



## Course Objectives

Pharmacokinetics is an integral part of any submission to a Regulatory Authority whether it is for IND/CTA approval or a new drug application. It is important that your staff have a good background understanding of this subject.

Our most popular course lasts 1 day and provides participants with an overview of the principles of pharmacokinetics and PKPD modelling. Examples from the literature and the speakers own experience are given to demonstrate how PK together with a knowledge of the drug regulatory environment can be used to deliver a robust drug development programme.

## Typical course agenda

- 9.00 Introduction
- 9.10 What is PK and why is it important?
- 9.50 Pre-clinical/clinical interface
- 10.30 Coffee
- 11.00 Factors influencing PK variability
- 12.00 Learning in action session
- 12.30 Lunch
- 1.30 Bioavailability and bioequivalence studies
- 2.15 PKPD Modelling and simulation
- 3.00 Coffee
- 3.30 Learning in action session
- 4.30 Summary and questions
- 4.45 Close

## Course participants

Our courses have benefitted staff working in both clinical and pre-clinical project teams and include: project and programme managers, physicians, regulatory staff, clinical scientists, clinical research associates, data managers and statisticians.

Specialist PK and PK/PD courses have been given to pharmaceutical scientists and pre-clinical DMPK personnel . These courses have covered topics such as deconvolution to aid formulation selection and the basics of PK/PD modelling.