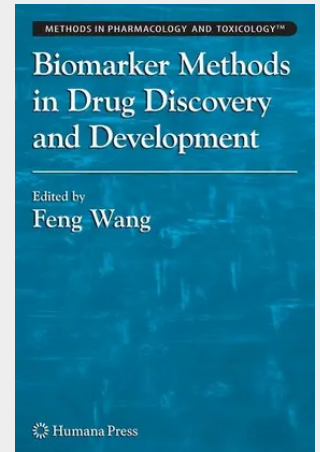


Biomarker Methods in Drug Discovery and Development

In this book, expert researchers provide a tool box for those who have a general interest in biomarker research and for those currently specializing in certain technologies but desiring an understanding of other available methodologies. Its chapters include validated, mature methods as well as new, incredibly promising protocols which aim to apply multiple technologies at different molecular levels in order to surmount the monumental and complex task of transforming the pharmaceutical research and development processes. As a volume in the Methods in Pharmacology and Toxicology™ series, this book offers user-friendly, step-by-step laboratory protocols for readily reproducible experiments. Comprehensive and state-of-the-art, this is the perfect biomarker technical guideline and reference to stimulate more exciting biomarker research and technology development.

The pharmaceutical industry has faced many significant challenges since the early 1990s. The fundamental issue that needs to be addressed is how to improve the efficiency of drug discovery and development. The current research and development (R&D) cost for developing a new therapeutic drug is greater than \$800 million. Additionally, it takes an average of 12 years to get a new drug to market with an attrition rate greater than 90%. Reviewing the overall pharmaceutical R&D process, it has become clear that many of the drug failures are due to our lack of knowledge in population diversity, which is responsible for differences in drug efficacy and toxicity. In fact, not a single approved drug is 100% safe and efficacious for all patients. For researchers, the key question is: How can we discover biomarkers that can be used to distinguish patients who will respond to the drug without adverse effects from those who will not respond and/or will have adverse effects? There is tremendous urgency to address this question. Biomarkers also fit perfectly with the vision of personalized medicine, the new expectation of medical practice. This is why biomarker research has been a central focus in many research labs across academia, government agencies, and the pharmaceutical industry. There are many different ways to define biomarkers based on molecular properties, applications, and methods.



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