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4.5.2 Clarification/Product Specification Procedure; 4.5.3 Detailed Design Procedure; 4.5.4 Design Verification/Validation/Evaluation Procedure; 4.5.5 Design Changes; 4.5.6 Control of Documents; 4.5.7 Risk Assessment Procedure; 4.6 Implementing a Procedure; 4.7 Summary; References; 5 Developing Your Product Design Specification; 5.1 Introduction; 5.2 Developing the Statement of Need (or Brief); 5.2.1 Identifying the "One Thing"; 5.2.2 Formalizing the Statement of Need; 5.3 The Product Design Specification (PDS); 5.3.1 Essential Elements of a PDS; 5.3.1.1 Customer
5.3.1.2 Regulatory and Statutory
5.3.1.3 Technical; 5.3.1.4 Performance; 5.3.1.4.1 Biomechanics; 5.3.1.5 Sales; 5.3.1.6 Manufacturing; 5.3.1.7 Packaging and Transportation; 5.3.1.8 Environmental; 5.3.1.9 Summary; 5.4 Finding, Extracting, and Analyzing the Content; 5.4.1 Focus Groups; 5.4.2 Regulatory Bodies; 5.4.3 Immersion; 5.4.4 Libraries; 5.4.4.1 Standards; 5.4.4.2 Journals and Learned Publications; 5.4.4.3 Books; 5.4.4.4 Librarians; 5.4.5 Technical Literature; 5.4.5.1 General Trade Magazines; 5.4.5.2 Catalogs, Fliers, and Trade Literature; 5.4.6 The Internet; 5.4.7 Conferences and Symposia
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7.2 Optimization

Sommario/riassunto

This book provides the bridge between engineering design and medical device development. There is no single text that addresses the plethora of design issues a medical devices designer meets when developing new products or improving older ones. It addresses medical devices' regulatory (FDA and EU) requirements--some of the most stringent engineering requirements globally. Engineers failing to meet these requirements can cause serious harm to users as well as their products' commercial prospects. This Handbook shows the essential methodologies medical designers must understand to ensure thei
