

New Drug Development: A Regulatory Overview

Revised Eighth Edition



MARK MATHIEU

PAREXEL

New Drug Development A Regulatory Overview

Mark P. Mathieu



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New Drug Development Second Edition provides an overview of the design concepts and statistical practices involved in therapeutic drug development This wide spectrum of activities begins with identifying a potentially useful drug candidate that can perhaps be used in the treatment or prevention of a condition of clinical concern and ends with marketing approval being granted by one or more regulatory agencies In between it includes drug molecule optimization nonclinical and clinical evaluations of the drug s safety and efficacy profiles and manufacturing considerations The more inclusive term lifecycle drug development can be used to encompass the postmarketing surveillance that is conducted all the time that a drug is on the market and being prescribed to patients with the relevant clinical condition Information gathered during this time can be used to modify the drug for example dose prescribed formulation and mode of administration in terms of its safety and its effectiveness The central focus of the first edition of this book is captured by its subtitle *Design Methodology and Analysis* Optimum quality study design and experimental research methodology must be employed if the data collected numerical representations of biological information are to be of optimum quality Optimum quality data facilitate optimum quality statistical analysis and interpretation of the results obtained which in turn permit optimum quality decisions to be made Rational decision making is predicated on appropriate research questions and optimum quality numerical information The book took a non computational approach to statistics presenting instead a conceptual framework and providing readers with a sound working knowledge of the importance of design methodology and analysis Not everyone needs to be an expert in statistical analysis but it is very helpful for work or aspire to work in the pharmaceutical and biologics industries to be aware of the fundamental importance of a sound scientific and clinical approach to the planning conduct and analysis of clinical trials **New Drug Development** Mark P. Mathieu,1997

Burger's Medicinal Chemistry, Drug Discovery and Development, 8 Volume Set ,2021-04-20 Burger s Medicinal Chemistry Drug Discovery and Development Explore the freshly updated flagship reference for medicinal chemists and pharmaceutical professionals The newly revised eighth edition of the eight volume Burger s Medicinal Chemistry Drug Discovery and Development is the latest installment in this celebrated series covering the entirety of the drug development and discovery process With the addition of expert editors in each subject area this eight volume set adds 35 chapters to the extensive existing chapters New additions include analyses of opioid addiction treatments antibody and gene therapy for cancer blood brain barrier HIV treatments and industrial academic collaboration structures Along with the incorporation of practical material on drug hunting the set features sections on drug discovery drug development cardiovascular diseases

metabolic diseases immunology cancer anti Infectives and CNS disorders The text continues the legacy of previous volumes in the series by providing recognized renowned authoritative and comprehensive information in the area of drug discovery and development while adding cutting edge new material on issues like the use of artificial intelligence in medicinal chemistry Included Volume 1 Methods in Drug Discovery edited by Kent D Stewart Volume 2 Discovering Lead Molecules edited by Kent D Stewart Volume 3 Drug Development edited by Ramnarayan S Randad and Michael Myers Volume 4 Cardiovascular Endocrine and Metabolic Diseases edited by Scott D Edmondson Volume 5 Pulmonary Bone Immunology Vitamins and Autocoid Therapeutic Agents edited by Bryan H Norman Volume 6 Cancer edited by Barry Gold and Donna M Huryn Volume 7 Anti Infectives edited by Roland E Dolle Volume 8 CNS Disorders edited by Richard A Glennon Perfect for research departments in the pharmaceutical and biotechnology industries Burger s Medicinal Chemistry Drug Discovery and Development can be used by graduate students seeking a one stop reference for drug development and discovery and deserves its place in the libraries of biomedical research institutes medical pharmaceutical and veterinary schools

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