

"Expediting Drug and Biologics Development: A Strategic Approach, Third Edition"

Steven E. Linberg, editor, 2006, 401 pages, PAREXEL International, \$331.00

Review by Norman M. Goldfarb

"Expediting Drug and Biologics Development: A Strategic Approach" combines the high-level perspective of strategy with the detail of expediting. The book reads like a series of focused seminars, rather than a superficial overview. It is ideal for clinical research personnel and pharmaceutical, biotech, medical center, and other executives who want to understand the development process after the discovery phase (research).

This book has been selected for
[The First Clinical Research Bookshelf](#)
Essential reading for clinical research professionals

Dr. Linberg and 37 other contributors have written 30 essays that cover the development process from preclinical testing to postmarketing safety assessment:

- Beginning at the Destination: A Corporate Culture
- Project Management and Pharmaceutical Development
- Integration of CMC into Drug Development: Avoiding the Common Delays
- Nonclinical Development
- Clinical Development Plans: Target Product Profile
- Information Systems in Support of Pharmaceutical Development
- Title 21 CFR Part 11
- Format and Content of the Common Technical Document (CTD)
- Streamlining the Drug Development and Approval Process
- Meeting with the FDA
- The Investigational New Drug Application
- The Investigator's Brochure
- The Phases of Clinical Development
- Clinical Trials Enrolling Children
- Clinical Study Reports
- Standard Data Presentations
- Analysis Plans
- Data Capture
- The Clinical Protocol
- Informed Consent and IRB Review
- Clinical Trial Operations
- Clinical Monitoring
- An Integrated Approach to Data Management
- Evaluation of Safety During Clinical Drug Development
- Developing a Risk Minimization Action Plan

- Assembling and Filing the Common Technical Document
- The FDA Marketing Application Review Process
- Preparing for FDA Inspection
- Preparing for an FDA Advisory Committee Meeting
- Postmarketing Safety Assessment

The first essay includes an anonymous quote: "Experience is the hardest kind of teacher. It gives you the test first and the lesson afterwards." By reading this book, you can skip a lot of painful lessons of experience.

The book is available at <http://www.barnettinternational.com/>

Reviewer

Norman M. Goldfarb is Managing Director of First Clinical Research LLC, a provider of clinical research best practices information, consulting and training services. Contact him at 1.650.465.0119 or ngoldfarb@firstclinical.com.