

Mastering and Managing the FDA Maze, Second Edition: Medical Device Overview

By Gordon Harnack


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The number of FDA regulations and the agency's increased expectations is staggering and their content tedious, creating a regulated industry need for compliance insight and appropriate detail. This book is the reference needed to successfully navigate through the FDA maze! The target audiences for this desk reference include: Regulatory professionals, who know their responsibility to keep their firm's employees trained and competent on FDA device regulations and who need a preliminary desk reference that can be used throughout their enterprise to help train and ensure compliance Neophytes, who know nothing about FDA but need a resource that provides both broad and specific information in sufficient detail to be useful Beginners, who know a little about FDA, need to know more, and need a reference tool to help them be more effective and productive on the job Intermediates, who knows enough about FDA to know they need to know more and who need a reference tool that provides them with both more basics and executable detail Busy managers, who need to know regulatory requirements and FDA expectations in order to manage compliance in their specific activity Busy executives (CEOs, COOs, and operations managers, whom FDA holds responsible for all regulatory compliance), who also need a desk reference with specific information to quickly assess regulatory compliance, identify potential noncompliance, and review corrective, preventive, and compliance actions

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Mastering and Managing the FDA Maze, Second Edition: Medical Device Overview By Gordon Harnack Bibliography

- Sales Rank: #818038 in Books
- Published on: 2014-08-15
- Original language: English
- Dimensions: 11.00" h x 8.50" w x 1.25" l, 2.95 pounds
- Binding: Paperback
- 484 pages

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