

# AAPS *Connection*

American Association of Pharmaceutical Scientists

March 2013

## **AAPS Workshop on Biorelevant In Vitro Performance Testing of Orally Administered Dosage Forms**

March 18–19, 2013  
Bethesda North Marriott Conference Center  
Bethesda, MD

### **Background**

Biorelevant in vitro performance testing of orally administered dosage forms has become an important tool for the assessment of drug product in vivo behaviour. Biorelevant dissolution/release testing is useful for the evaluation of formulation and food effects on plasma levels and intraluminal dosage form performance after administration of oral drug products. Biorelevant testing has been utilized to decrease the number of in vivo studies required during the drug development process and to mitigate the risk related to in vivo bioequivalence studies. Data on the luminal environment, its simulation, and biorelevant in vitro performance testing methodologies that can be applied during product development will be presented and discussed. Case studies from industry will describe the application of biorelevant testing methodologies for formulation design, selection, and development. Presentations from the U.S. Food and Drug Administration and European Medicines Agency will discuss the use of biorelevant testing in the evaluation of a drug's performance.

For more information visit  
[www.aaps.org/biorelevant](http://www.aaps.org/biorelevant).

## **AAPS Workshop on Bioanalysis of Antibody Drug Conjugates**

May 18, 2013  
Sheraton San Diego Hotel and Marina  
San Diego, CA

### **Goals and Objectives**

The objectives of bioanalysis are to provide key information for ADC development by

- selecting the most promising ADCs in discovery,
- understanding preclinical safety for IND package,
- supporting clinical development and regulatory submission, and
- meeting post-approval commitments.

The complexity of the ADCs requires using a multidisciplinary large molecule/small molecule bioanalytical approach and sophisticated analytical techniques, such as

- analytical techniques used in ADCs in discovery,
- pharm sci analytical methodologies used for characterization of the ADC DS and DP,
- biotransformation data to understand the fate of ADCs in vivo,
- bioanalytical assays supporting preclinical studies,
- clinical bioanalytical assays, and
- immunogenicity assays.

The lack of established regulation for ADCs in general and ADC analysis in particular and the complexity of ADCs justifies discussing these above topics at a single meeting bringing together scientists of different specialties and educational background.

For more information visit  
[www.aaps.org/ADC](http://www.aaps.org/ADC).

## **AAPS Workshop on Biologic Drugs: Recent Trends in Formulation, Manufacture and Characterization**

May 18–19, 2013  
Sheraton San Diego Hotel and Marina  
San Diego, CA

## Summary/Description

Products containing biotechnologically produced drugs are often applied parentally, imposing special requirements on the formulation composition, product specification, packaging materials and manufacture. Many aspects relating to parenteral dosage forms containing biologics are not applicable to similar small molecule products. In addition, current developments and trends will be highlighted, including use of VHP for decontamination, special production conditions for so-called “armed antibodies” or the prevention of aggregates, and particles formation.

## Goals and Objectives

The workshop will teach on some basics and discuss cutting-edge developments with regards to formulation, manufacture, and characterization of biologics drug product.

For more information visit  
[www.aaps.org/biologicdrugs](http://www.aaps.org/biologicdrugs).

## AAPS Immunogenicity Training Course II–Advanced Topics in Evaluation of the Immunogenicity of Biotherapeutics

May 18–19, 2013  
 Sheraton San Diego Hotel and Marina  
 San Diego, CA

## Goals and Objectives

Following its introduction in 2009, the two-day training course “Development of Ligand Binding Analytical Methods to Support Immunogenicity Testing: Theoretical to Practical Considerations” has been offered each year (2009, 2010, 2011) at the National Biotech conference. Recently, there has been a great amount of interest in offering an advanced course that goes beyond the basics to address a broader range of topics of interest in greater depth. This interest has been kindled by the greater number of companies entering the biotech arena, increased complexity associated with the elucidation of the immune response and the effect of anti-drug antibodies upon safety and efficacy. This led to the

introduction of a new course in 2012 that provides in-depth training in the more advanced methods and approaches for detection, characterization, and titer assessment of anti-drug antibodies, prediction and prevention of immunogenicity, new technologies, additional statistical models for immunogenicity assessment, and detection and characterization of immune complexes. As a result of its popularity and demand, we are offering this course at the 2013 National Biotech Conference.

For more information visit,  
[www.aaps.org/immunogenicity](http://www.aaps.org/immunogenicity).

## 2013 AAPS National Biotechnology Conference

May 20–22, 2013  
 Sheraton San Diego Hotel and Marina  
 San Diego, CA

## Overview

Come join us for the 2013 AAPS National Biotechnology Conference! The scientific programming will feature 19 symposia, 16 roundtables and mini-symposia, 8 sunrise sessions, 3 short courses, 2 workshops, an advanced immunogenicity training course, and a new session, Regional Biotech Highlights from San Diego.

The conference programming highlights include Advances in Cellular Therapeutics, Tissue Engineering and Regenerative Medicine, Evolving Regulatory Landscape of Biosimilars, and Clinical Impact of Immunogenicity– Recommendations of the AAPS Therapeutic Protein Focus Group White Paper.

For more information visit  
[www.aaps.org/nationalbiotech](http://www.aaps.org/nationalbiotech).

## New AAPS Member Benefit

AAPS has initiated a new ePosters viewing service. Posters presented at future AAPS Annual Meetings and AAPS National Biotechnology Conferences will be available for viewing after each meeting has taken place. Viewing is limited to AAPS members as well as nonmembers and exhibitor attendees of specific meetings.



The 2012 AAPS Annual Meeting and Exposition posters are available at [www.aaps.org/ePosters](http://www.aaps.org/ePosters).

## Upcoming AAPS Meetings

Log onto [www.aaps.org/meetings](http://www.aaps.org/meetings) for details

- **March 18-19, 2013**

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- **September 9-10, 2013**

**2013 AAPS Workshop on Inhaled Drug Products: Current Practices and the Future on In Vitro Testing Technologies and Regulation**

USP Meetings Center, Rockville, MD

- **November 10-14, 2013**

**2013 AAPS Annual Meeting and Exposition**

Henry B. Gonzalez Convention Center, San Antonio, TX



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