

1. Record Nr.	UNINA9910462130303321
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Titolo	Medical device design [[electronic resource]] : innovation from concept to market / / Peter J. Ogrodnik
Pubbl/distr/stampa	Boston, : Academic Press, 2013
ISBN	1-283-75437-1 0-12-391943-6
Edizione	[1st ed.]
Descrizione fisica	1 online resource (369 p.)
Disciplina	610.28 610.284
Soggetti	Biomedical engineering Engineering design Electronic books.
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Note generali	Description based upon print version of record.
Nota di bibliografia	Includes bibliographical references and index.
Nota di contenuto	Front Cover; Medical Device Design; Copyright Page; Contents; Preface; Acknowledgements; 1 Introduction; 1.1 What Is Design?; 1.2 The Design Life Cycle; 1.3 Medical Devices Definitions; 1.4 Summary; References; 2 Classifying Medical Devices; 2.1 Introduction: Why Classify?; 2.2 Classification Rules; 2.3 Classification Case Study; 2.3.1 EU Classification; 2.3.2 USA Classification; 2.3.3 Special Cases; 2.4 Classification Models; 2.5 Classification and the Design Process; 2.6 Summary; References; 3 The Design Process; 3.1 Design Process versus Design Control; 3.2 Design Models 3.2.1 Pahl and Beitz, and Pugh3.2.2 Divergent-Convergent Model; 3.3 Managing Design; 3.3.1 Common Design Management Models; 3.3.1.1 Serial Design; 3.3.1.2 Ad Hoc Feedback; 3.3.1.3 Concurrent Design/Concurrent Engineering; 3.3.1.4 Collaborative Models; 3.3.1.5 Holistic Models; 3.3.1.6 Which Model Is Best for Me?; 3.4 Cross-Reference with Regulatory Requirements; 3.5 Summary; Tasks; References; Further Reading; 4 Implementing Design Procedures; 4.1 Introduction; 4.2 Review of Guidelines; 4.3 Overall Procedure; 4.4 Audit /Review Procedure; 4.5 The Design Process; 4.5.1 New Product Procedure

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; 5.4.8 Others; 5.5 Summary; References; 6 Generating Ideas and Concepts; 6.1 Introduction; 6.2 The "Engineer's Notebook"; 6.3 Creative Space; 6.3.1 The White Room; 6.3.2 Personal Space; 6.4 Generating Concepts/Ideas; 6.4.1 Radial Thinking; 6.4.2 Inversion (or Word Association); 6.4.3 Analogue; 6.4.4 Brainstorming; 6.4.5 Discretizing; 6.4.6 Morphological Analysis; 6.4.7 Research; 6.4.8 We Have Ideas!; 6.5 Selecting Concepts and Ideas; 6.5.1 Morphological Analysis; 6.5.2 Criteria Assessment; 6.5.3 Weighted Criteria Assessment; 6.6 Summary; References; 7 Quality in Design; 7.1 Introduction; 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