

Oracle Argus Safety User Guide

Gerhard Fortwengel

Oracle Argus Safety User Guide:

Guide for Investigator Initiated Trials Gerhard Fortwengel, 2011 An essential manual for beginners and senior researchers alike For academic medical faculty unfamiliar with national and international regulations the prospect of initiating and managing a clinical trial can be intimidating. The development of protocols and case report forms compliance with regulatory requirements the monitoring of clinical trials as well as the responsibilities of documentation are just some of the tasks the sponsor investigator is faced with This book covers the entire spectrum of a clinical trial reviewing the different stages step by step financial planning crucial aspects of trial design the authorization process and finally documentation Moreover it contains helpful tips a practical glossary instructions and a large number of resources related to the relevant regulations and forms conforming to the International Conference on Harmonization and Good Clinical Practice This makes the publication at hand an essential cookbook for both academic faculty new to clinical trials as well as seasoned sponsors Signal Analysis in Pharmacovigilance Anoop Kumar, 2024-09-26 This book provides detailed concepts and information on principles and processes of signal analysis in pharmacovigilance along with case studies It covers the fundamental concepts and principles of pharmacovigilance emphasizing the need for robust signal detection and analysis methods The book reviews the diverse array of databases and tools employed for signal detection including electronic health records EHRs social media mining claims data and distributed data networks In turn the book discusses the application of molecular dynamics molecular docking and the use of the FDA Adverse Event Reporting System FAERS database in signal analysis Toward the end the book explores the identification validation and assessment of signals associated with vaccines This book is useful for graduate post graduate students of pharmaceutical sciences and scientists in pharmacology research and drug development Computer Aided Pharmaceutics and Drug Delivery Vikas Anand Saharan, 2022-05-30 This book examines the role of computer assisted techniques for discovering designing optimizing and manufacturing new effective and safe pharmaceutical formulations and drug delivery systems. The book discusses computational approaches statistical modeling and molecular modeling for the development and safe delivery of drugs in humans The application of concepts of QbD Quality by Design DoE Design of Experiments artificial intelligence and in silico pharmacokinetic assessment simulation have been made a lot easier with the help of commercial software and expert systems This title provides in depth knowledge of such useful software with illustrations from the latest researches The book also fills in the gap between pharmaceutics and molecular modeling at micro meso and maro scale by covering topics such as advancements in computer aided Drug Design CADD drug polymer interactions in drug delivery systems molecular modeling of nanoparticles and pharmaceutics bioinformatics This book provides abundant applications of computers in formulation designing and characterization are provided as examples case studies and illustrations Short reviews of software databases and expert systems have also been added to culminate the interest of readers for novel applications in formulation

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