ISO 13485: A Complete Guide to Quality Management in the Medical Device Industry

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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 author’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 — the table of contents is identical to the ISO 13485 Standard’s table of contents — making it user friendly, familiar, and unintimidating. You can use the book as a consulting session — read it, explore it ,extract ideas — 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.

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