Pharmacokinetics–ADME Fundamentals

Course Outline

First Day

08.00: Registration

08.30-10.00: Review of Learning Objectives

10.30-12.00: Absorption Considerations:
- Routes of administration
- Formulation and delivery systems
- Anatomical and physiological constraints
- Drug properties affecting absorption
- Kinetics of absorption
- Route regimen and formulation – keys to improving bioavailability

15.00-16.30: Distribution and Disposition:
- Blood and lymph - the body’s two circulatory systems
- Organs and perfusion; blood-brain barrier, CDF barrier
- Exposure route considerations
- Transporters and Effluxors

17.00-18.30 Disposition Kinetics:
- Volume of distribution
- Clearance rates
- AUC
- Drug half-life calculations

Second Day

08.30-10.00: PK models
- Approaches to quantitating distribution
- Surrogates and reality: PD

10.30-12.00: Metabolism:
- Sites of metabolism
- Metabolizing Enzymes: P450, CYP9, NATs, MAOs and other
- Phase I & II reactions

13.00-14.30: Elimination:
- Renal elimination
- Bilary elimination
- Other pathways of elimination
- Clearance rates and models

Assessment Opportunity

14.45-17.00: ADME Modifiers:
- Genetic variability and species difference
- Physiological factors
- Diet
- Disease
- Drug composition and form
- Sensitization/tolerance
- Common problems failures and their solution
- PK Wizard and Other Tools

Learning Objectives

Upon completion of this course, participants should have:
- A basic understanding of the concepts involved. Practical solutions to them will be provided to illustrate the application of principles in real life situations.
- The ability to understand the concepts involved, and apply them to real life situations.

Who Should Attend

Recommended Reading

Who We Are

Text

Course Description

Who We Are

Text

Course Location

Additional Faculty

Course Director

First Day
Third Day
Past Participants Have Said:
Fourth Day

This course is designed for a broad range of personnel in the pharmaceutical and medical device industries that need a basic understanding of ADME/pharmacokinetics, especially as it pertains to drug and device development. It should be especially valuable for:
- Those needing a basic understanding of the processes involved in absorption, disposition, metabolism and elimination of drugs
- Managers of pharmacology and toxicology studies
- Scientists that direct or evaluate pre-clinical studies
- Chemists, engineers and other scientists involved in drug and device development
- Biomedical engineers

- Shyanne C. Gad, B.S. (Whittier College, Chemistry and Biology, 1970) and Ph.D. in Pharmacology/Toxicology (Texas, 1977) DABT, ATS, is the principal of Gad Consulting Services, a sixteen year old consulting firm with six employees and more than 450 clients in the US and overseas. Prior to this, he served in director-level and above positions at Searle, Synergen and Becton Dickinson, as a manager of the toxicology lab at Allied Signal, and at Chemical Hygiene Fellowship at Carnegie Mellon Institute.

- Dr. Gad has published 44 books and more than 350 chapters, articles and abstracts in the fields of toxicology, statistics, pharmacology, drug and medical device development and safety assessment. He has previously served as a Counselor and President for ACT, as President of three SOT specialty sections and the Roundtable of Toxicology Consultants, as a reviewer for NIH, and editor of two journals. He has also conducted the triennial salary survey for toxicologists. He has more than 34 years of broad based experience in these fields.

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Client Site

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