.....the practical approach

Qserve's Startup Services

"Getting a medical device to market can be a burdensome process due to the obligations and requirements. The requirements vary from one market to another. It is of utmost importance to have a clear market strategy available to reduce time to market and start selling your device as soon as possible. Qserve can support you with that".

Robert Paassen - *Startup Lead*

First Steps in Regulatory Affairs/Quality Assurance

- Begin by classifying your device and determining which product requirements are applicable, while also considering relevant ISO standards. In order to freeze your design, we will make sure you will obtain comprehensive understanding.
- Freeze the design of your device before conducting testing to ensure consistency and accuracy in the testing process.
- When establishing your Quality Management System (QMS), prioritize essential Standard Operating Procedures (SOPs) such as document and record control, design and development, risk management, and supplier control.
- Document every decision made regarding your device (design).
- Identify and understand all interdependencies during the development and testing phases; these are crucial components of your regulatory and clinical strategy.

How Can We Help You?

- Support you in defining a custom regulatory and clinical strategy.
- Deliver hands-on support.
- Teach you and your team on the different aspects of regulatory, quality, and clinical affairs.
- We are available for ad hoc questions and help you make decisions.

"Ready to navigate the complex journey to market approval for your startup? Discover how Qserve's dedicated practical approach can guide and support you every step of the way. Contact us today to learn more and embark on your path to success".

Ricardo Azuero
Business Development Specialist

Qserve's Practical Approach

Qserve is solution-oriented. We strive to find the best solutions for challenges startups may face. If the regulatory landscape changes during your development phase, we assist in translating these changes into potential solutions for your processes and devices.

Services Specifically Intended For Startups

Startup Academy

- Participate in monthly onsite and hybrid training sessions to collaborate with peers, share insight, and learn from each other's experiences.

Phone A Friend

- Our ad hoc support contract provides you with the flexibility to consult with any Qserve specialist at your convenience.

Furthermore, it extends benefits for other services such as remote training modules, template packages, and review services.

Startup QA/RA Officer Support

- Onsite RA/QA expertise is vital from the start, ensuring that medical device startups can effectively navigate regulations, maintain quality and compliance, and manage risks, all crucial elements for their success and growth in the highly regulated medical device industry. Qserve offers essential onsite RA/QA support tailored to your needs. Please contact us for the full list of advantages and the flexible costs.

Testimonial: "Communication runs smoothly and Qserve is flexible in planning meetings. Qserve responds quickly to questions and has enough expertise to answer them properly. The accessible contact is nice for a startup given the dynamics in developing a medical device." ***Slam Orthopedic***

Testimonial: "Qserve provided invaluable support during our CE certification. Their flexibility, prompt responsiveness, and solution-oriented approach were crucial for our startup. I recommend Qserve to any medtech company seeking efficient and pragmatic assistance in navigating the certification process." ***ProVinci Medtech***

For more information, please reach out to

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