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Writing and Managing SOPs for GCP

Susanne Prokscha



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Writing and Managing SOPs for GCP is the first book to discuss managing Standard Operating Procedures (SOPs) for Good Clinical Practice (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.

The idea of specifically calling out approaches to SOP creation and maintenance in an effort to make it easier for users to stay in compliance is a theme found throughout all book chapters. Examples in each chapter provide accurate reflections of real-world experiences to illustrate the discussion. The book also includes an example "SOP of SOPs" along with an associated SOP template.

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