FDA Regulatory Affairs: Third Edition

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FDA Regulatory Affairs is a roadmap to prescription drug, biologics, and medical device development in the United States. Written in plain English, the concise and jargon-free text demystifies the inner workings of the US Food and Drug Administration (FDA) and facilitates an understanding of how the agency operates with respect to compliance and product approval, including clinical trial exemptions, fast track status, advisory committee procedures, and more.

The **Third Edition** of this highly successful publication:

- Examines the harmonization of the US Federal Food, Drug, and Cosmetic Act with international regulations on human drug, biologics and device development, research, manufacturing, and marketing
- Includes contributions from experts at organizations such as the FDA, National Institutes of Health (NIH), and PAREXEL
- Focuses on the new drug application (NDA) process, cGMPs, GCPs, quality system compliance, and corresponding documentation requirements
- Provides updates to the FDA Safety and Innovation Act (FDASIA), incorporating pediatric guidelines and follow-on biologics regulations from the 2012 Prescription Drug User Fee Act (PDUFA) V
- Explains current FDA inspection processes, enforcement options, and how to handle FDA meetings and required submissions

Co-edited by an industry leader (Mantus) and a respected academic (Pisano), **FDA Regulatory Affairs, Third Edition** delivers a compilation of the selected US laws and regulations as well as a straightforward commentary on the FDA product approval process that’s broadly useful to both business and academia.

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