



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

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Examines harmonization of the US Federal Food, Drug, and Cosmetic Act with international regulations as they apply to human drug and device development, research, manufacturing, and marketing. The *Second Edition* focuses on the new drug approval process, cGMPs, GCPs, quality system compliance, and corresponding documentation requirements. Written in a jargon-free style, it draws information from a wide range of resources. It demystifies the inner workings of the FDA and facilitates an understanding of how it operates with respect to compliance and product approval.

FDA Regulatory Affairs:

- provides a blueprint to the FDA and drug, biologic, and medical device development
- offers current, real-time information in a simple and concise format
- contains a chapter highlighting the new drug application (NDA) process
- discusses FDA inspection processes and enforcement options
- includes contributions from experts at companies such as Millennium and Genzyme, leading CRO's such as PAREXEL and the Biologics Consulting Group, and the FDA

Three all-new chapters cover:

- clinical trial exemptions
- advisory committees
- provisions for fast track

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