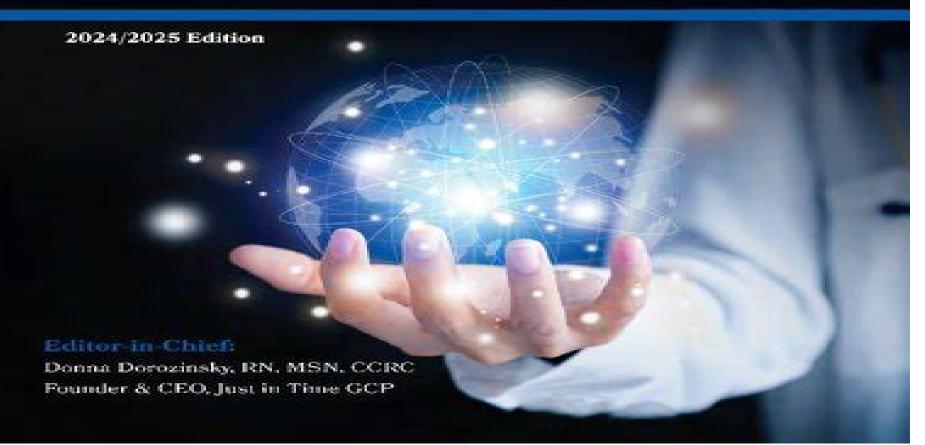
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evolution of regulations investigator and sponsor responsibilities and clinical trial protocols Written by clinicians for clinicians the book represents a valuable read also for researchers pharmacists and all professionals involved in applications to the ethic committees whose approval is required for new clinical studies **Good Clinical Practice Guide** Gary L. Chadwick, David G. Forster, Cynthia M. Gates, Jamie Gault, JoAnn Giannone, Diane Paul, Deborah Rosenbaum, Carmen Wantowski, Jaime Arango, Karen Arts, Paul Braunschweiger, Karen Hansen, 2012-09-17 The Good Clinical Practice GCP Guide is a logical extension of the CITI Program s web based Good Clinical Practice GCP training and is based on the CITI Program s recognized content It is intended to serve as a quick reference guide for GCP using Drugs and Biologics as well as Devices

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Using Clinical Practice Guidelines to Evaluate Quality of Care, 1995

Good Clinical Practices in Pharmaceuticals Graham P. Bunn, 2024-11-26 Good clinical practice GCP is a set of internationally recognized ethical and scientific quality requirements that must be followed when designing conducting recording and reporting trials that involve the participation of human subjects Compliance with GCP assures patients and the public that the rights safety and wellbeing of people taking part in studies are protected and that research data is reliable Presents details on GCP the international ethical scientific and practical standard to which all clinical research is conducted

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Clinical Pharmacology: Current Topics and Case Studies Markus Müller, 2016-03-15 This revised and extended second edition focuses on current and emerging topics in drug development their molecular mechanisms of action as well as regulatory issues In addition in depth insights into clinical drug research and trial methodology are presented on the basis of concrete case studies This updated book makes a valuable contribution to the field of Clinical Pharmacology and serves as a must have guide for professors researchers and advanced students from academia and pharmaceutical industry

Validation of Chromatography Data Systems Robert D. McDowall, 2016-11-25 Guiding chromatographers working in regulated industries and helping them to validate their chromatography data systems to meet data integrity business and regulatory needs This book is a detailed look at the life cycle and documented evidence required to ensure a system is fit for purpose throughout the lifecycle Initially providing the regulatory data integrity and system life cycle requirements for computerised system validation the book then develops into a guide on planning specifying managing risk configuring and testing a chromatography data system before release This is followed by operational aspects such as training integration and IT support and finally retirement All areas are discussed in detail with case studies and practical examples provided as appropriate The book has been carefully written and is right up to date including recently released FDA data integrity guidance It provides detailed guidance on good practice and expands on the first edition making it an invaluable addition to a chromatographer s book shelf Quality Assurance Implementation in Research Labs Akshay Anand, 2021-08-17 This book is a comprehensive and timely compilation of strategy methods and implementation of a proof of concept modified quality module of Good Laboratory Practices GLP This text provides a historical overview of GLP and related standards of quality assurance practices in clinical testing laboratories as well as basic research settings It specifically discusses the need and challenges in audit documentation and strategies for its implications in system dependent productivity striving research laboratories It also describes the importance of periodic training of study directors as well as the scholars for standardization

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