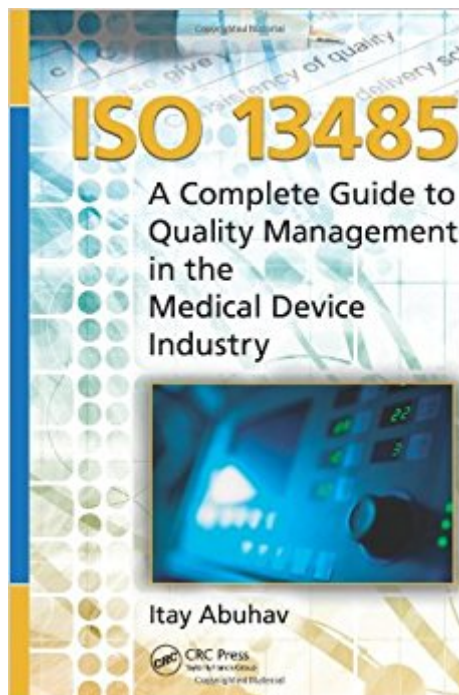




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ISO 13485: A Complete Guide To Quality Management In The Medical Device Industry



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 author's experience and spanning different sectors and fields of the medical device industry, the book translates the extraordinary 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 unthreatening. 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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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!

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