QuantPharm LLC

Advanced PK-PD Consulting

49 Flints Grove Drive,
North Potomac, MD 20878

(301) 767 5566
www.quantpharm.com

QuantPharm LLC is a consulting company specializing in advanced quantitative modeling, simulation, drug development and clinical pharmacology consulting to support pharmaceutical and biotechnology industries. QuantPharm LLC offers:

Support for Model-Based Drug Development:

- **Population (nonlinear mixed-effects) PK and PK-PD data analyses, including preparation of FDA submission-ready reports;**
- **Population pharmacokinetic and pharmacodynamic modeling and clinical trial simulation to support drug development programs;**
- **Population PK-PD analysis of continuous or categorical responses, count data, survival, time-to-event, or QTc prolongation data;**
- **Design and analysis of pediatric studies;**
- **Optimal Study Design – endpoints, sampling times, number of subjects, etc.**

Pharmacokinetic and Pharmacodynamic Analysis for Biologics:

- **Client support for model-based drug development of biologics;**
- **Mechanistic modeling of monoclonal antibodies and other biologics with target-mediated drug disposition;**
- **Analysis of the preclinical data and scale up of the preclinical models to human for biologics with target-mediated drug disposition;**
- **Design and analysis of first-in-man, Phase 1, Phase 2 and Phase 3 studies for drugs described by the target-mediated drug disposition (TMDD) equations.**

Clinical Pharmacology Consulting:

- **General PK and PK-PD consulting;**
- **Preparation of pharmacokinetic/pharmacodynamic sections of Phase 1 - Phase 3 study protocols;**
- **Critical review of the sponsor's protocols.**

In Vitro - In Vivo Correlation (IVIVC) Analysis:

- **Convolution-based In Vivo–In Vitro Correlation (IVIVC) Modeling;**
- **Level-A nonlinear mixed effects IVIVC modeling.**

On-demand Support of Sponsor's Modeling Efforts:

- **Data management support including preparation of the Nonmem-ready data files;**
- **Nonmem (including Nonmem 7) control stream development and debugging;**
- **S-plus and R script development;**
- **Expert support and critical review of population PK and PK-PD analyses;**
- **Expert support and critical review of the sponsor's IVIVC analyses;**
- **Preparation of publications.**

Training courses or workshops:

- **Mixed effects modeling using Nonmem: from data preparation to model evaluation (beginners to advanced levels);**
- **In-Vivo In-Vitro Correlations: theory, applications, and IVIVC model development;**
- **Pharmacokinetic/pharmacodynamics modeling of biologics with Target-Mediated Drug Disposition;**
- **R for pharmacometric data management and model diagnostics.**

We guarantee fast turn-around time and complete transfer of know-how related to the sponsor's projects. Strict confidentiality, scientific expertise and integrity, high efficiency and close collaboration with the sponsor form the foundation of our services.