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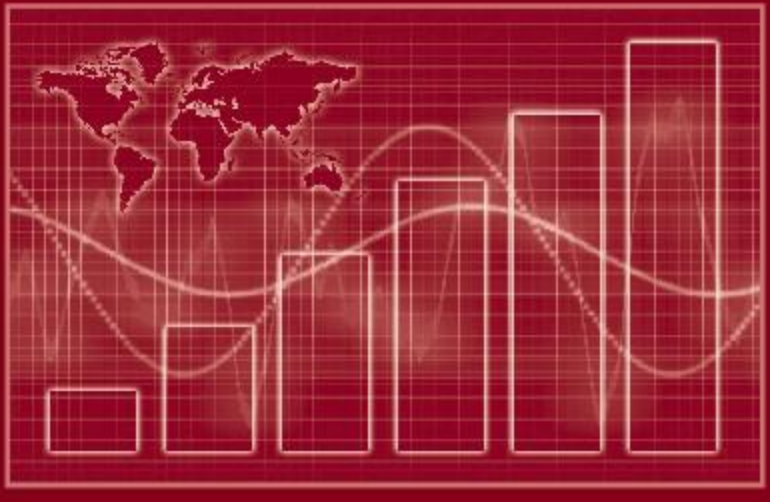

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To my wife, Phyllis

always present,
always sensitive,
always inspirational

—S. B.

To Sanford Bolton
my mentor who kindled my love of statistics,
and to my wife, Marty,
who did the same for the other areas of my life

—C. B.

Preface

This is the fifth edition of *Pharmaceutical Statistics*. The first edition was published 25 years ago when there were no statistical texts, as far as I know, which were directed toward nonstatistician researchers in academia or the pharmaceutical industry. Although, such a book was not immediately recognized as being an important adjunct to pharmaceutical research, soon after its publication, the passage of time has clearly confirmed the need for a statistics book that is useful for the pharmaceutical scientist. The practical examples with a discussion of the pharmaceutical and clinical consequences have helped to give the pharmaceutical researcher another dimension.

When I first wrote this book in the early 1980s, using a typewriter and two fingers, one of my aims was to document my experience and have a book that could be my personal reference. In each new edition, I have added new material based on new experiences that I think will be useful to the pharmaceutical community as well as to enhance the book as my own reference.

This new edition has some new features. We have expanded some of the tables in the appendix to make them more complete. A more detailed explanation of one- and two-sided statistical tests and when they are applicable has been included. We have updated some of the material related to clinical trials. We have updated statistical applications to bioequivalence, as well as various designs used in bioequivalence studies. A program to calculate the number of subjects in bioequivalence trials under a number of assumptions has been added to the disk accompanying the book. We have also added some new material explaining in more detail the assumptions and applications of nonparametric methods, including application of the binomial distribution to put upper confidence limits on the proportion of successes and failures in a sample. We have included the application of confidence intervals for a ratio, using a method based on Fieller's Theorem. An interesting relationship between the mean and median of a sample is included, with a derivation.

Finally, we have done our best to remove typos and any errors that we have discovered from the fourth edition. Unfortunately, with so much material, it seems impossible to be perfect. However, we strive for perfection, to do our best, and we look forward to comments, criticisms, and ideas from our readers to improve the book, or include new material for the sixth edition.

Before leaving this introduction, again I give thanks to my teachers, my students, my colleagues, my readers, and my work with pharmaceutical problems from pharmaceutical firms of all sizes and shapes that continue to challenge and teach me.

I want to acknowledge those who have helped me both as a person and scientist, and helped me grow. In particular, I owe debts of gratitude to two mentors, now deceased, Dr. Takeru Higuchi and Dr. John Fertig. I acknowledge the institutions that encouraged me to write this book, and allowed me to apply the knowledge to apply statistical applications to pharmaceutical problems, that is, University of Wisconsin, Columbia University and St. John's University in Queens, NY. Finally, thanks to my family, friends, and students, all of whom have made my life more full and have been my family. Special thanks to my wife, Phyllis Bolton, Mohan Sondhi, Salah Ahmed, Spiro Spireas, Charles DiLiberti, Chuck Bon Jerry Reinstein, Robert and Maria Bell, Lama Pema, Mrs. Popoff, and The University of Arizona Guitar Department, to mention only a few.

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