



FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics

David Mantus

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This book covers the regulatory process for getting pharmaceuticals, biologics, and medical devices approved. It examines the pertinent aspects of the Federal Food, Drug and Cosmetic Act as it applies to human drug and device development, research, manufacturing, and marketing. Topics include: the drug approval process, Current Good Manufacturing Practices, Good Clinical Practices, Quality System Compliance and the corresponding documentation requirements, and FDA inspection processes and enforcement options. Although many references exist on this subject, this one is written in a general prose style that makes it useful to both students and professionals.

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