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phase; 5.2.1 - Detailed Drawings and Specifications of Components; 5.2.2 - Calculations/Simulations Demonstrating Performance and Quality in Design; 5.2.2.1 - FMEA; 5.2.2.2 - Optimisation; 5.2.2.3 - Design for X 5.2.2.4 - Validation and Verification 5.2.2.5 - Design for Manufacture; 5.3 - Prototype to final design; 5.3.1 - Link Between this Stage and the Previous Stage; 5.3.2 - Detailed Drawings and Specifications; 5.3.2.1 - A Reminder About Logging Modifications; 5.3.2.2 - Transition from FMEA to Risk Analysis (RA); 5.3.2.3 - Essential Requirements (Especially for EU); 5.3.2.4 - Validation, Verification and Clinical Evaluation; 5.3.2.5 - IFUs, Labelling, Other Instructions and Markings; 5.4 - Summary; Chapter 6 - The Home Run; 6.1 - A summary of activity; 6.2 - The technical file 6.3 - A note about manufacturing 6.4 - A note about post market surveillance (PMS); 6.5 - The final furlong; 6.5.1 - EU; 6.5.2 - FDA; 6.6 - Continual improvement; References; I - Essential Requirements; I - General requirements; II - Requirements regarding design and construction

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#### Sommario/riassunto

The Case Studies in Medical Devices Design series consists of practical, applied case studies relating to medical device design in industry. These titles complement Ogorodnik's Medical Device Design and will assist engineers with applying the theory in practice. The case studies presented directly relate to Class I, Class IIa, Class IIb and Class III medical devices. Designers and companies who wish to extend their knowledge in a specific discipline related to their respective class of operation will find any or all of these titles a great addition to their library. Class 1 Devices is a com

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