

New Drug Development: A Regulatory Overview

Revised Eighth Edition



MARK MATHIEU

PAREXEL

New Drug Development A Regulatory Overview New Drug Development Mathieu

**Institute of Medicine, Committee on
Contraceptive Research and
Development**

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New Drug Development Mark P. Mathieu, 1987 **New Drug Development** Mark P. Mathieu, Anne G. Evans, Parexel International Corporation, 2005-01-01 New Drug Development J. Rick Turner, 2010-07-16 **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**, 1985 **Drug Development** Charles E. Hamner, 2019-06-12 Published in 1990 Overall the volume stands as a relatively comprehensive but not exhaustive summation of the complex process of drug development A Comprehensive Guide to Toxicology in Preclinical Drug Development Ali S. Faqi, 2012-11-02 A Comprehensive Guide to Toxicology in Preclinical Drug Development is designed for toxicologists who need a thorough understanding of the drug development process This multi contributed reference will provide a detailed picture of the complex and highly interrelated activities of preclinical toxicology in both small molecules and biologics **Contraceptive Research and Development** Institute of Medicine, Committee on Contraceptive Research and Development, 1996-11-04 The contraceptive revolution of the 1960s and 1970s introduced totally new contraceptive options and launched an era of research and product development Yet by the late 1980s conditions had changed and improvements in contraceptive products while very important in relation to improved oral contraceptives IUDs implants and injectables had become primarily incremental Is it time for a second contraceptive revolution and how might it

happen Contraceptive Research and Development explores the frontiers of science where the contraceptives of the future are likely to be found and lays out criteria for deciding where to make the next R D investments The book comprehensively examines today s contraceptive needs identifies niches in those needs that seem most readily translatable into market terms and scrutinizes issues that shape the market method side effects and contraceptive failure the challenge of HIV AIDS and other sexually transmitted diseases and the implications of the women s agenda Contraceptive Research and Development analyzes the response of the pharmaceutical industry to current dynamics in regulation liability public opinion and the economics of the health sector and offers an integrated set of recommendations for public and private sector action to meet a whole new generation of demand Pharmaceutical Project Management Anthony Kennedy,2008-03-17 Encompassing the full spectrum of project management s role and responsibility encountered in the pharmaceutical industry Pharmaceutical Project Management outlines the key objectives risks and challenges of each stage of the pharmaceutical lifecycle from discovery and preclinical phases through clinical development manufacturing registration *Vaccinology* Gregg N. Milligan,Alan D. T. Barrett,2014-12-04 *Vaccinology An Essential Guide* outlines in a clear practical format the entire vaccine development process from conceptualization and basic immunological principles through to clinical testing and licensing of vaccines With an outstanding introduction to the history and practice of vaccinology it also guides the reader through the basic science relating to host immune responses to pathogens Covering the safety regulatory ethical and economic and geographical issues that drive vaccine development and trials it also presents vaccine delivery strategies novel vaccine platforms including experimental vaccines and pathogens antigen development and selection vaccine modelling and the development of vaccines against emerging pathogens and agents of bioterror There are also sections devoted to veterinary vaccines and associated regulatory processes *Vaccinology An Essential Guide* is a perfect tool for designed for undergraduate and graduate microbiologists and immunologists as well as residents fellows and trainees of infectious disease and vaccinology It is also suitable for all those involved in designing and conducting clinical vaccine trials and is the ideal companion to the larger reference book *Vaccinology Principles and Practice* Analytical Testing for the Pharmaceutical GMP Laboratory Kim Huynh-Ba,2022-03-31 Provides practical guidance on pharmaceutical analysis written by leading experts with extensive industry experience *Analytical Testing for the Pharmaceutical GMP Laboratory* presents a thorough overview of the pharmaceutical regulations working processes and drug development best practices used to maintain the quality and integrity of medicines With a focus on smaller molecular weight drug substances and products the book provides the knowledge necessary for establishing the pharmaceutical laboratory to support Quality Systems while maintaining compliance with Good Manufacturing Practices GMP regulations Concise yet comprehensive chapters contain up to date coverage of drug regulations pharmaceutical analysis methodologies control strategies testing development and validation method transfer electronic data documentation and more Each chapter includes a table of contents definitions of acronyms a

reference list and ample tables and figures Addressing the principal activities and regulatory challenges of analytical testing in the development and manufacturing of pharmaceutical drug products this authoritative resource Describes the structure roles core guidelines and GMP regulations of the FDA and ICH Covers the common analytical technologies used in pharmaceutical laboratories including examples of analytical techniques used for the release and stability testing of drugs Examines control strategies established from quality systems supported by real world case studies Explains the use of dissolution testing for products such as extended release capsules aerosols and inhalers Discusses good documentation and data reporting practices stability programs and the Laboratory Information Management System LIMS to maintain compliance Includes calculations application examples and illustrations to assist readers in day to day laboratory operations Contains practical information and templates to structure internal processes or common Standard Operating Procedures SOPs Analytical Testing for the Pharmaceutical GMP Laboratory is a must have reference for both early career and experienced pharmaceutical scientists analytical chemists pharmacists and quality control professionals It is also both a resource for GMP laboratory training programs and an excellent textbook for undergraduate and graduate courses of analytical chemistry in pharmaceutical sciences or regulatory compliance programs

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