SiTec PharmaBio

Biosafety of Biological Drug Products

16-17 October 2017

Parc Científic de Barcelona
UNIVERSITAT DE BARCELONA

Baldiri Reixac, 10 - 08028 Barcelona - Spain

Course Topics Include:

- Determine Special Regulatory and Safety Considerations Governing Biologics
- Explore Manufacturing Controls Required to Bring a Product from Laboratory to Market
- Comprehend Special Concerns Regarding Appropriate Animal Testing for Biologically-Derived Substances

Who Should Attend

This course will be valuable to a broad range of professionals in the biotechnology industry including:

- Scientific
- Managerial
- Regulatory

Scientific personnel will gain more familiarity with the regulatory rationale for testing requirements. Regulatory and managerial personnel will have an opportunity to learn more about the technical aspects of various assays.

Learning Objectives

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

- Determine special regulatory and safety considerations governing biologics
- Identify various types of assays required to be performed on biologics at the R&D, preclinical, clinical, and market stage of product development
- Explore manufacturing controls required to bring a product from laboratory to market
- Comprehend special concerns regarding animal testing for biologically-derived substances

Course Description

This course will introduce the unique perspectives and considerations of safety testing of biological drug products in contrast to typical safety testing of chemically-derived pharmaceuticals. Regulatory recommendations and requirements at each level of development will be outlined and accepted methods will be discussed in detail.

The course will also use the history of the last 25 years of safety assessment of biologically derived therapeutics and a case study approach to identifying current approach strengths, weaknesses and successful pathways.

Course Director

Dr. Shayne C. Gad has been the Principal of Gad Consulting Services for 25 years. His 40 years of experience includes safety assessment in the medical device, biotechnology, pharmaceutical and chemical industries. He has published 48 books and more than 350 abstracts, articles, and chapters in the fields of toxicology, statistics and safety assessment, pharmaceutical and medical device development, and is on the editorial boards of the Journal of Applied Toxicology, The International Journal of Toxicology, the Journal of Inhalation Toxicology and the Journal of Acute Toxicology. He was Editor-in-Chief for Toxicology Methods, and has successfully opened 113 INDs in the past 23 years. He served on the Consumer Product Safety Commission Toxicology Advisory Board, and numerous NIH review committees and Advisory Boards.
Dr. Gad received his Ph.D in Pharmacology/ Toxicology from the University of Texas at Austin and is a Diplomate of the American Board of Toxicology and a Fellow of the Academy of Toxicologic Sciences. He is a Past President of the American College of Toxicology, three SOT specialty sections and the Roundtable of Toxicology Consultants.

Course offered by CfPA
THE CENTER FOR PROFESSIONAL ADVANCEMENT
FOUNDED 1967

COURSE OUTLINE

FIRST DAY

8:30-9:00

Registration

9:00-17:30

Introduction
- Definitions
- Extent of Market
- Factors of Influence
- Regulation: U.S.; European
- Materials

Consideration of Supply and Chemistry

Production of Products and Special Considerations

Biosafety Testing in Vitro
- Sterility
- Endotoxins, Pyrogenicity, and Bio Burden
- Immunology
- Allergenicity

Safety Assessment of Biological Products
The Current General Case and 30 Years Experience

SECOND DAY

9:00-17:30

Vaccines, Tissue and Gene Therapies

Traditional Toxicology

Selection of Appropriate Animal Models

Overcoming Target Specificity in Safety Assessment

Sources of Concern:
What have we learned in 25 years?

Purification and Process Validation

Biosafety Testing In-Vitro

Biosimilars

Case Studies

TUITION AND PAYMENT

Early registration:**
(received before August 11, 2017) - Euro 1750+VAT/1575+VAT (group discount*)

Regular registration:
(received after August 11, 2017) - Euro 1950+VAT/1755+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.
** Early Registration means: registrations forms received by the deadline and payments made within one week from invoice date. Otherwise regular registration fee will be applied

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 October 2, 2017 will be invoiced completely. All cancellations will be subject to euro 300 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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