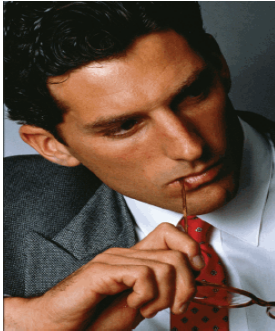


From FDA Compliance to ISO 13485 Certification

Three Key Steps to Selling to the Global Marketplace



Want to sell your devices internationally? ISO 13485 is your passport to the global market, a necessity for exporting products to many countries across the globe. If you're already compliant with FDA 21 CFR Part 820, your job is almost done – the regulations are practically interchangeable. But knowing the few key differences will give you a strategic advantage as you plan your ISO 13485 compliance program.

ISO 13485 requires a quality manual. While Part 820 requires manufacturers to document quality system procedures, it does not call for a formal quality manual. ISO 13485 calls for organizations to establish and maintain a quality manual that details the scope of the quality management system, the documented procedures established for the QMS, and a description of the interaction between quality processes. The benefits of writing a quality manual extend beyond compliance with requirements, since a manual is helpful in training personnel and as a quick reference during quality assessments.

ISO 13485 is focused on customer requirements. The language of Part 820 indicates that manufacturers should focus on building safe and effective devices, without referencing customers specifically. ISO 13485 requires that top management “ensure that customer requirements are determined and are met.” This may involve a stronger focus on creating customer feedback tools and building customer input into device design, manufacturing, distribution and support. This can only benefit the company by improving marketability and building customer loyalty.

ISO 13485 requires consistent risk management processes. While Part 820 mentions risk management only in the context of design validation, ISO 13485 recognizes that risk management is a process that should be conducted throughout the product life cycle. However, the standard does not go into specifics, leaving those details for ISO 14971, Application of Risk Management for Medical Devices. For certification to both ISO standards, it is important to show evidence that you consistently assess and mitigate risks throughout all product realization stages. This will help you eliminate potential product problems, identify trends, and consistently build improvements into your quality processes.

When you develop your compliance programs to align with these key principles, you'll easily attain ISO certification.