A Practical Guide to Quality Management in Clinical Trial Research

Graham Ogg

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Setting up a GXP environment where none existed previously is a very daunting task. Getting staff to write down what they do for every task is a correspondingly difficult and time-consuming exercise. Examining how to maintain quality control in clinical trial research, A Practical Guide to Quality Management in Clinical Trial Research provides a cornerstone of knowledge for establishing a quality system that complies with the relevant regulations. There are many books available that cover how to interpret regulations. Going a step or two further, this book provides practical advice that is useful on a daily basis.

The book contains information for various standards including GLPs, GCPs, and GMPs. It gives detailed explanations of how to prepare, update, and maintain SOPs and includes advice on training and development of personnel. Drawing directly on his years of experience, the author delineates a from-the-trenches methodology that creates a value-added quality management system from a business perspective. He provides a solid foundation as well as tips and techniques for establishing a quality system that will comply with all the relevant regulations. The author's integrated approach and anecdotal style turns technically accurate information into easy reading. The book arms you with tools and concepts that you can use to go beyond regulatory compliance and move into the realm of business quality improvement.

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