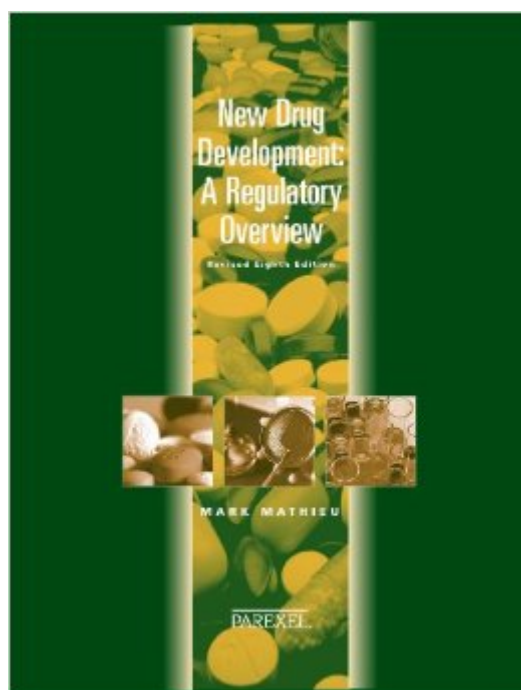


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# New Drug Development: A Regulatory Overview (New Drug Development ( Mathieu))



## Synopsis

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.

## Book Information

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## Customer Reviews

*Biologics Development: A Regulatory Overview*, by Mark Mathieu is a 330 page book, containing 15 chapters. The paper is a off-white. There are about ten tables and flow charts, and reproductions of two forms, FDA Form 356h and the MedWatch form. This is a review of the second edition (but the

currently available edition is still very short, around 350 pages). Overall, the book is a walk-through that takes us along various rules in Title 21 of the CFR. The book is useful, in that it teaches a pharma or biotech employee things that management might not have time to teach. This book fills a niche, in that other books on clinical trials generally fail to disclose back and forth communications between the sponsor and FDA. But for the price charged for this book, the book does not go far enough. It is only an overview or introduction. We learn that CBER has an office called OCTMA that provides guidance on how to go about filing an IND. We learn that the IND must be submitted using Form 1571, and that INDs include the Investigator's Brochure and Clinical Study Protocol (pages 64-66) to be used in the Phase I study, and that the CSP must be accompanied with the Consent Form. We learn that Institutional Review Board (IRB) approval is not needed for submitting an IND, but IRB approval is required before carrying out the actual study. We learn that the Chemistry, Manufacturing, and Control Data (CMC) part of the IND includes drug substance, drug product, placebo (page 67), labels, and environmental analysis requirements sections, and that the Pharmacology & Toxicology Data section includes animal studies, in vitro studies, previous human experience, studies.

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