



ISO 13485 Starter Guide (Paperback)

By MR Emmet Tobin

Createspace Independent Publishing Platform, 2016. Paperback. Condition: New. Language: English . Brand New Book ***** Print on Demand *****.This short concise book provides an introduction to ISO 13485. It introduces the core themes of the standard to those who wish to work in regulated industries such as medical devices, highlighting key areas and practices. It is a perfect introduction for operators, factory workers, engineers and managers wishing to learn the fundamentals. It is also a useful pocket reference book, small enough to slip into a case or pocket. ISO 13485 is the Quality management standard of choice for manufactures of medical devices. Revised in 2016, ISO 13485:2016 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements. 1 The scope of the standard can apply to any organization or company involved in throughout the life-cycle of a product, including design and/or development, production, storage and distribution, installation, or servicing of a medical device and design and development or provision of technical or professional services. (Page count 86 pages).



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