



# Handbook of Anticancer Pharmacokinetics and Pharmacodynamics (Cancer Drug Discovery and Development)

From Humana Press

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## Handbook of Anticancer Pharmacokinetics and Pharmacodynamics (Cancer Drug Discovery and Development) From Humana Press

There are many steps on the road from discovery of an anticancer drug to securing its final approval by the Food and Drug Administration. In this thoroughly updated and expanded second edition of the *Handbook of Anticancer Pharmacokinetics and Pharmacodynamics*, leading investigators synthesize an invaluable overview of the experimental and clinical processes of anticancer drug development, creating a single indispensable reference that covers all the steps from the identification of cancer-specific molecular targets to screening techniques and the development and validation of bioanalytical methods to clinical trial design and all phases of clinical trials. The authors have included new material on phase 0 trials in oncology, organ dysfunction trials, drug formulations and their impact on anticancer drug PK/PD including strategies to improve drug delivery, pharmacogenomics and cancer therapy, high throughput platforms in drug metabolism and transport pharmacogenetics, imaging in drug development and nanotechnology in cancer.

Authoritative and up-to-date, *Handbook of Anticancer Pharmacokinetics and Pharmacodynamics, 2nd Edition* provides in one comprehensive and highly practical volume a detailed step-by-step guide to the successful design and approval of anticancer drugs.

- Road map to anticancer drug development from discovery to NDA submission
- Discussion of molecular targets and preclinical screening
- Development and validation of bioanalytical methods
- Chapters on clinical trial design and phase 0, I, II, III clinical trials
- Pharmacokinetics, pharmacodynamics, pharmacogenomics, and pharmacogenetics of anticancer agents
- Review of the drug development process from both laboratory and clinical perspectives
- New technological advances in imaging, high throughput platforms, and nanotechnology in anticancer drug development

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- Sales Rank: #3550554 in Books
- Published on: 2014-01-11
- Original language: English
- Number of items: 1
- Dimensions: 10.10" h x 2.00" w x 7.10" l, 4.80 pounds
- Binding: Hardcover
- 836 pages

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## **Editorial Review**

### **Review**

"...an invaluable overview of the experimental and clinical processes that lead to anticancer drugs, creating a single indispensable reference that covers all the steps from the identification of cancer-specific targets to phase III clinical trials." - Tumori

### **From the Back Cover**

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### **About the Author**

**Dr. Michelle Rudek** received her BS in Pharmacy from the University of Pittsburgh and her dual Pharm.D., Ph.D. from Virginia Commonwealth University in a joint clinical pharmacology/oncology program with the National Cancer Institute. Dr. Rudek joined Johns Hopkins University in 2001 and is currently an Associate Professor of Oncology and Director of the Analytical Pharmacology Core Laboratory. Her research program is focused on clinical pharmacology with a focus on early phase drug development and special populations including AIDS malignancy and organ dysfunction.

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**Dr. William Douglas Figg** received his B.S. (Hon) from Georgetown College, his B.S. in Pharmacy from Samford University and his Pharm.D. from Auburn University. He completed his clinical pharmacy internship at the University of Alabama at Birmingham Hospital and his fellowship in drug development at the University of North Carolina-Chapel Hill. Dr. Figg also received an M.B.A. degree from a combined program at Columbia University and London Business School. He joined the Medical Oncology Branch, National Cancer Institute, National Institutes of Health in 1992. He has patented more than 80 new anticancer agents and four pharmacogenetic tests.

**Dr. Howard McLeod** is Fred Eshelman Distinguished Professor and Director, UNC Institute for Pharmacogenomics and Individualized Therapy, University of North Carolina, Chapel Hill. Dr. McLeod holds appointments in the UNC Schools of Pharmacy and Medicine, the Carolina Center for Genome Sciences, and the Lineberger Comprehensive Cancer Center. Dr. McLeod is chair of the NHGRI eMERGE network external scientific panel and is a member of the FDA committee on Clinical Pharmacology. He is a member of the NIH NHGRI Advisory Council. Since 2002, Dr. McLeod has been vice chair for Pharmacogenomics for the NCI clinical trials cooperative group CALGB/ALLIANCE, overseeing the largest oncology pharmacogenomics portfolio in the world.

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