

FINAL STUDY REPORT MODULES

This report consists of 5 modules

Those not supplied in this submission are obtainable from the sponsor on request

MODULE I:	CORE REPORT AND STUDY PUBLICATIONS Introduction Rationale Objectives Methodology Efficacy Results Safety Results Discussion / Conclusions Appendices
MODULE II:	PRESTUDY DOCUMENTS AND STUDY METHODOLOGY Protocol and Amendment History Blank CRF Patient Information Sheet Glossary of Original and Preferred Terms Randomization List Reporting Analysis Plan (RAP) Certificates of Analysis List of Investigators List of Responsible Ethics Committees
MODULE III:	INDIVIDUAL PATIENT LISTINGS OF DEMOGRAPHIC AND EFFICACY DATA Demographic Data Listings Previous and Concomitant Diseases Previous and Concomitant Medications Efficacy Listings
MODULE IV:	INDIVIDUAL PATIENT LISTINGS OF SAFETY DATA Laboratory Parameters Vital Signs Data
MODULE V:	STATISTICAL REPORT

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LP Steffe



Nonclinical Study Report Audit:

Nonclinical Study Contracting and Monitoring William F. Salminen, Joe M. Fowler, James Greenhaw, 2012-12-31
Nonclinical Study Contracting and Monitoring A Practical Guide offers a systematic and straightforward handbook for obtaining high quality preclinical Good Laboratory Practice GLP studies This book is full of real world examples processes procedures useful templates checklists and sample reports to provide readers with a better understanding of exactly what happens during all stages of a GLP study and the critical aspects of GLP study design and conduct Designed for both the novice and experienced scientist this book covers the GLP regulations and how they impact preclinical studies the differences between GLP non GLP and peer reviewed studies preclinical GLP study design laboratory selection contracts and business ethics how to obtain test material for the study animal sourcing and release for study preparation of a draft report and much more By illustrating the overall big picture and tying it together with the individual steps this book is an essential resource to help scientists ensure a high quality GLP study that passes both scientific and regulatory scrutiny Includes both the big picture look at complex processes such as contracting toxicology and safety studies with CROs as well as a detailed account of each individual step Contains several real world examples of problems in preclinical studies to provide you with an idea of the types of challenges that are routinely encountered and how this book can help you avoid these issues Provides monitoring checklists through the book that will help you comply with each GLP requirement and maintain compliance throughout the entire process Both entry level and experienced scientists involved in nonclinical toxicology study monitoring will benefit from the ideas examples discussions and strategies presented throughout this book *Guidelines for Laboratory Quality Auditing* Donald C. Singer, Ronald P. Upton, 2014-07-22 This single source reference provides practical guidance for the quality auditing of a chemical or biological testing laboratory helping to develop or improve quality control and quality assurance programs in order to meet certification standards or pass external source audits *Guidelines for Laboratory Quality Auditing* Singer, 1992-11-23 This single source reference provides practical guidance for the quality auditing of a chemical or biological testing laboratory helping to develop or improve quality control and quality assurance programs in order to meet certification standards or pass external source audits **GLP Quality Audit Manual** Milton A. Anderson, 2000-06-22 Designed to enable readers to plan and execute their own audits this comprehensive guide presents discussions of and practical applications related to establishing a GLP QA unit and performing effective GLP audits The first section provides the foundation of information needed for designing and initiating a Good Laboratory Practice quality assurance program Section II contains ready to use audit checklists and regulatory references that are in accordance with the most recent regulations Section III comprises the full texts of the relevant standards and regulations along with the Principles of Good Laboratory Practice *Laboratory Auditing for Quality and Regulatory Compliance* Donald C. Singer, Raluca-Ioana Stefan, Jacobus F. van Staden, 2005-07-25 Identifying current tools techniques and approaches for the

evaluation of laboratory operations this reference reviews the latest regulatory standards and auditing practices to test laboratory safety quality and performance Handbook of Bioequivalence Testing Sarfaraz K. Niazi,2007-08-22 As the generic pharmaceutical industry continues to grow and thrive so does the need to conduct efficient and successful bioequivalence studies In recent years there have been significant changes to the statistical models for evaluating bioequivalence and advances in the analytical technology used to detect drug and metabolite levels have made

