SiTec PharmaBio

NON-CLINICAL DRUG SAFETY EVALUATION AND DRUG DEVELOPMENT

A Comprehensive Explanation of the Non-Clinical Development of Drugs and Biologics

14 - 16 May 2012

Course Topics Include:

- Pharmaceutical Toxicology
- ADME Evaluation
- The IND Game
- Developing Oncology Drugs
- Meeting 505(B)(2) Requirements

Parc Cientific de Barcelona
Baldiri Reixac, 10
08028 Barcelona - Spain

Course Description

This course provides a comprehensive explanation of the nonclinical development of drugs and biologics, emphasizing the principles of pharmaceutical toxicology and the assessment of product safety. In addition to the different types of toxicity studies in modern pharmaceutical development, it also describes the relationship between pharmacology, clinical trial design, regulatory strategy and project management.

Emphasis will be placed on how toxicity studies are integrated into the multidisciplinary development plans of new drugs and biologics, and how they affect development decisions.

Regulatory affairs will be covered, and descriptions given of the European and the U.S. FDA requirements, the new drug review process, and common regulatory errors.

The goal of this course is to give a working knowledge of pharmaceutical toxicology and drug development to enable you to develop new drugs faster and more efficiently.

There will be ample opportunities for participants to introduce topics for discussion and to interact with the faculty. The "IND Game" will provide practical experience in early drug development.

Who Should Attend

This course is designed for a broad range of pre-clinical, clinical, management, investment, and regulatory personnel in both established and emerging pharmaceutical companies. It will be of special value to:

- Scientists who wish to gain an understanding of pharmaceutical toxicity studies
- Managerial personnel
- Project management staff
- Regulatory Scientist involved in preclinical development
- Investors

Learning Objectives

Upon completion of this course, you will be able to:

- Address the strategic, scientific and regulatory concerns for the non-clinical development of drugs and biologics
- Determine how toxicology studies fit into the multidisciplinary development scheme for new drug development and influence development strategies
- Better prepare yourself for a wide range of positions in pharmaceutical R&D

Course Director

Shayne 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, an eighteen 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 42 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.

Course offered by The Center For Professional Advancement

COURSE OUTLINE

FIRST DAY

8:30–9:00
Registration

9:00-17:30
- Review of Learning Objectives
- Introduction
- History and Importance of Non-Clinical Safety
- Overview of the Drug Development Process
- Reviewing Prior Art: Sources of Information for Consideration in Study and Program Design
- Toxicokinetics and Pharmacokinetics
- Contracting Studies to Outside Labs
- Study Requirements & Guidelines: Good Laboratory Requirements & Animal Welfare
- Toxicological: Manifestations/Mechanisms/ Endpoints (Tox M, M, & E)
- Basic Principles of Toxicity Testing

SECOND DAY

9:00–18:30

- Single-dose and Subacute Toxicity Studies
- Repeat-dose Toxicity Studies–Test Item Calculator
- Nonclinical dose selection
- Genotoxicity Studies
- Carcinogenicity Studies
- Local Tissue Tolerance
- Safety Pharmacology Studies for Human Pharmaceuticals
- Reproduction and Development Toxicity Studies
- Additional Special Studies: Immunotoxicology, Dermal Sensitization and Phototoxicity.
- Strategic Planning of the Non-Clinical Phase
- Safety Testing of Biotechnology Derived Products
- The "IND Game": Starting off

THIRD DAY

9:00-17:30

- The "IND Game": Presentations from working groups; Additional information to integrate
- Safety Data Documentation: IB and Common Technical Document (CTD)
- Formulations and Excipients
- Regulatory Requirements and Procedures: The FDA, ICH, and Japan
- European Regulatory Requirements
- The IND Game: Case Studies
- Early Tox and ADME
- Impurities and Degradents
- Oncology
- Dermal and Inhalation Products
- Animal to Man and the Transition to "First in Man" Clinical Studies
- Phase I: FIM Design and Safety Adverse Event Assessments
- Individual Assessment

TUITION AND PAYMENT

Early registration:
(received before March 15th, 2012)
Euro 1700+VAT/1530+VAT (group discount*)

Regular registration:
(received after March 15th, 2012)
Euro 1900+VAT/1710+VAT (group discount*)

(Fee includes course materials, lunches and coffee breaks) Participants are responsible for their own hotel reservations.

*Group discount is for two or more enrollments from the same company.

Payable by bank transfer upon issuing an invoice.
Payment instructions will be provided upon registration.

Registration

Name .....
Surname .....
Position .....
Organization .....
VAT/C.F. .....
Address. .....
Postal Code .....
City .....
Country .....
Phone/Fax .....
Participant e-mail .....
Billing e-mail .....

PLEASE RETURN BY FAX OR E-MAIL

General information

Cancellations received after May 2nd 2012 will be invoiced completely. Substitutions may be made at any time. Payment is due once the participant receives an invoice. Certificates will be issued to participants upon completion of the course.

For Information please contact us at:

Office: +34 93 4487156
Cell: +34 691676055
Fax: +34 93 4037109
e-mail: info@sitec-pharmabio.com