ISO 13485 Company and Device Certification

A Clearer Vision of Quality

01 THE CHALLENGE

A state-of-the-art ophthalmology company focused on diabetic retinopathy tasked Critical Software with certifying their medical device development processes according to ISO 9001:2008 and ISO 13485 standards. The device certification was undertaken to Class IIa standards as set out in the European Council Directive 2007/47/EC (the Medical Devices Directive).

02 THE SOLUTION

As an ISO 13485-certified company, we began by employing the expertise that gave us our accreditation to implement a gap analysis of the client's Quality Management System (QMS). We then put in place processes and helped to create the necessary supporting documentation to comply with applicable regulations.

Parallel to this, we defined the project's overall structure and assisted the development and verification & validation (V&V) teams with all of the activities necessary to meet the requirements of the certification class.

Working closely with the client's in-house development team, we were involved in the entire medical device development process and ensured that the client's QMS was defined according to EU requirements.

Our work involved close liaison with relevant certification authorities and on-site support during audits, providing the necessary safety and compliance cases to enable the client's device to achieve CE marking.

03 THE RESULTS

Our work delivered a fully certified QMS to all relevant standards, increasing the trustworthiness of development, verification and validation processes.

The successful QMS implementation, alongside our development and V&V teams' rigorous adherence to policies and procedures, meant the device was certified to Class IIa standards.

Our ISO 13485 consultancy and expert support in interacting with the national certification authorities decreased any risks of audit failure and ensured medical device development processes were safe and possessed an efficient time-to-market.

04 THE TECHNOLOGY

- Gap analysis
- Document templates
- Project quality plans
- Verification & validation expertise
- Documentation to EU standards
- Business support for external audits

Critical software

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LRQA CERTIFIED ISO 13485

ABOUT CRITICAL SOFTWARE

Critical Software provides systems and software services for safety, mission and business-critical applications. We work closely with our clients, helping them to meet the most demanding standards for performance and reliability.

We were founded in 1998, with NASA our very first client. Today, we work across many international industries and have offices across the globe.

Certified B Corporation

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We are CMMI Maturity Level 5 rated.
For a list of our certifications & standards visit our website.