

AAPS Connection

American Association of Pharmaceutical Scientists

April 2014

Accelerating Science to Impact Health—The AAPS Foundation

The American Association of Pharmaceutical Scientists has established a premier information network for pharmaceutical scientists around the world. In order to have a greater impact in advancing the contributions of the pharmaceutical sciences to global health, a new philanthropic arm of AAPS has been formed—the AAPS Foundation.



The AAPS Foundation will enhance pharmaceutical science research and increase the development of scientists who are prepared to engage research with an even greater level of skill.

We encourage you to join us and contribute to the AAPS Foundation. It is important now more than ever that pharmaceutical scientists develop skills that will meet the world's evolving health challenges, but these needs and personal development gaps cannot be addressed without dynamic and up-to-date initiatives. And the reality is that these initiatives, while making a positive impact, will require generous contributions from AAPS's members and friends. Your support of the AAPS Foundation can help ensure that current and future pharmaceutical scientists are fully prepared to meet the challenges found in the discovery and development of today's modern medicines.

AAPS is committed to the principle that 100% of your tax-deductible contribution will go toward the foundation's programs. The AAPS Foundation offers an array of donor levels to best suit your needs. Other vehicles for individual contributions include corporate matching gifts, gifts of stock, estate-planned gifts, and gifts of honoraria.

Help shape and ensure the future of the pharmaceutical sciences by supporting a tradition of developing science, impacting global health, and growing future scientists.

Contribute to the AAPS Foundation today!
www.aaps.org/foundation

AAPS Webinars—An Exclusive Member Benefit



Webinars offer a great opportunity to receive the latest information on pharmaceutical science topics without the need for travel or spend time away from home and office. Plan to participate in our upcoming live events, replay a past session in our archives, or submit a proposal for organizing your own webinar.

Tips for the Best Webinar Experience

- Use a wired network connection (Ethernet) rather than a Wi-Fi hotspot.
- Whenever possible, use a desktop rather than a laptop.

April 10, 2014

Animal Models for Predicting Food Effects on Class IV Compounds and/or Enabling Formulations in Humans

April 24, 2014 (Rescheduled from January 16, 2014)

Optimization of Dose Finding in Phase 2b Dose-ranging Trials: Considerations for Model-based Design and Analysis

Funded by an educational grant from



For more information visit www.aaps.org/webinars.

AAPS Workshop on Method Development, Validation and Trouble Shooting of Ligand Binding Assays: Get your Resolution from the Industry and Regulatory Experts

May 18, 2014

Sheraton San Diego Hotel & Marina
San Diego, CA



AAPS members save hundreds of dollars at early registration for all AAPS Meetings. Go to www.aaps.org/tojoin.

Overview

The emergence of therapeutic proteins in the treatment of diseases has exploded in recent years. The diversity of these molecules has evolved from the antibodies to conjugates such as ADCs, pegylated proteins, etc. The complexity of bioanalytical techniques has increased, and more hybrid methods are being used for analysis.

The regulatory guidances, white papers, and other initiatives are also expanding the scope of analysis. On the regulatory front, the FDA issued the draft guidance on Bioanalytical Methods Validation in September 2013, a draft FDA guidance on immunogenicity was released in February 2013, and other regulatory agencies (EMA, Japan, etc.) have released their guidance documents.

In addition, multiple other activities through the different focus groups of the AAPS (LBABFG, TPIFG, PABC, Biotherapeutic ADME, BTM etc.) and the Global Bioanalytical Consortium is underway to address the unmet needs of the bioanalytical community.

Goals and Objectives

- To provide practical tips and resolution for issues related to developing and validating ligand binding assays in a regulated environment
- To provide a forum for the attendees to openly discuss their technical and scientific questions in Ligand Binding assays in support of Pharmacokinetic, Pharmacodynamic, Biomarker, and Immunogenicity assays
- To discuss other aspects such as approaches to investigate unusual PK behavior and implementation of new technology for bioanalysis

For more information visit www.aaps.org/LBAWorkshop.

2014 AAPS National Biotechnology Conference

May 19–21, 2014

Sheraton San Diego Hotel and Marina
San Diego, CA



AAPS members save hundreds of dollars at early registration for all AAPS Meetings. Go to www.aaps.org/tojoin.

Cosponsored by



The 2014 AAPS National Biotechnology Conference presentations and discussions should be of interest to scientists who are devoted to advancing health through innovations in biotherapeutics.

One Conference—Four Conference Workstreams

- Biomanufacturing
- Biomarkers and PK/PD
- Research and Discovery
- Immunogenicity and Administration Routes

For more information visit www.aaps.org/nationalbiotech.

Be Recognized by Your Peers at the 2014 AAPS Annual Meeting and Exposition

The AAPS awards program provides a wonderful opportunity for scientists and graduate students to be recognized and honored for their valuable contributions to the pharmaceutical sciences. Please view the 2014 awards and travelships offered at our Annual Meeting and Exposition, and nominate your colleague today. Award nomination material can be found at www.aaps.org/AMAwards.

AAPS Regulatory Affairs 101



Essentials of Regulatory Affairs for Pharmaceutical Scientist eLearning Series

“The AAPS eCourse Essentials of Regulatory Affairs for Pharmaceutical Scientists eCourse was created as an introduction to regulatory science and the intricacies of the field

including regulatory process for market approval, compliance, and regulatory intelligence. In order to meet the latest demands of expanding into emerging markets, the course also has two lectures covering market approval around the globe.” —Shelley Durazo, Ph.D. Candidate

Overview

The objective of this course is to provide an overview as well as cross-functional training in regulatory sciences to better understand current regulatory processes from discovery to commercialization of pharmaceutical products. Designed with pharmaceutical scientists in mind, this series offers information on:

- The purpose and governance of domestic and international regulatory agencies
- U.S. regulatory processes from early through late stage development
- Domestic and international regulations that govern development, manufacturing, and distribution of pharmaceutical and biopharmaceutical products
- Key tools, including regulatory intelligence, to navigate through the complex regulatory environment and stay current on regulations

See a full listing of AAPS Regulatory Affairs 101’s instructors, reviewers, and CORE team members.



AAPS members save on this exclusive member benefit. Bulk pricing available/contact Meredith Weston at WestonM@aaps.org. Go to www.aaps.org/tojoin.

The 2013 AAPS Annual Meeting and Exposition ePosters are available to AAPS members



This year’s collection includes 457 posters of the 2184 presented at the meeting.

AAPS members have access with their membership login and password.

Nonmember and exhibitor Annual Meeting attendees have special access to this member exclusive benefit.

Visit www.aaps.org/eposters/

SEE YOU IN SAN DIEGO AT THE 2014 AAPS ANNUAL MEETING AND EXPOSITION, NOVEMBER 2-6, 2014.

www.aaps.org/annualmeeting



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2107 Wilson Blvd., Suite 700, Arlington, Va. 22201-3042 Ph: +1.703.243.2800

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