New Drug Development: A Regulatory Overview (8th Edition)

Description:

New Drug Development: A Regulatory Overview

Go inside the drug development and FDA regulatory process with today's most authoritative and popular reference on the topic. In its all-new 2008 edition, New Drug Development: A Regulatory Overview addresses the most cutting-edge developments redefining how new drugs are developed and regulated today, including:

- How the FDA Amendments Act of 2007 will affect everything from drug reviews to postmarketing requirements.

- How the CDER's efforts to integrate a "culture of drug safety" has affected the center's structure and its new drug review and approval processes.

- How CDER's much-anticipated January 2008 transition to the eCTD as the “only valid esubmission format” will affect the FDA's drug submission and review process.

- How the FDA and industry are already integrating pharmacogenomics, computer simulation, and other emerging technologies to inform key decisions.

- Which drug development strategies are fulfilling their promise and offering optimal returns for industry, given the explosion of accelerated development/approval programs and pilot programs to speed the drug development and review process.

Find out why New Drug Development is pharma/biotech's "go-to" resource for regulatory, clinical, project management, training, and other drug development disciplines navigating the FDA's drug development approval processes.

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