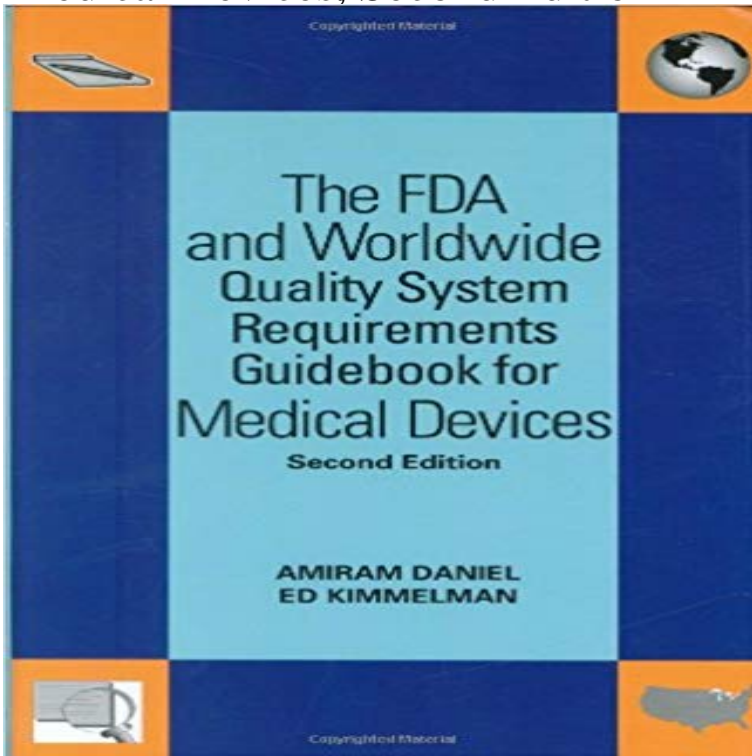


# The FDA and Worldwide Quality System Requirements Guidebook for Medical Devices, Second Edition



This new and expanded second edition maintains the organizational approach of the first and includes the requirements and guidance contained in the Quality System Regulation (QSReg), the ISO 13485:2003 standard, the ISO/TR 14969:2004 guidance document, and, as appropriate, a number of the FDA and Global Harmonization Task Force (GHTF) guidance documents. This second edition also addresses a number of additional topics, such as the incorporation of risk management into the medical device organization's QMS, QMS issues related to combination products, the key process interactions within a QMS, effective presentation of and advocacy for a QMS during FDA inspections and third-party assessments, and future FDA compliance and standards activities. The organization of the guidebook is based on the order of the requirements in the QSReg. For each substantive requirement section there is: A verbatim statement of the QSReg requirement. A description of the comparable requirement in ISO 13485:2003, focusing on any additions to or differences from the requirements contained in the QSReg. Excerpts of the FDA responses to relevant comment groups contained in the Preamble to the QSReg. Excerpts from various FDA guidance documents related to quality management systems. A description of the relevant guidance contained in ISO/TR 14969:2004, focusing on any additions to or differences from the guidance in the Preamble and other FDA guidance documents, and, if useful, excerpts from relevant GHTF guidances. Authors notes giving guidance derived from the authors sixty years of regulatory compliance experience. This guidance book is meant as a resource to manufacturers of medical devices, providing up-to-date information concerning required and recommended quality system practices. It should be used as a companion to the regulations/standards

themselves and texts on the specific processes and activities contained within the QMS.

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