



How to Validate a Pharmaceutical Process (Expertise in Pharmaceutical Process Technology)

Steven Ostrove

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How to Validate a Pharmaceutical Process provides a “how to” approach to developing and implementing a sustainable pharmaceutical process validation program. The latest volume in the *Expertise in Pharmaceutical Process Technology Series*, this book illustrates the methods and reasoning behind processes and protocols. It also addresses practical problems and offers solutions to qualify and validate a pharmaceutical process. Understanding the “why” is critical to a successful and defensible process validation, making this book an essential research companion for all practitioners engaged in pharmaceutical process validation.

- Thoroughly referenced and based on the latest research and literature
- Illustrates the most common issues related to developing and implementing a sustainable process validation program and provides examples on how to be successful
- Covers important topics such as the lifecycle approach, quality by design, risk assessment, critical process parameters, US and international regulatory guidelines, and more

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