# Validation By Design®: The Statistical Handbook for Pharmaceutical Process Validation

*Lynn Torbeck*

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**Validation By Design®: The Statistical Handbook for Pharmaceutical Process Validation** Lynn Torbeck
This book offers an overview of the statistical issues expressed and implied in the U.S. FDA`s Guidance for Industry Process Validation: General Principles and Practices, Draft, November 2008. The need for this book is illustrated by the many inquires the author receives about how to use and implement basic statistics and designed experiments, DOE, for pharmaceutical process validation. There is clearly confusion and concern about meeting general regulatory requirements and this book answers those questions. It is an invaluable resource for anyone concerned with statistical aspects of validating a drug, biologic or animal health manufacturing process.

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