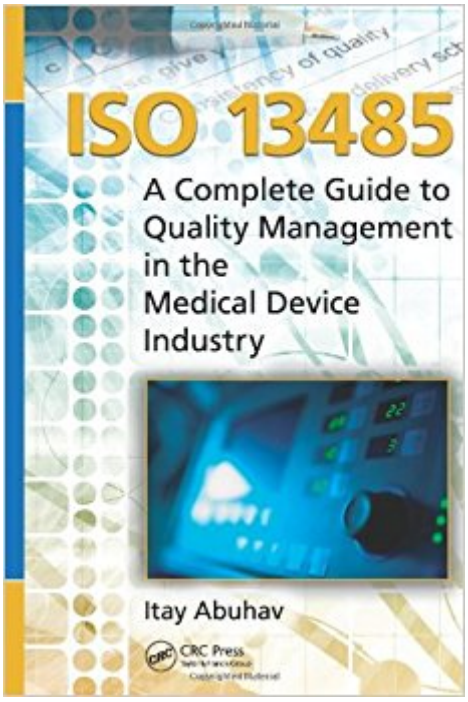
ISO 13485: A Complete Guide To Quality Management In The Medical Device Industry



Synopsis

Although complex and lengthy, the process of certification for the ISO 13485 can be easily mastered using the simple method outlined in ISO 13485: A Complete Guide to Quality Management in the Medical Device Industry. Written by an experienced industry professional, this practical book provides a complete guide to the ISO 13485 Standard certification for medical device manufacturing. Filled with examples drawn from the authorÃ¢â ¬â„¢s experience and spanning different sectors and fields of the medical device industry, the book translates the extra ordinary requirements and objectives of the standard into feasible activities and tasks. The book provides a full analysis of each clause and sub clause through quality perspectives: the implications on an organization, its processes, management, human resources, infrastructures, work environment, control and effectiveness, documentations and records. The book is organized like the standard itself Ã¢â ¬â ¢ the table of contents is identical to the ISO 13485 StandardÃ¢â ¬â„¢s table of contents Ã¢â ¬â ¢ making it user friendly, familiar, and unintimidating. You can use the book as a consulting session Ã¢â ¬â ¢ read it, explore it ,extract ideas Ã¢â ¬â ¢ and draw on the information and knowledge that suits you and your organization, and then apply it effectively to your quality management system and processes.

Book Information

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Customer Reviews

Eng. Itay Abuhav, based in Switzerland, served for many years as a quality manager and consultant for international companies in various fields and industries among them the medical device industry.

He has certified and provided consultation to a number of medical device factories in quality management for the ISO 13485 standard.

This was an excellent book. It has been referenced multiple times in my organization when trying to seek more guidance for compliance. However it was published before the ISO 13485:2016 standard was published. Therefore, one must be careful to ensure that this is not your only guide. Thus cannot give it a 5 star rating

Thank you!

ISO 13485: A Complete Guide to Quality Management in the Medical Device Industry ISO 13485:2016, Third Edition: Medical devices - Quality management systems - Requirements for regulatory purposes ISO 13485:2003, Medical devices - Quality management systems - Requirements for regulatory purposes ISO 10005:2005, Quality management systems - Guidelines for quality plans ISO/TS 20022-3:2004, Financial services - UNIversal Financial Industry message scheme - Part 3: ISO 20022 modelling guidelines ISO 20022-1:2004, Financial services - UNIversal Financial Industry message scheme - Part 1: Overall methodology and format specifications for inputs to and outputs from the ISO 20022 Repository ISO/TS 20022-5:2004, Financial services - UNIversal Financial Industry message scheme - Part 5: ISO 20022 reverse engineering ISO/TS 20022-4:2004, Financial services - UNIversal Financial Industry message scheme - Part 4: ISO 20022 XML design rules ISO 10007:2003, Quality management systems - Guidelines for configuration management How to Add a Device to Account: How to add a device to my account - 3 easy steps in few minutes Design Controls for the Medical Device Industry Medical Science and Medical Industry: The Formation of the American Pharmaceutical Industry (Henry E. Sigerist Series in the History of Medicine) ISO/TS 22004:2005, Food safety management systems - Guidance on the application of ISO 22000:2005 ISO/IEC 27002:2005, Information technology - Security techniques - Code of practice for information security management (Redesignation of ISO/IEC 17799:2005) Medical Terminology: Medical Terminology Easy Guide for Beginners (Medical Terminology, Anatomy and Physiology, Nursing School, Medical Books, Medical School, Physiology, Physiology) American Medical Association Complete Medical Encyclopedia (American Medical Association (Ama) Complete Medical Encyclopedia) ISO 14971:2007, Medical devices - Application of risk management to medical devices ISO 14971:2000, Medical devices -- Application of risk management to medical devices Iso 15189:2012, Medical laboratories - Requirements for

quality and competence Medical Terminology: Medical Terminology Made Easy: Breakdown the Language of Medicine and Quickly Build Your Medical Vocabulary (Medical Terminology, Nursing School, Medical Books)