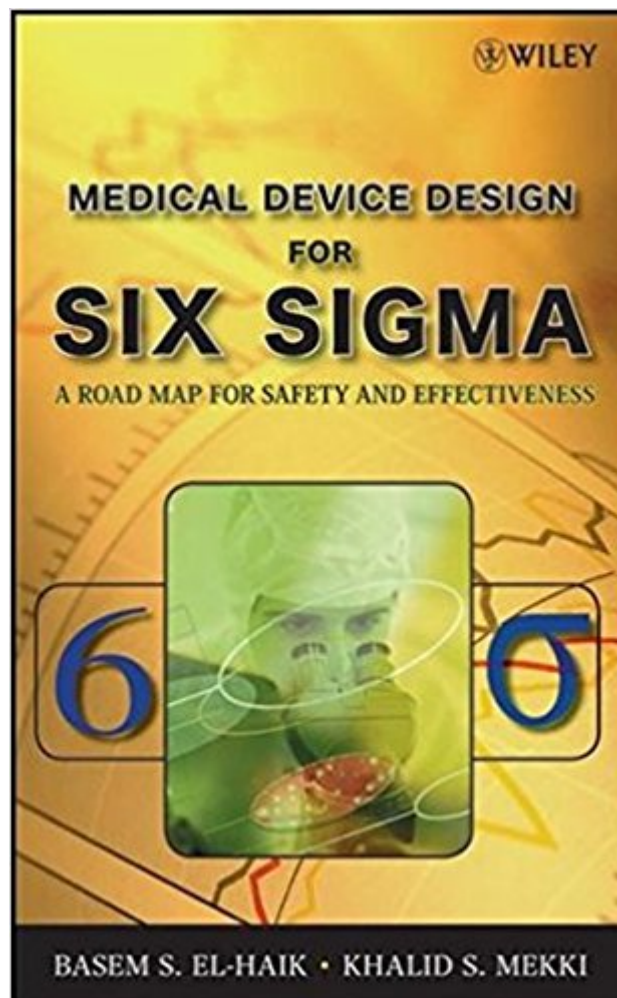




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# Medical Device Design For Six Sigma: A Road Map For Safety And Effectiveness



## Synopsis

The first comprehensive guide to the integration of Design for Six Sigma principles in the medical devices development cycle **Medical Device Design for Six Sigma: A Road Map for Safety and Effectiveness** presents the complete body of knowledge for Design for Six Sigma (DFSS), as outlined by American Society for Quality, and details how to integrate appropriate design methodologies up front in the design process. DFSS helps companies shorten lead times, cut development and manufacturing costs, lower total life-cycle cost, and improve the quality of the medical devices. Comprehensive and complete with real-world examples, this guide: Integrates concept and design methods such as Pugh Controlled Convergence approach, QFD methodology, parameter optimization techniques like Design of Experiment (DOE), Taguchi Robust Design method, Failure Mode and Effects Analysis (FMEA), Design for X, Multi-Level Hierarchical Design methodology, and Response Surface methodology Covers contemporary and emerging design methods, including Axiomatic Design Principles, Theory of Inventive Problem Solving (TRIZ), and Tolerance Design Provides a detailed, step-by-step implementation process for each DFSS tool included Covers the structural, organizational, and technical deployment of DFSS within the medical device industry Includes a DFSS case study describing the development of a new device Presents a global prospective of medical device regulations Providing both a road map and a toolbox, this is a hands-on reference for medical device product development practitioners, product/service development engineers and architects, DFSS and Six Sigma trainees and trainers, middle management, engineering team leaders, quality engineers and quality consultants, and graduate students in biomedical engineering.

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## Customer Reviews

"The book is well-written and the authors use well versed descriptions, easy to read figures and tables, and industry-related examples and case studies to explain what can be very complex concepts and processes. This book would be a valuable resource for anyone in the field of medical device design." (Doody's Book Reviews, October 2008)

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I had read this book with great interest. The reader will find inside many examples of case studies regarding how to apply Six sigma tools in the medical device industry. The concepts are probably explained very quickly, so the topics are clearly understandable to people already familiar with Six

Sigma (at least at green belt level). Very usefully for BB / MBB to set up a deployment project of DFSS in the company. Good job done by the authors!

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