Translational Medicine Joy A. Cavagnaro,Mary Ellen Cosenza,2021-11-25 Translational Medicine Optimizing Preclinical Safety Evaluation of Biopharmaceuticals provides scientists responsible for the translation of novel biopharmaceuticals into clinical trials with a better understanding of how to navigate the obstacles that keep innovative medical research discoveries from becoming new therapies or even making it to clinical trials The book includes sections on protein based therapeutics modified proteins oligonucleotide based therapies monoclonal antibodies antibody drug conjugates gene and cell based therapies gene modified cell based therapies combination products and therapeutic vaccines Best practices are defined for efficient discovery research to facilitate a science based efficient and predictive preclinical development program to ensure clinical efficacy and safety Key Features Defines best practices for leveraging of discovery research to facilitate a development program Includes general principles animal models biomarkers preclinical toxicology testing paradigms and practical applications Discusses rare diseases Discusses What Why When How highlighting different considerations based upon product attributes Includes special considerations for rare diseases About the Editors Joy A Cavagnaro is an internationally recognized expert in preclinical development and regulatory strategy with an emphasis on genetic medicines Her 40 year career spans academia government FDA and the CRO and biotech industries She was awarded the 2019 Arnold J Lehman Award from the Society of Toxicology for introducing the concept of science based case by case approach to preclinical safety evaluation which became the foundation of ICH S6 She currently serves on scientific advisory boards for advocacy groups and companies and consults and lectures in the area of preclinical development of novel therapies Mary Ellen Cosenza is a regulatory toxicology consultant with over 30 years of senior leadership experience in the biopharmaceutical industry in the U S Europe and emerging markets She has held leadership position in both the American College of Toxicology ACT and the International Union of Toxicology IUTOX and is also an adjunct assistant professor at the University of Southern California where she teaches graduate level courses in toxicology and regulation of biologics **FDA Compliance Policy Guides Manual** ,1973 Schalm's Veterinary Hematology Marjory B. Brooks,Kendal E. Harr,Davis M. Seelig,K. Jane Wardrop,Douglas J. Weiss,2022-04-12 SCHALM S VETERINARY HEMATOLOGY An updated guide to veterinary hematology with expanded coverage on a variety of topics The revised seventh edition of Schalm s Veterinary Hematology is updated to provide a comprehensive review of all topics related to disorders of the blood in animals Designed as a gold standard reference this text covers a wide range of species in both confined and free range populations reflects the

