



Biomarkers in Drug Development: A Handbook of Practice, Application, and Strategy

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Discover how biomarkers can boost the success rate of drug development efforts

As pharmaceutical companies struggle to improve the success rate and cost-effectiveness of the drug development process, biomarkers have emerged as a valuable tool. This book synthesizes and reviews the latest efforts to identify, develop, and integrate biomarkers as a key strategy in translational medicine and the drug development process. Filled with case studies, the book demonstrates how biomarkers can improve drug development timelines, lower costs, facilitate better compound selection, reduce late-stage attrition, and open the door to personalized medicine.

Biomarkers in Drug Development is divided into eight parts:

- Part One offers an overview of biomarkers and their role in drug development.
- Part Two highlights important technologies to help researchers identify new biomarkers.
- Part Three examines the characterization and validation process for both drugs and diagnostics, and provides practical advice on appropriate statistical methods to ensure that biomarkers fulfill their intended purpose.
- Parts Four through Six examine the application of biomarkers in discovery, preclinical safety assessment, clinical trials, and translational medicine.
- Part Seven focuses on lessons learned and the practical aspects of implementing biomarkers in drug development programs.
- Part Eight explores future trends and issues, including data integration, personalized medicine, and ethical concerns.

Each of the thirty-eight chapters was contributed by one or more leading experts, including scientists from biotechnology and pharmaceutical firms, academia, and the U.S. Food and Drug Administration. Their contributions offer pharmaceutical and clinical researchers the most up-to-date understanding of the strategies used for and applications of biomarkers in drug development.

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