HOW TO VALIDATE A PHARMACEUTICAL PROCESS

Steven Ostrove
"How to Properly Validate a Pharmaceutical Process" provides a how to approach to developing and implementing a sustainable process validation program. This book addresses the practical problems and offers solutions to qualify and validate a pharmaceutical process. It contains numerous case studies throughout and covers important topics such as the lifecycle approach, quality by design, risk assessment, critical process parameters, US and international regulatory guidelines and more. This book illustrates the methods and reasoning behind processes and protocols.

Understanding the why is critical to a successful and defensible process validation making this book an essential research for all practitioners engaged in pharmaceutical process validation. Thoroughly referenced and based on the latest research and literature, Part of the Expertise in Pharmaceutical Process Technology Series, a collection of practical books based on the latest scientific research and edited by well-recognized expert, Michael Levin, illustrates the most common issues related to developing and implementing a sustainable process validation program and provides valuable examples on how to be successful.

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