

# Preface

Modeling and simulation tools have long been used in engineering and aerospace industries to develop products that would be prohibitively expensive to optimize through iterative improvement of prototypes. Modern drug development is now adapting and integrating analogous tools based on information from all phases of the development process. This integrative approach is now recognized as the discipline of pharmacometrics. With the increased regulatory burden and high expectations from prescribers and patients, it is neither cost-effective nor time-efficient to tackle all open questions experimentally. An increasing number of decisions are now based on appropriate modeling and simulation, which allows integration of all available knowledge in a quantitative and objective way.

This book provides an update on the current state of pharmacometrics in drug development. After an introduction of the basic and underlying pharmacokinetic and pharmacodynamic concepts of pharmacometrics in drug development, the book presents numerous specific applications as examples that utilize pharmacometrics with modeling and simulations over a variety of therapeutic areas. These chapters were contributed and written by leading scientists from academia, the pharmaceutical industry, and regulatory agencies. The examples illustrate how results from all phases of drug development can be integrated in a more timely and cost-effective process. The process of applying pharmacometric decision tools during drug development can allow data-based objective decision making. At the same time, the process can identify redundant or unnecessary experiments as well as some costly clinical trials that can be avoided. In addition to cost savings by the expedited development of successful drug candidates, pharmacometrics has an important economic impact in drug product selection. Unsuccessful drug candidates can be identified early and discontinued without expending efforts required for additional studies and allocating limited resources. Hence, pharmacometric modeling and simulation has become a powerful tool to bring new and better medications to the patients at a faster pace and with greater probability of success. We hope that this book will help to spread modeling and simulation activities in drug development and that it will initiate many more applications in the future.

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Orlando, FL, USA  
Gainesville, FL, USA

Stephan Schmidt, PhD  
Hartmut Derendorf, PhD

Applied Pharmacometrics

Schmidt, S.; Derendorf, H. (Eds.)

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