most recent trends in hematology diagnostics and discusses recent advances in traditional techniques Edited and written by an international team of experts in the field the book represents an accessible yet in depth resource for information on veterinary hematology The new edition includes a hemolymphatic tissue section that covers current understanding of basic science and the species specific hematology section is further expanded from previous editions New chapters address emerging topics in hematology and existing chapters have been revised and rearranged to improve readability and simplify access to the material This seventh edition Updates the most complete reference on veterinary hematology across species Contains a new section on basic biology of hemolymphatic tissues Expands coverage of species specific hematology Presents new and emerging topics in blood disorders and diagnostic techniques Features a reorganized contents list for an integrated easy to use reference Written for veterinary clinical pathologists and residents diagnostic laboratory staff internists and specialists Schalm s Veterinary Hematology is the most comprehensive and up to date reference on the topic Regulated Bioanalytical Laboratories Michael Zhou,2011-03-31 This book provides useful information for bioanalytical analytical scientists analysts quality assurance managers and all personnel in bioanalytical laboratories through all aspects of bioanalytical technical and regulatory perspectives within bioanalytical operations and processes Readers learn how to develop and implement strategies for routine non routine and standard bioanalytical methods and on the entire equipment hardware and software qualification process The book also gives guidelines on qualification of certified standards and in house reference material as well as on people qualification Finally it guides readers through stressless internal and third party laboratory audits and inspections It takes account to most national and international regulations and quality and accreditation standards along with corresponding interpretation and inspection guides The author elaborates on highly comprehensive content making it easy not only to learn the subject but also to quickly implement the recommendations **A Comprehensive Guide to Toxicology in Nonclinical Drug Development** Ali S. Faqi,2024-02-11 Selected for 2025 Doody s Core Titles in Toxicology A Comprehensive Guide to Toxicology in Nonclinical Drug Development Third Edition is a valuable reference providing a complete understanding of all aspects of nonclinical toxicology in pharmaceutical research This updated edition has been expanded and re developed covering a wide range of toxicological issues in small molecules and biologics Topics include ADME in drug discovery pharmacokinetics toxicokinetics formulations and genetic toxicology testing The book has been thoroughly updated throughout to reflect the latest scientific advances and includes new information on antiviral drugs anti diabetic drugs immunotherapy and a discussion on post pandemic drug development challenges and opportunities This is an essential and practical resource for all toxicologists involved in nonclinical testing in industry academic and regulatory settings Provides updated unique content not covered in one comprehensive resource including chapters on stem cells antiviral drugs anti diabetic drugs and immunotherapy Includes the latest international guidelines for nonclinical toxicology in both small and large molecules Incorporates practical examples in order to illustrate day to day

activities and expectations associated with working in nonclinical toxicology **Handbook** World Health Organization,2009

A new edition of one of Zola s lesser known novels from the Rougon Macquart Cycle Finding the young Ang lique on their doorstep one Christmas Eve the pious Hubert couple decide to bring her up as their own As the girl grows up in the vicinity of the town s towering cathedral and learns her parents trade of embroidery she becomes increasingly fascinated by the lives of the saints a passion fueled by her reading of the Golden Legend and other mystical Christian writings One day love in the shape of F licien Hautecoeur enters the dream world she has constructed around herself bringing about upheaval and distress Although it provides a detailed portrait of provincial 19th century life and it adheres to a naturalist approach The Dream eschews many of the characteristics of Zola s other novels of the Rougon Macquart cycle such as a pronounced polemical agenda or a gritty subject matter offering instead a timeless lyrical tale of love and innocence *CDER ... Report to the Nation* Center for Drug Evaluation and Research (U.S.),2002 **Quality** Kathleen E. McCormick,Janet H. Sanders,2022-07-14 Quality second edition provides comprehensive application of regulatory guidelines and quality concepts and methodologies related to pharmaceutical manufacturing It is an excellent resource for practitioners those pursuing pharmaceutical related certifications and for students trying to learn more about pharmaceutical manufacturing This book provides the background theory applied descriptions of the guidelines and concepts plus questions and problems at the end of the chapters that will help provide practice for the reader to apply the concepts In this book the authors share their combined 60 years of extensive practical experience in the industry and in process improvement combined with detailed understanding of the needs of the industry and education system This book provides real life examples from industry and guidelines for practical application of tools that can be referenced by operators engineers and management This book is fully revised updated and expanded with new content in areas such as QbD Lean Six Sigma basic data analysis and CAPA tools Fully revised updated and expanded new edition Features new topics such as QbD Lean Six Sigma basic data analysis and CAPA tools Includes end of chapter summaries and end of chapter question and or problems Provides detailed steps and examples for applying the guidelines and quality tools Written in an accessible style making the content easy to understand and apply **Comprehensive Toxicology** ,2017-12-01 Comprehensive Toxicology Third Edition Fifteen Volume Set discusses chemical effects on biological systems with a focus on understanding the mechanisms by which chemicals induce adverse health effects Organized by organ system this comprehensive reference work addresses the toxicological effects of chemicals on the immune system the hematopoietic system cardiovascular system respiratory system hepatic toxicology renal toxicology gastrointestinal toxicology reproductive and endocrine toxicology neuro and behavioral toxicology developmental toxicology and carcinogenesis also including critical sections that cover the general principles of toxicology cellular and molecular toxicology biotransformation and toxicology testing and evaluation Each section is examined in state of the art chapters written by domain experts providing key information to support the investigations of researchers across the medical

