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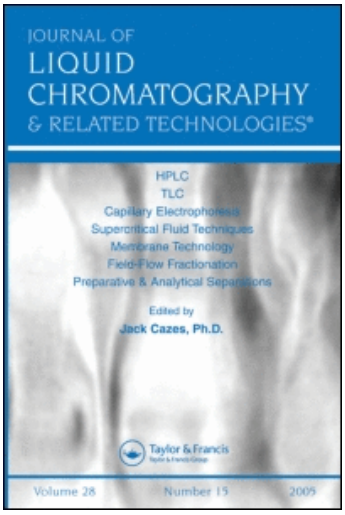

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The Book Corner

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THE BOOK CORNER

RELIABLE DESIGN OF MEDICAL DEVICES, Richard C. Fries, Marcel Dekker, Inc., New York, 1997, 703 pages, $195.00, ISBN: 0-8247-9843-0.

This book has been written with the intention of collecting, in one place, the current state of affairs pertaining to the design of medical devices. The author points out how the design and functional complexity of medical devices has increased during the recent past, and how this affects the nature of the devices required for current use. His particular concern is that, as device functionality becomes more intricate, concerns arise regarding efficacy, safety, and reliability, which play an ever-increasing role.

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These ever-increasing requirements are counter-balanced by the concerns of the commercial side of the business, which seeks to have the devices produced for the lowest cost in the shortest time possible. Medical device development is seen as a complex process that requires the careful integration of diverse disciplines, technical activities, standards, regulatory requirements, and administrative project controls. The need for systematic approaches to product development and maintenance is necessary to ensure a safe and effective device for the user and patient, an economical and competitive success for the manufacturer, and a reliable, cost-effective, investment for the user.

For his approach, the author has chosen the Reliability Assurance program. In this manner, one can provide the theoretical and practical tools by which the probability and capability of systems and their components to perform required functions can be specified, predicted, designed, tested, and demonstrated. His primary goal is to acquaint the developer of medical devices, as well as the purchaser of medical equipment, with the basic concepts and major issues of medical device reliability, to describe current product development processes and techniques, and to provide a basis for evaluating new technologies. He seeks to provide a practical approach to the formation and operation of a reliable assurance program, emphasizing a practical approach.

The book has been organized so as to follow the typical product development process. The first section introduces the reader to the concept of medical devices as being compromised of hardware and software. The concept of hardware/software failure is discussed as a prelude to the discussion of Reliability Assurance, and the section concludes with reviews of current device safety, and of economics ideas and issues.

Section 2 deals with the forest of device standards and regulations as these exist on both the domestic and the international scene. Domestically, the role of FDA in the regulation of medical devices is discussed, along with current guidelines and regulations, including the pending guideline on Human Factors. Internationally, the Medical Device Directives, and their impact on the product development process, are discussed. Other hardware regulations and standards are then reviewed, including ISO, IEEE, and military standards.

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Section 3 deals with the specification and design of a medical device, beginnning with the definition of the product. As part of developing the specification of the device, risk management and human factors are considered, as well as the use of metrics. The hardware discussion addresses design alternatives, selecting components that will meet the intended use of the device, establishing a safety margin, establishing load protection, developing a Requirements Traceability Matrix, and selecting among various design technologies. The software discussion addresses design alternatives, selecting the software architecture, choice of methodology, selection of language, developing a Requirements Traceability Matrix, and selecting among various design techniques. Finally, the coding of the software concludes the design portion of the life cycle.

Section 4 discusses system verification and validation, whereby one proves that the design meets its specifications. The basics and various types of testing are reviewed, followed by the various types of testing which can be conducted. Verification and validation are discussed for both hardware and software, with examples being taken from actual product development activity. The section concludes with an analysis of test data that has been accumulated, and the calculation of reliability parameters.

Section 5 deals with manufacturing as a continuation of the product development process. A device may be reliably designed, but if it is not reliably manufactured, it will not be a success. The current Good Manufacturing Practices regulations are discussed. The possible outsourcing of manufacturing is discussed, and critically compared to the analogous in-house process.

Configuration management and its many implications are also reviewed. Finally, techniques for the analysis of field data are discussed in relation to the building of an efficient database for all product development personnel.

This book represents a comprehensive and encompassing view of the entire procedure which accompanies the design, development, and eventual manufacture of a medical device. Written by an author who has clearly lived the process (and survived), it is amply evident to this reviewer that one need acquire no other book if one was to undertake a similar mission. Those seeking to succeed in the area of medical device manufacture must acquire and read this book cover-to-cover if they wish to maintain a competitive advantage. Readers should note that this volume makes a very appropriate companion to that written by S. C. Gad, *Safety Evaluation of Medical Devices*, which was recently issued by the same publisher and is reviewed below.

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SAFETY EVALUATION OF MEDICAL DEVICES, Shayne Cox Gad, Marcel Dekker, Inc., 1997, 388 pages, $165.00, ISBN: 0-8247-9827-9.

This volume has been written with the sole objective of providing a practical guide for those who are responsible for, or concerned with, ensuring the safety of medical devices for patients, health care providers, and those involved in their manufacture. As such, the basic aspects of device regulation and materials utilized in devices have been addressed. In areas where it was deemed appropriate, the history and underlying science have also been presented to allow the reader to make an informed decision.

The first chapter provides a solid introduction, covering the scope of medical devices and their markets, a brief history of medical devices, the regulatory basis of safety evaluation, and toxicity testing as it applies to devices. The second chapter is one of the most useful in the book, in that it lays out a road map for developing a test program. This chapter is followed by a short outline of sampling and sample preparation.

At this point, the author catalogs the diverse range of possible testing in a series of chapters which are replete with illustrative examples. Covered in this sequence are the testing programs related to cytotoxicity, blood compatibility, irritation and pyrogenicity, immunotoxicology, implantation studies, genotoxicity, subchronic and chronic toxicity, carcinogenicity, reproductive, and developmental toxicity.

The volume ends with several special topics chapters, which cover important topics not treated in the earlier chapters. The science of dealing with sterility and heavy metals is touched upon, and a solid coverage of clinical studies for medical devices follows. A number of special studies and special cases are treated in the following chapter. However, the author saves the best for last, discussing a number of highly relevant case histories and providing the history as to how these problems were resolved.

The author has attempted to present a program for the safety evaluation of devices and device materials, as would be implemented during the overall development of new products. The approach appears to be sound, and the quantity of practical information (a lot of which has been drawn from the author's experience) makes this book very worthwhile for workers in the field. In fact, this volume makes a very appropriate companion to that written by R. C. Fries, *Reliable Design of Medical Devices*, which was recently issued by the same publisher and is reviewed above.

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