


WRITING AND MANAGING SOPs FOR GCP



SUSANNE PROKSCHA



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Writing And Managing Sops For Gcp

Susanne Prokscha

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Writing and Managing SOPs for GCP Susanne Prokscha, 2015-07-29 This book discusses managing SOPs for GCP from conception to retirement. It recommends approaches that have a direct impact on improving SOP and regulatory compliance. Throughout the text, the book provides a user's point of view to keep topics focused on the practical aspects of SOPs and SOP management.

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Practical Guide to Clinical Data Management Susanne Prokscha, 2024-07-03 The management of clinical data from its collection during a trial to its extraction for analysis has become critical in preparing a regulatory submission and obtaining approval to market a treatment. Groundbreaking on its initial publication nearly 14 years ago and evolving with the field in each iteration since then, this latest volume includes revisions to all chapters to reflect the recent updates to ICH E6 Good Clinical Practices, electronic data capture, and interactive response technologies. Keeping the coverage practical, the author focuses on the most critical information that impacts clinical trial conduct, providing a full end-to-end overview for clinical data managers. Features: Provides an introduction and background information for the spectrum of clinical data management tasks. Outstanding text in the industry and has been used by the Society for Clinical Data Management in creating its certification exam. Explains the high-level flow of a clinical trial from creation of the protocol through study lock. Reflects electronic data capture and interactive response technologies. Discusses using the concept of three phases in the clinical data management of a study: study startup, study conduct, and study closeout. To write procedures and train staff.

Clinical Trial Project Management Ashok Kumar Peepliwal, 2023-11-15 *Clinical Trial Project Management* provides a detailed overview of how to conduct clinical trials in an international context. The process of conducting clinical studies across nations is based on a set of regulatory regimes developed by respective regulatory agencies. The book focuses on clinical study protocol approval processes, Ethics Committee approval processes, clinical study feasibility, site selection, site initiation, site monitoring, database lock, site close-out, clinical data processing and management, SAE reporting and compensation, randomization, procedure, pharmacovigilance, statistical tools, BA/BE studies, and clinical study report writing, etc., covering the entire clinical trial process of conductance. In addition to that, the author also incorporated the clinical trial approval process of USFDA, EMA, and JAPAN to conduct the clinical trials. Covers how to conduct clinical trials in detail. Present useful basic and advanced statistical tools. Provides real-time project management methods like Program Evaluation Review Technique (PERT) and Critical Path Method (CPM). To manage complex projects are described in the book.

Principles and Practice of Pharmaceutical Medicine Lionel D. Edwards, Anthony W. Fox, Peter D. Stonier, 2011-07-12 The new edition of *Principles*

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Regulated Bioanalysis: Fundamentals and Practice Mario L. Rocci Jr.,Stephen Lowes,2017-04-24

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