



## Bioanalytical Method Development & Validation (Includes 3 Workshops)

**Registration Fee: £865**

**Date: May 5-6, 2010**

**Course Duration: Two Days 8:45am-5:00pm**

### Course Description

This highly unique and focused course provides a sensible approach to develop reproducible bioassays using live systems and/or biologically derived reagents. These approaches will be supplemented by guidelines to meet regulatory requirements according to their application. In addition, a workshop on writing validation protocols will provide hands-on experience to cover this pivotal document. During the course students will also hear case studies that will add relevance to the lecture materials and provide a launch point for class discussion.

### Key Topics & Agenda

#### Day 1

Introduction to Potency Bioassays

GMP and GLP overview

Differences between GMP and GLP Expectations

Development:

- Early and Late Stage Development
- Selecting Methods and type of assays
  - Enzymatic
  - Cellular
  - Microbial
  - Animal Studies
- Feasibility and Optimization Parameters
- Standard and Controls
- Eliminating Edge and Hook Effects
- Setting System Suitability Criteria
- Interpreting the new USP 111 Chapter on Bioassays – NEW!

Phase I/II qualification

Pre-validation:

- Improving Ruggedness
- Parallelism
- Process Controls
- Setting Realistic Specs for Validation

Validation

Understanding & Planning for Bioassay Method Transfers

Validation Protocol for GMP Potency Bioassays



## **Workshop 1**

- **Validation Protocol Workshop for GMP Potency Bioassays**

## **Day 2**

Overview of Typical Bioanalytical Assays:

ELISA, RIA, Biacore and Electrochemoluminescence

PK/PD

Current Crystal City incurred sample testing expectations for PK work – NEW!

### **Workshop 2**

- **Validation Protocol Workshop for PK/PD Assays**

Immunogenicity

### **Workshop 3**

- **Validation Protocol Workshop for Immunogenicity Assays**

Review of several cut-point methods – NEW!

Limits Tests, including qPCR technology

Biomarker

Method Writing

- Method Writing Exercise

## **Faculty**

### **Dr. Ana Menendez**

Industry recognized scientific director with 25 years of progressively responsible and diverse accomplishments in drug discovery and late stage assay development. Validated and implemented all the immunological and biological assays for Mylotarg and other recently FDA approved biological products. Initiated and led several productive multi-corporate international collaborations and departments. Scientific expertise covers several therapeutic areas including a Ph.D. in Microbiology/Immunology and extensive background in oncology.

Dr. Ana Menendez is responsible at Catalent Pharma Solutions for the release tests required to verify the functionality and purity of biotechnology products and the complex processes involved in their manufacture. Dr. Menendez joined Catalent Pharma Solutions from Bristol-Myers Squibb (BMS) where she held a number of positions of increasing responsibility from 1995 to 2001. From 1982 to 1995, Dr. Menendez pioneered monoclonal antibody technology at American Cyanamid/Wyeth and was responsible for all the immunoassays and in vitro bioassays for Mylotarg, an anticancer monoclonal antibody – toxin conjugate that was approved in 2000. Dr. Menendez obtained her Ph.D. in Microbiology/Immunology from NY Medical College.

## **Who Should Attend**

- **Research & Development Laboratory**
- **Product Development Laboratory**
- **Contract Laboratory**
- **Analytical laboratory**
- **Quality Control & Quality Assurance**
- **Product Submission**
- **Consultants**



## COURSE MATERIAL AND CERTIFICATE OF ATTENDANCE

- All participants will receive a specially prepared course manual.
- All participants will receive a certificate of attendance upon completion of the course.

## Location

### The Waldorf Hilton, London

Located in the heart of London's West End, it's 5 minutes' walk from Covent Garden Market, 10 minutes' walk from Trafalgar Square and the London Eye. The hotel is within 90 minutes of London's 3 major airports: Heathrow, Gatwick and Stansted.

#### Address:

#### The Waldorf Hilton, London

Aldwych, London WC2B 4DD, UK

Ph# 020 7836 2400

**Please note that participants are responsible for arranging their own travel and hotel accommodations.**

## Registration

Please refer to the **register** tab on the CATD website ([www.catdglobal.com](http://www.catdglobal.com)) or click on the title of the course on the conferences/meeting or home page to register on line. If you have any problem registering please do not hesitate to contact us at [info@catdglobal.com](mailto:info@catdglobal.com) or call us at + 44 (0) 20 8485 1234 or fax us at + 44 (0) 20 8485 1234

#### \*Registration Fee Includes:

*Presentation Materials, Luncheon, and Refreshment*

**\*Please indicate any special Dietary requirements when registering for the course**

## Contact for More Information

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