Current Issues in Medical Device Quality Systems, David M. Links and Edward J. McDonnell, MPH editors, Association for the Advancement of Medical Instrument, 3330 Washington Blvd., Suite 400, Arlington, VA 2220-4598, 1997, 257pp, $225.00.

This book provides a valuable source for medical device developers and manufacturers about the current FDA requirements and interpretations in CGMP (Current Good Manufacture Practice). It also offers numerous helpful information and road maps in the establishment of the Medical Device Quality Systems.

Contributors of the 16 articles in this book ranges from the quality professionals who are specialized in the medical device quality system, current medical device company quality and regulatory officials, to current, or retired FDA officers. This diverse backgrounds in the contributing authors provide the readers with a well balanced perspectives in the interpretations of the CGMP and methods of compliance.

Topics discussed includes the overview of CGMP, quality system organization and management, various aspects of the Quality Assurance (Design Control QA, Supplier QA, Sterilization QA, Software Validation, Process Validation and Verification), Documentation requirement (includes the Device master record and device history record), how to prepare, manage, and handle the FDA audit. Several expository essays in the evolution of the CGMP, most recent FDA's regulatory mandates, and future issues.

One of the issue discussed is the uniformity of the quality system requirement. Although the requirements and methods of implementing the quality system are similar for the medical device companies and other type of companies. And the trend of the CGMP requirements converging with the ISO 9000, the intent of the quality system implementation and emphasizes are drastically different. One is emphasized in the compliance and the effect of the implementing the system because of its legal consequences, and the other is emphasized in the establishment of a quality system that contains the elements which will sustain the continuous improvement. One is mandatory and the other is voluntary.

This book is strongly recommended for all medical device companies or professionals in the associated fields to understand CGMP and its implementation.

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