

# AAPS Connection

American Association of Pharmaceutical Scientists

April 2013

## AAPS Workshop on Bioanalysis of Antibody Drug Congugates

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 multi-disciplinary 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 ADC 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 backgrounds.

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

To 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 Biotechnology 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 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 Biotechnology 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, Clinical Impact of Immunogenicity, and Recommendations of the AAPS Therapeutic Protein Focus Group White Paper.

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

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

September 9–10, 2013  
USP Meetings Center  
Rockville, MD

### Summary/Description

This workshop will provide a thorough update of various *in vitro* testing procedures and upcoming technologies for Orally Inhaled and Nasal Drug Product (OINDP). Three sessions are considered for this workshop:

- Statistical techniques
- Aerosol characterization procedures
- Combination product development strategies.

All topics were selected by a panel of subject matter experts (SMEs) from the AAPS Inhalation and Nasal Technology Focus Group, International Pharmaceutical Aerosol Consortium on Regulation and Science, United States Pharmacopeial Convention (USP), and the United States Food and Drug Administration. These topics will provide valuable feedback to industry and academia on the regulatory landscape and the pipeline of OINDPs in the USA and world market. Proceedings should be published as a white paper in a peer-reviewed journal by participating organizations. Proceedings should be available at the INTFG, AAPS website for future access to AAPS members and workshop attendees.

### Goals and Objectives

- Learn the current regulatory developments and future perspectives of statistical approaches and aerosol characterization techniques for OINDPs.

- Learn the current developments and future perspectives of USP chapters related to OINDPs.
- Learn the current developments and future perspectives of combination product development.

For more information visit

[www.aaps.org/IDP](http://www.aaps.org/IDP).

## Upcoming AAPS Meetings

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

- **May 18, 2013**

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

Sheraton San Diego Hotel and Marina, San Diego, CA

- **May 18-19, 2013**

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

Sheraton San Diego Hotel and Marina, San Diego, CA

- **May 18-19, 2013**

**AAPS Immunogenicity Training Course II— Advanced Topics in Evaluation of the Immunogenicity of Biotherapeutics**

Sheraton San Diego Hotel and Marina, San Diego, CA

- **May 20-22, 2013**

**2013 AAPS National Biotechnology Conference**

Sheraton San Diego Hotel and Marina, San Diego, CA

- **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



AAPS Connection

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