealth of qualifications to act as your US Agent and Official Correspondent.

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