

The five drug development phases



New Drug Development

Mark P. Mathieu



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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

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Global New Drug Development Jan A. Rosier,Mark A. Martens,Josse R. Thomas,2014-07-03 The development of new drugs is very complex costly and risky Its success is highly dependent on an intense collaboration and interaction between many departments within the drug development organization external investigators and service providers in constant dialogue with regulatory authorities payers academic experts clinicians and patient organizations Within the different phases of the drug life cycle drug development is by far the most crucial part for the initial and continued success of a drug on the market This book offers an introduction to the field of drug development with a clear overview of the different processes that lead to a successful new medicine and of the regulatory pathways that are used to launch a new drug that are both safe and efficacious This is the most comprehensive and detailed book on drug development I have ever read and I feel that it is likely to become a staple of drug development courses such as those taught at Masters Level in my own University I think in the light of increasing integration of company and academic approaches to drug development both sides can read this book and therefore this book could not be more timely Professor Mike Coleman University of Aston UK from his review of the final manuscript

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