# AAPS Connection

**American Association of Pharmaceutical Scientists** 

March

2014

## Accelerating Science to Impact Health: The AAPS Foundation

During the last quarter century, the American Association of Pharmaceutical Scientists (AAPS) established a



premier information network for pharmaceutical scientists around the world. Not only do programs at AAPS cater to specific professional development needs, but they help advance the contributions of the pharmaceutical sciences to global health. Now the AAPS Foundation, the new philanthropic arm of AAPS, has an even greater impact, a dimension beyond the programs that AAPS has nurtured and supported for over 25 years. The AAPS Foundation, through your generous support, will be able to enhance the opportunities for current and future generations of pharmaceutical scientists to conduct research, provide education, and leverage training. Your support of the Foundation will enable pharmaceutical scientists to go above and beyond current accomplishments, staying ahead of the curve in the rapid and constant advancement of medical and pharmaceutical sciences.

#### **AAPS Foundation Mission**

The AAPS Foundation is dedicated to the support of scientists and initiatives that advance the discovery, development, and manufacture of drugs by attracting and providing resources used to advance research, education, and training.

#### **AAPS Foundation Vision**

The AAPS Foundation seeks to empower pharmaceutical scientists and to expand and engage the interests of a future generation of scientists in a manner that positively impacts the pharmaceutical sciences and creates solutions addressing vital

needs found in the treatment of disease and the maintenance of health.

#### **AAPS Foundation Future**

The AAPS Foundation provides new mechanisms to support and impact the success of pharmaceutical scientists. Specifically, your gift to the AAPS Foundation will provide vital funding initially for three strategic priorities, including support on multiple levels of pharmaceutical research, education, and training. With your help, we can ensure success for the future of pharmaceutical scientists worldwide with new programs that fill critical needs in these areas:

- Grants and Fellowships
- Education
- Leadership Institute

#### Now Up to You

We encourage you to join us and contribute to the AAPS Foundation. AAPS is committed to the principle that 100% of your tax-deductible contribution will go toward the Foundation's programs, The operating expenses of the AAPS Foundation will be a standard part of AAPS's administrative budget.

It is more important now than ever that pharmaceutical scientists develop skills that will meet the world's evolving health challenges, 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.



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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 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.

All AAPS live webinars and archived replays are available exclusively to regular members. eSubscribers may view only archived versions after a 30 day delay. In addition, there is no longer an option for telephone dial-in; webinar audio is computer-based (voice-over-internet), requiring the use of headphones or amplified speakers.

#### March 6, 2014

Time-to-Event Analysis for the Pharmacometrician: A Focus on Evaluation of the Hazard Function

#### March 13, 2014

Building Robust Stability Trending Programs: A Case Study

March 20, 2014 (Rescheduled from October 31, 2013) Bioassay Development for Robust Use

#### March 27, 2014

Application of Process Capability Indices in the Production of Biopharmaceutical Products

For more information visit www.aaps.org/webinars

# The 2013 AAPS Annual Meeting and Exposition ePosters are now 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

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



#### **AAPS Regular Member SAVINGS**

AAPS members save, <\$xxx>at early registration. Early registration expires April 4, 2014.

#### **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 have 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.



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# 2014 AAPS National Biotechnology Conference

May 19-21, 2014 Sheraton San Diego Hotel and Marina, San Diego





#### **AAPS Regular Member SAVINGS**

AAPS members save, \$335.00 at early registration. Early registration expires April 4, 2014.

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 <a href="http://www.aaps.org/AMAwards/">http://www.aaps.org/AMAwards/</a>.



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