



Why do you need to get ISO 13485 Certified?

Whether you are looking to operate internationally or expand locally, ISO 13485 Certification can help you improve overall performance, eliminate uncertainty, and widen market opportunities. Companies with this certification communicate a commitment to quality to both customers and regulators.

- Increase access to more markets worldwide with certification
- Outline how to review and improve processes across your organization
- Increase efficiency, cut costs and monitor supply chain performance
- Demonstrate that you produce safer and more effective medical devices
- Meet regulatory requirements and customer expectations

ISO 13485 is in part designed to produce a management system that facilitates compliance to the requirements of customers and global regulators. Benefits can be reaped from being both ISO 9001 and ISO 13485 certified, because ISO 9001 focuses on business aspects not found in ISO 13485 that are good for all businesses.

If the proper management system framework is in place it should facilitate the identification and implementation of country-specific requirements for the management system of medical device manufacturers. ISO 13485 is not specific enough to contradict country specific requirements, and should serve as a baseline management system for all.