Pharmaceutical Equipment Validation: The Ultimate Qualification Guidebook

By Phil Cloud

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While FDA regulations, cGMP, GLP, GCP, and the industry standard ISO 9000 require that documentation be established and followed, they do not provide guidelines on how to produce that documentation. Pharmaceutical Equipment Validation gives details on how to demonstrate compliance, what data to use, and how to produce the appropriate documentation. This book's user-friendly diagrams and other clear graphics illustrate key ideas throughout each protocol, offering a bird's-eye view of what is coming next-and they quickly guide you through the equipment validation. The author provides a thorough understanding of how to prepare, test, and complete equipment qualification protocols. He also explains how to perform qualification testing and whether to test the equipment for a worst case scenario.

No other book deals exclusively with the key issues of equipment qualification and process validation for pharmaceutical process equipment-and provides instructions on how to achieve it. With pragmatic approach, this book includes 38 useful protocol templates, already completed, that provide instant answers to most protocol writing and testing questions. These templates cover specific equipment types, such, and provide accurate, industry acceptable equipment qualification protocols. Step-by-step, they show how to qualify each piece of equipment, and they provide a check for readers own protocols.

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