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WheelAir looks to boost its clinical research with appointment of Non-Executive Director

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and international regulation over the last twenty years, while necessary, has only served to amplify these costs. In response to this escalation, developmental strategies have shifted towards a more global approach. In order to create the most cost-effective and safe processes, it is critical for those bringing drugs to market to

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understand both the globally accepted regulations and the local variations.

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The Nonhuman Primate in Drug

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Development and Safety Assessment is a valuable reference dedicated to compiling the latest research on nonhuman primate models in nonclinical safety assessment, regulatory toxicity testing and translational science. By covering important topics such as study planning and conduct, inter-species genetic drift, pathophysiology, animal

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by authors with experience in the industry and drug regulation, this comprehensive and authoritative guide provides a shoulder to lean on throughout your pharmaceutical career.

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risking strategies and designs of safety assessment programs for novel biopharmaceuticals and vaccines, as well as follow-on biologics or "biosimilars" A multi-authored book with chapters written by qualified experts in their respective fields

The premise of Quality by Design (QbD) is

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that the quality of the pharmaceutical product should be based upon a thorough understanding of both the product and the manufacturing process. This state-of-the-art book provides a single source of information on emerging statistical approaches to QbD and risk-based pharmaceutical development. A

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comprehensive resource, it combines in-depth explanations of advanced statistical methods with real-life case studies that illustrate practical applications of these methods in QbD implementation.

This book serves as a reference text for regulatory, industry and academic

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statisticians and also a handy manual for entry level Statisticians. Additionally it aims to stimulate academic interest in the field of Nonclinical Statistics and promote this as an important discipline in its own right. This text brings together for the first time in a single volume a comprehensive survey of methods important to the nonclinical

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science areas within the pharmaceutical and biotechnology industries. Specifically the Discovery and Translational sciences, the Safety/Toxicology sciences, and the Chemistry, Manufacturing and Controls sciences. Drug discovery and development is a long and costly process. Most decisions in the drug development process are made



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with incomplete information. The data is rife with uncertainties and hence risky by nature. This is therefore the purview of Statistics. As such, this book aims to introduce readers to important statistical thinking and its application in these nonclinical areas. The chapters provide as appropriate, a scientific background to the topic, relevant regulatory

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guidance, current statistical practice, and further research directions.

Intravenous infusion is a necessary mode of delivery for many pharmaceuticals currently on the market or undergoing clinical trials. The technique of prolonged intravenous delivery in conscious, free-moving animal

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models has broadened the opportunity to study and evaluate the safety and efficacy of these therapeutic products. For the first time, the collective sciences involved in the understanding of this mode of drug delivery are brought together in one publication.

Non-Clinical Vascular Infusion  
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the scientific principles behind the delivery systems, from both physical and physiological standpoints. The book addresses body fluid dynamics, describes the scientific processes necessary to understand the various aspects of the physico-chemical issues relating to vascular infusion delivery, and discusses vascular infusion dynamics. It

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also considers all the essential elements of the preparation of a formulation intended for vascular delivery as well as assessment of compatibility of the formulation with the dosing apparatus. This volume, along with Volume II: The Techniques, provides a foundation of knowledge on infusion technology and its importance for safe

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clinical use of substances via this route of delivery. Features Identifies and shares best practices for non-clinical vascular infusion Presents modern practices and procedures in line with up-to-date equipment development Offers recommendations for in-life assessments in order to monitor the success or problems with the vascular

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