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Autore	Burdick Richard K
Titolo	Statistical Applications for Chemistry, Manufacturing and Controls (CMC) in the Pharmaceutical Industry / / by Richard K. Burdick, David J. LeBlond, Lori B. Pfahler, Jorge Quiroz, Leslie Sidor, Kimberly Vukovinsky, Lanju Zhang
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Nota di bibliografia	Includes bibliographical references at the end of each chapters and index.
Nota di contenuto	Chapter 1. Introduction -- Chapter 2. Statistical Methods for CMC Applications -- Chapter 3. Process Design: Stage 1 of the FDA Process Validation Guidance -- Chapter 4. Process Qualification: Stage 2 of the FDA Process Validation Guidance -- Chapter 5. GMP Monitoring and Continuous Process Verification: Stage 3 of the FDA Process Validation Guidance -- Chapter 6. Analytical Procedures -- Chapter 7. Specifications -- Chapter 8. Stability -- Chapter 9. Analytical Comparability and Similarity.
Sommario/riassunto	This book examines statistical techniques that are critically important to Chemistry, Manufacturing, and Control (CMC) activities. Statistical methods are presented with a focus on applications unique to the CMC in the pharmaceutical industry. The target audience consists of statisticians and other scientists who are responsible for performing statistical analyses within a CMC environment. Basic statistical concepts are addressed in Chapter 2 followed by applications to specific topics related to development and manufacturing. The mathematical level

assumes an elementary understanding of statistical methods. The ability to use Excel or statistical packages such as Minitab, JMP, SAS, or R will provide more value to the reader. The motivation for this book came from an American Association of Pharmaceutical Scientists (AAPS) short course on statistical methods applied to CMC applications presented by four of the authors. One of the course participants asked us for a good reference book, and the only book recommended was written over 20 years ago by Chow and Liu (1995). We agreed that a more recent book would serve a need in our industry. Since we began this project, an edited book has been published on the same topic by Zhang (2016). The chapters in Zhang discuss statistical methods for CMC as well as drug discovery and nonclinical development. We believe our book complements Zhang by providing more detailed statistical analyses and examples.