veterinary food environment and chemical research industries and national and international regulatory agencies Thoroughly revised and expanded to 15 volumes that include the latest advances in research and uniquely organized by organ system for ease of reference and diagnosis this new edition is an essential reference for researchers of toxicology Organized to cover both the fundamental principles of toxicology and unique aspects of major organ systems Thoroughly revised to include the latest advances in the toxicological effects of chemicals on the immune system Features additional coverage throughout and a new volume on toxicology of the hematopoietic system Presents in depth comprehensive coverage from an international author base of domain experts

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

Pocket Oncology Alexander Drilon, Michael Postow, 2014 Pocket Oncology developed and edited by oncologists at Memorial Sloan Kettering Cancer Center is a simple yet comprehensive review of basic principles of cancer management Prepared in the style and format of books in the popular Pocket Notebook series Pocket Oncology is intended as a quick reference presented in easy to read bulleted text and using diagrams and charts where appropriate Each oncologic disease is presented on two facing pages that review initial clinical presentation pathophysiology staging current standard of care treatments and active areas of current research Edited by Alexander Drilon and Michael Postow the content of the book has been written by medical oncology fellows and each disease entity has been authoritatively reviewed by an oncologist with specific expertise in each subspecialty of oncology Features simple comprehensive review of basic principles of oncology in easy to read bulleted text using diagrams and charts where appropriate its small size makes it easy to carry the pocket of a lab coat for quick reference to information while in the hospital or oncology clinic perfect for medical students residents fellows physician assistants and nurses who perform daily oncologic care

Fundamentals of Biologicals Regulation Rebecca Sheets, 2017-12-01 Fundamentals of Biologicals

Regulation Vaccines and Biotechnology Medicines serves as an introduction to the international regulatory arena in which biologicals are developed and offers an overview of the processes and insight into the scientific concepts underpinning global regulations This book will provide multiple levels of readership with guidance on basic concepts a detailed look at regulatory challenges and practical insight into how regulators consider regulatory science and regulatory process issues across various regions With numerous case studies learning activities and real world examples across several classes of biotechnological products this book is a valuable and comprehensive resource for graduate students professors regulatory officials and industry scientists working with biologicals Provides a broad overview and introduction to the regulatory processes from product development pathways through clinical trials and product development stages and beyond Includes FDA EMA ICH and WHO recommendations and guidelines so readers can compare and contrast the different regulatory regions with their expectations and understand why they are different Contains chapters on some of the exceptions to the process including how biosimilars and in vitro diagnostics are regulated Includes numerous case studies learning activities and real world examples across several classes of biotechnological products

Industrial Pharmacy Dr Muralidhar, Dr Narmada, 2024-02-03 *Industrial Pharmacy From Pilot Plant to Market* is a comprehensive guide that provides practical approaches to pharmaceutical product development With 37 exhaustive chapters it covers important topics such as pilot plant scale up techniques technology transfer protocols regulatory requirements quality management systems and Indian regulatory requirements The book helps readers understand the significance of personnel requirements space requirements raw materials and relevant documentation for solids liquid orals and semi solids It also provides insights into WHO guidelines for technology transfer clinical research protocols quality management concepts ISO quality systems standards and Indian regulatory requirements This book is an essential resource for pharmaceutical professionals and students who seek to advance healthcare through innovative pharmaceutical product development

