

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

Informa Healthcare USA - Regulatory submissions for healthcare products: A primer

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

Written in a jargon-free style, it draws information from a wide range of resources.

Regulatory submissions for healthcare products: A primer

Pisano was the recipient of the Special Service Award for the Enhancement of Regulatory Education from the Regulatory Affairs Professionals Society in 2000.

FDA Regulatory Affairs pdf

Written in a jargon-free style, it draws information from a wide range of resources. For example, new law enacted in 2012 increased by 60 days both standard and priority review times necessary for NDA processing 8 months for priority review and 12 months for standard review.

Fda Regulatory Affairs a Guide for Prescription Drugs Medical Devices and Biologics

Primary interest in this book from scientist's point of view are chapters about IND and NDA applications.

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