#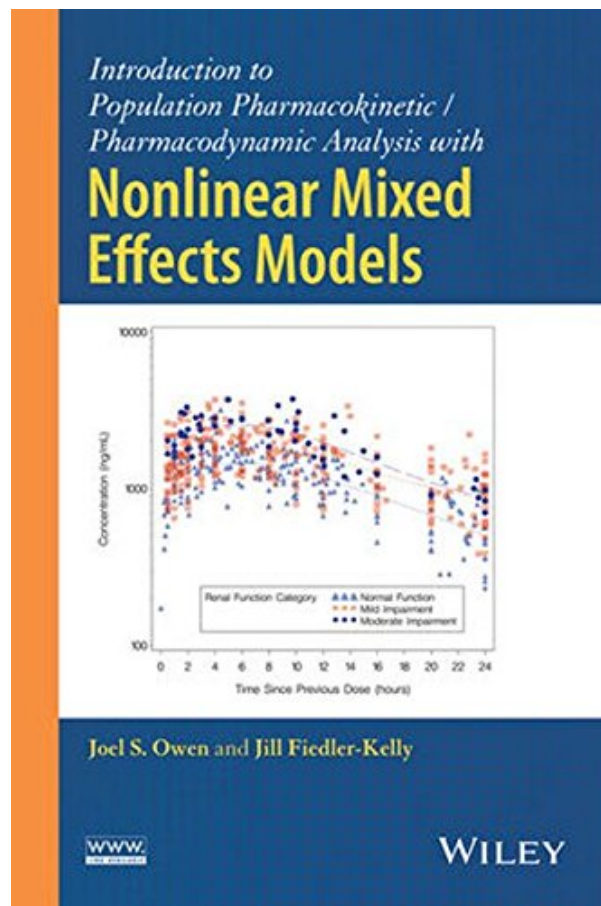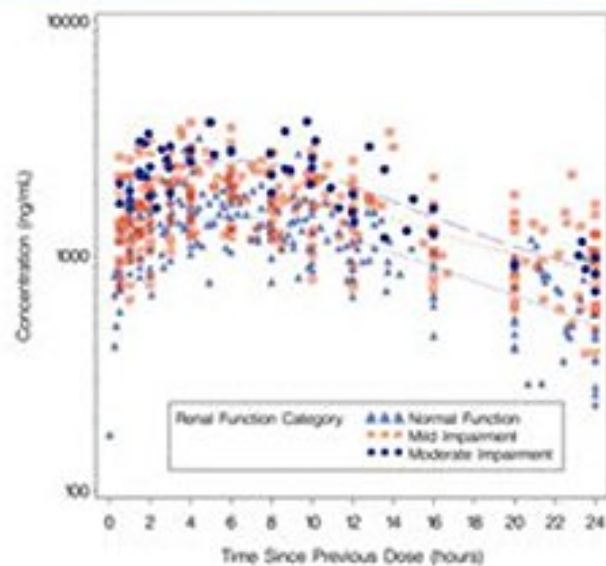 INTRODUCTION TO POPULATION PHARMACOKINETIC / PHARMACODYNAMIC ANALYSIS WITH NONLINEAR MIXED EFFECTS MODELS BY JOEL S. OWEN, JILL FIEDLER-K

Introduction to Population Pharmacokinetic / Pharmacodynamic Analysis with Nonlinear Mixed Effects Models

Joel S. Owen and Jill Fiedler-Kelly

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"This book may make the "User Guide V experience" a story from the good old times for the next generation of pharmacometricians." (CPT: Pharmacometrics & Systems Pharmacology, 22 December 2014)

From the Back Cover

A Guide to the Most Powerful Tool for Population Pharmacokinetic / Pharmacodynamic Analysis

Population pharmacokinetic / pharmacodynamic analysis using Nonlinear Mixed Effects Modeling (NONMEM) is an approach that has gained substantial importance in pharmacometrics. NONMEM is the primary tool employed and is the keystone in novel initiatives on quantitative model-based drug development led by the US FDA, professional organizations, and the pharmaceutical industry

This book uses a hands-on approach to introduce all aspects of NONMEM, how to use the system, and the concepts behind specific methods. As a didactic tool, it gives the reader an overview and provides critical information, including:

- Fundamentals: Population model concepts and terminology
- Requisite concepts for using NONMEM: writing control streams, model building, and evaluation aspects
- Examples of nonlinear modeling concepts and estimation basics with discussion on Bayesian analysis and PK/PD modeling

- Guidelines on data set requirements and structures, interpretation of the output, simulation using NONMEM, and quality control of pharmacometric anlayses

This book also features a supplementary website with datasets, programming code, and exercises and solutions to provide readers with a practical understanding of population modeling. The authors are leading scientists with real-world experience who bring their critical thinking and problem solving perspectives together in this user-friendly guidebook.

About the Author

Joel S. Owen is Professor of Pharmaceutics at Union University, Jackson, Tennessee and President and Principal Scientist of Joel S. Owen, LLC. He has led workshops on NONMEM and PK/PD modeling concepts and applications and served as Director PK/PD at Cognigen Corporation in Buffalo, New York. He has published 16 articles in research publications.

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This book provides a user-friendly, hands-on introduction to the Nonlinear Mixed Effects Modeling (NONMEM) system, the most powerful tool for pharmacokinetic / pharmacodynamic analysis.
• Introduces requisite background to using Nonlinear Mixed Effects Modeling (NONMEM), covering data requirements, model building and evaluation, and quality control aspects
• Provides examples of nonlinear modeling concepts and estimation basics with discussion on the model building process and applications of empirical Bayesian estimates in the drug development environment
• Includes detailed chapters on data set structure, developing control streams for modeling and simulation, model applications, interpretation of NONMEM output and results, and quality control
• Has datasets, programming code, and practice exercises with solutions, available on a supplementary website

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