

Anticancer drug development guide : preclinical screening, clinical trials, and approval /

Teicher, Beverly A. (1952-) Andrews, Paul A. Humana Press, 2004

Monografía

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In this thoroughly updated and expanded second edition of Beverly Teicher's widely used classic survey, Anticancer Drug Development Guide: Preclinical Screening, Clinical Trials, and Approval, leading cancer researchers from pharmaceutical companies, government laboratories, and academia provide a step-by-step guide to anticancer drug development from initial design through FDA approval. The authors have included new material on the use of high-throughput screening in industry, on specialized in vitro/in vivo procedures employed by the National Cancer Institute (NCI) in preclinical drug evaluations, and on nonclinical testing to support both human clinical trials, as well as trials of biologic oncology products. There are also new chapters on health-related quality of life (HRQL) issues in cancer clinical trials, and FDA review and requirements for approval of oncologic products. The chapters on phase I, II, and III clinical trials and on novel phase II clinical trial designs for targeted therapies have been significantly updated, along with those on cancer drug development in Europe, on working with the NCI, as well as on the FDA's role in cancer drug development and in setting requirements for approval. Authoritative and up-to-date, Anticancer Drug Development Guide: Preclinical Screening, Clinical Trials, and Approval takes oncologists, pharmacologists, medicinal chemists, and other cancer researchers on an encyclopedic tour of the cancer drug development and approval process, moving from the design and execution of high-throughput screens, to preclinical testing, to safety and toxicity testing under FDA requirements, to early clinical trials, and on to final FDA approval

Título: Anticancer drug development guide preclinical screening, clinical trials, and approval edited by Beverly A. Teicher, Paul A. Andrews

Edición: 2nd ed

Editorial: Totowa, N.J. Humana Press 2004

Descripción física: 1 online resource (xiv, 450 pages) illustrations

Mención de serie: Cancer drug discovery and development

Bibliografía: Includes bibliographical references and index

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ISBN: 1592597394 electronic bk.) 9781592597390 electronic bk.) 1588292282 alk. paper) 9781588292285 alk. paper)

Materia: Antineoplastic agents- Development Antineoplastic Agents- standards Clinical Trials Drug Approval Drug Design Drug Evaluation, Preclinical Anticancéreux- Dévelopment MEDICAL- Oncology HEALTH & FITNESS- Diseases- Cáncer Antineoplastic agents- Development

Autores: Teicher, Beverly A. (1952-) Andrews, Paul A.

Enlace a formato físico adicional: Print version Anticancer drug development guide. 2nd ed. Totowa, N.J. : Humana Press, 2004 1588292282 (DLC) 2003024925 (OCoLC)53443077

Punto acceso adicional serie-Título: Cancer drug discovery and development

Baratz Innovación Documental

- Gran Vía, 59 28013 Madrid
- (+34) 91 456 03 60
- informa@baratz.es