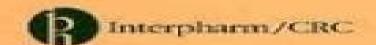
HANDBOOK OF SOPS FOR GOOD CLINICAL PRACTICE

SECOND EDITION

Celine M. Clive



Handbook Of Sops For Good Clinical Practice

Daria Mochly-Rosen, Kevin Grimes

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Sciences Pantheon Award for Academia Non Profits Research The new edition updates every chapter with the latest developments since the 2014 publication of the first edition **Clinical Trials Audit Preparation** Vera Mihajlovic-Madzarevic, 2010-09-29 A must have guide for any professional in the drug manufacturing industry The Good Clinical Practice GCP audit is a tedious but necessary exercise that assures that all parties do their job properly and in compliance with the applicable FDA code Clinical Trials Audit Preparation demystifies the audit process for all parties involved including clinical research sponsors clinical investigators and institutional review boards This book provides a step by step explanation of the FDA audit procedures for clinical trials and of how pharmaceutical companies clinical investigators and institutional review boards should prepare for regulatory audits The book emphasizes the processes and procedures that should be implemented before a clinical audit occurs making this an imperative guide to any professional in the drug manufacturing industry including drug manufacturing companies regulatory affairs personnel clinical investigators and quality assurance professionals Among the topics discussed Good Clinical Practices and therapeutic product development in clinical research The roles of the sponsor of a clinical investigation the IRB or independent ethics committee The roles and responsibilities of the clinical trial investigator The inspection preparation The Audit Report and the Form 483 Warning letters issued to clinical investigators and clinical trial sponsors and their impact on product development Index ,2006 Every 3rd issue is a quarterly cumulation Handbook of Bioequivalence Testing Sarfaraz K. Niazi, 2014-10-29 As the generic pharmaceutical industry continues to grow and thrive so does the need to conduct adequate efficient bioequivalence studies In recent years there have been significant changes to the statistical models for evaluating bioequivalence In addition advances in the analytical technology used to detect drug and metabolite levels have m Step-by-step Guide to Clinical Trials Marilyn Mulay, 2001 Provides a practical approach to understanding the components of a clinical research trial as well as the tools to conduct a well organized study Designed for those interested in developing or enhancing skills to coordinate all aspects of clinical trials such as regulatory requirements budgeting contracts patient recruitments and participation and gathering and recording clear invaluable data

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