

# FDA regulatory affairs - a guide for prescription drugs, medical devices, and biologics

**Informa Healthcare USA - Fda Regulatory Affairs a Guide for Prescription Drugs Medical Devices and Biologics**



Description: -

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Government Regulation -- United States.  
Equipment and Supplies -- standards -- United States.  
Biological Products -- standards -- United States.  
United States Government Agencies -- United States.  
Drug Industry -- standards -- United States.  
Pharmaceutical industry -- United States.  
Drug development -- United States.  
United States. -- Food and Drug Administration.  
United States -- Food and Drug Administration -- Rules and practice.  
FDA regulatory affairs - a guide for prescription drugs, medical devices, and biologics  
-FDA regulatory affairs - a guide for prescription drugs, medical devices, and biologics  
Notes: Includes bibliographical references and index.  
This edition was published in 2008



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## **FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and ...**

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## **FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics by Douglas J. Pisano**

. The Second Edition focuses on the new drug approval process, cGMPs, GCPs, quality system compliance, and corresponding documentation requirements.

### **Guidance, Compliance & Regulatory Information (Biologics)**

Chapter about IND is also quite good. The Second Edition focuses on the new drug approval process, cGMPs, GCPs, quality system compliance, and corresponding documentation requirements.

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