SiTec PharmaBio

SAFETY ASSESSMENT AND BIOCOMPATIBILITY EVALUATION

FOR REGISTRATION OF MEDICAL DEVICES AND COMBINATION PRODUCTS

11-13 June, 2014

Parc Científic de Barcelona

Baldiri Reixac, 10 - 08028 Barcelona - Spain

Course Topics Include:

- Principles of Testing Materials
- Products for Biocompatibility and Safety
- Regulatory Requirements for Development
- Marketing Approval of Medical Devices
- The Impact of FDA's GLP Regulations
- ISO Requirements
- Regulatory Path to the Clinic and Market
- Combination Products

Learning Objectives

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

- Explain both the nature of materials used in medical devices and of any associated drugs and their potential for causing adverse reactions
- List the methods for devising a sound safety evaluation program
- Outline the specific testing protocols for testing materials in vitro and in vivo
- Describe the significance of Good Laboratory Practice regulations for preclinical testing of materials

Course Description

The aim of this course is to review the principles of testing materials for biocompatibility. The full range of test methods will be discussed including chemical analysis, cell culture and other in vitro methods, acute animal studies including USP methods, thromboresistance, sensitization, long-term implant and other special studies. The nature of polymers and the sources of incompatibility will be discussed along with specific examples. Methods of testing will be related to the end use of a product. Examples of recommended testing programs will be presented, as well as the impact of FDA's Good Laboratory Practice regulations and ISO requirements on preclinical testing of materials and medical devices.

Who Should Attend

This course is intended for professionals who have responsibilities for the safety and marketing approval of medical devices and drug/device combination products. It will be especially valuable to:

- Scientists
- Engineers
- Biologists
- QA/QC
- Manufacturing personnel
- Regulatory affairs

These individuals may come from industrial, government, academic and/or contract testing facilities. The course should be especially useful for those newly assigned to product safety responsibilities although it also provides an opportunity for more experienced personnel to update their knowledge.

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, a nineteen year old consulting firm with six employees and more than 500 clients (including 50 device companies in the US and 30 overseas). Dr. Gad served in director-level and above positions at Searle, Synergen and Becton Dickinson. He has authored or edited more than 44 published books and more than 350 chapters, articles, and abstracts in the fields of toxicology, statistics, pharmacology, drug development, and safety assessment. He has more than 34 years of broad-based experience in toxicology, drug and device development, statistics and risk assessment. Dr. Gad has specific expertise in biocompatibility and risk assessment, neurotoxicology, in vitro methods, cardiovascular toxicology, inhalation toxicology, immunotoxicology, and genotoxicology. Past President of the American College of Toxicology, the Roundtable of Toxicology Consultants and three of SOT's specialty sections, and recipient of the American College of Toxicology Lifetime Contribution Award, he has direct involvement in the preparation of INDs (93 successfully to date), NDA, PLA, ANDA, 510(k), IDE, CTD, clinical data bases for phase 1 and 2 studies, and PMAs. Dr. Gad has consulted for FDA, EPA, and NIH, and has trained reviewers and has been an expert witness for the FDA.

Course offered by The Center For Professional Advancement

COURSE OUTLINE

FIRST DAY

8:30-9:00 **Registration**

9:00–17:00

Review of Learning Objectives

Medical Devices:
- Definitions: Medical Devices and Combination Products. Categories & Markets
- Approaches to Safety Evaluation in Combo and Device Development: Who Regulates
- Reviewing Prior Art: Sources of Information for Consideration in Study and Program Design

Regulatory Requirements:
- Current FDA, ISO and Pharmacopeia Requirements (ISO-10993-1)
- ICH Requirements

Toxicity:
- Toxicological Manifestations, Mechanisms and Endpoints
- Road Maps to Testing (ISO 10993-1 and ICH M-3 (R2))
- The CMC section: Physical and Chemical Properties of Materials
- Sample Selection and Preparation (ISO-10993-12)
- When the Drug Component is the Principal Mode of Action in a Combination Product

Optional Networking Opportunity

SECOND DAY

9:00-17:30

- Acute Systemic Safety Tests (ISO-10993-11)
- Cytotoxicity (ISO-10993-5)
- Hematocompatibility (ISO-10993-4)
- Local Tissue Tolerance: Irritation & Pyrogenicity (ISO-10993-6), (ISO-10993-10)
- Immunotoxicity (ISO-10993-20)
- Genotoxicity (ISO-10993-3)
- Implantation Studies (ISO-10993-6), (ISO-10993-8)
- Subchronic and Chronic Toxicity Studies Under the New FDA Interpretation
- Reproductive & Developmental Toxicology (ISO-10993-3)

17:30-19:00

Optional Evening Session
Case Histories and Problem Resolution

THIRD DAY

9:00-17:30

- Carcinogenicity (ISO-10993-3)
- Toxicokinetics for Medical Devices (ISO-10993-16)
- Contracting Studies to Outside Laboratories
- Risk Assessment for Medical Devices (EN 14971)
- Safety Considerations for Combination Products
- Leachable and Extractable (L&E) Studies and Associated Risk Assessment
- Leachable and Extractable Studies and Notified Bodies (EU) and the SFDA (China)
- Special Studies
- Clinical Safety Trials and Epidemiology Studies for Medical Devices
- FDA Regulatory Submissions: IDEs, INDs,510(k)s, PMAs and NDAs

Assessment Opportunity

TUITION AND PAYMENT

Early registration:
(received before March 14th, 2014) - Euro 1700+VAT/1530+VAT (group discount*)

Regular registration:
(received after March 14th, 2014) - Euro 1950+VAT/1750+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.....
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 20, 2014 will be invoiced completely. All cancellations will be subject to Euro 200 processing fee. 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:

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