Bioanalytical Aspects in Biological Therapeutics Xiaohui (Sophia) Xu, Weifeng Xu, 2022-07-06 *Bioanalytical Aspects in Biological Therapeutics* Deepen your understanding of how critical data are generated from bioanalysis In *Bioanalytical Aspects in Biological Therapeutics* a team of renowned chemists immunologists and biologists delivers a timely and practical exploration of the diverse scientific and technical literature on the bioanalytical investigation of current biotherapeutics under development The book discusses the challenges and considerations for bioanalytical support covering a wide range of central topics in the field including overview and basic immunology for testing of biological therapeutics pharmacokinetic aspects clinical immunogenicity prediction and testing biomarker testing biotransformation assessment for biologics statistical aspects of bioanalytical testing regulatory expectations and more Drug development and analysis professionals will learn how critical data are generated from bioanalysis and how proven tools and methods are applied to the development of biologics Alongside coverage of topics like PK immunogenicity neutralizing antibody assays and the importance of quality control for reagents readers will benefit from

A thorough overview of the development of biotherapeutics and the role played by bioanalytical tests as well as basic immunology for bioanalytical testing of biological therapeutics Comprehensive explorations of platform and instrument considerations in bioanalytical testing pharmacokinetics assays and biomarker analysis using LC MS LBA and other technologies Practical discussions of immunogenicity prediction preclinical and clinical anti drug antibody assays and bioanalytical schemes for anti drug neutralizing antibody assays In depth examinations of critical reagents in bioanalysis Regulatory expectations for bioanalytical method development validation and sample testing Perfect for pharmaceutical scientists in industry Bioanalytical Aspects in Biological Therapeutics will also earn a place in the libraries of pharmaceutical regulators and other professionals working in pharmaceutical companies as well as graduate students studying bioanalytical assays for biological therapeutics

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Table of Contents Nonclinical Study Report Audit

1. Understanding the eBook Nonclinical Study Report Audit
 - The Rise of Digital Reading Nonclinical Study Report Audit
 - Advantages of eBooks Over Traditional Books
2. Identifying Nonclinical Study Report Audit
 - Exploring Different Genres
 - Considering Fiction vs. Non-Fiction
 - Determining Your Reading Goals
3. Choosing the Right eBook Platform
 - Popular eBook Platforms
 - Features to Look for in a Nonclinical Study Report Audit
 - User-Friendly Interface
4. Exploring eBook Recommendations from Nonclinical Study Report Audit
 - Personalized Recommendations
 - Nonclinical Study Report Audit User Reviews and Ratings
 - Nonclinical Study Report Audit and Bestseller Lists
5. Accessing Nonclinical Study Report Audit Free and Paid eBooks
 - Nonclinical Study Report Audit Public Domain eBooks
 - Nonclinical Study Report Audit eBook Subscription Services
 - Nonclinical Study Report Audit Budget-Friendly Options

6. Navigating Nonclinical Study Report Audit eBook Formats
 - ePub, PDF, MOBI, and More
 - Nonclinical Study Report Audit Compatibility with Devices
 - Nonclinical Study Report Audit Enhanced eBook Features
7. Enhancing Your Reading Experience
 - Adjustable Fonts and Text Sizes of Nonclinical Study Report Audit
 - Highlighting and Note-Taking Nonclinical Study Report Audit
 - Interactive Elements Nonclinical Study Report Audit
8. Staying Engaged with Nonclinical Study Report Audit
 - Joining Online Reading Communities
 - Participating in Virtual Book Clubs
 - Following Authors and Publishers Nonclinical Study Report Audit
9. Balancing eBooks and Physical Books Nonclinical Study Report Audit
 - Benefits of a Digital Library
 - Creating a Diverse Reading Collection Nonclinical Study Report Audit
10. Overcoming Reading Challenges
 - Dealing with Digital Eye Strain
 - Minimizing Distractions
 - Managing Screen Time
11. Cultivating a Reading Routine Nonclinical Study Report Audit
 - Setting Reading Goals Nonclinical Study Report Audit
 - Carving Out Dedicated Reading Time
12. Sourcing Reliable Information of Nonclinical Study Report Audit
 - Fact-Checking eBook Content of Nonclinical Study Report Audit
 - Distinguishing Credible Sources
13. Promoting Lifelong Learning
 - Utilizing eBooks for Skill Development
 - Exploring Educational eBooks
14. Embracing eBook Trends
 - Integration of Multimedia Elements

- Interactive and Gamified eBooks

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