

AAPS Connection

American Association of Pharmaceutical Scientists

September 2012

2012 AAPS Annual Meeting and Exposition Keynote Speaker: Rebecca Skloot

Author of *The Immortal Life of Henrietta Lacks*

AAPS is pleased to announce that Rebecca Skloot will serve as the keynote speaker at the 2012 AAPS Annual Meeting and Exposition, which will take place October 14–18 in Chicago. Skloot is author of the best-selling book *The Immortal Life of Henrietta Lacks*, which took Skloot more than a decade to research and write and which more than 60 media have named the best book of 2010.



Skloot's book focuses on the life of Henrietta Lacks, better known as HeLa, whose cells were taken without her permission and became an important tool for medicine. Lacks is almost unknown, but Skloot and her book are quickly changing that.

For more information visit www.aaps.org.

AAPS 2012 Career Fair: Mark Your Calendar!



The 2012 American Association of Pharmaceutical Scientists Annual Meeting and Exposition will be held October 14–18 in Chicago. If you are an employer looking for highly qualified candidates or a job-seeker interested in available openings, be sure to register for the 2012 AAPS Career Fair, which will be held October 15–17 in conjunction with the 2012 AAPS Annual Meeting and Exposition.

The AAPS Career Fair brings together hiring companies and candidates in a highly interactive environment. Numerous employment listings will be on display through our job boards, and candidates may submit résumés onsite. Opportunities to connect with employers are plentiful, with employers conducting on-the-spot interviews during the AAPS Career Fair.

Registering with the AAPS Online Career Center will also help increase your visibility during this event. In today's technologically advanced, evolving marketplace, online job boards have become an increasingly efficient and effective way to reach highly qualified candidates.

Many hiring companies also place job postings online to reach an even broader audience. As a job-seeker, posting your résumé in advance will likely help put you one step ahead in your search.

To register with the AAPS Online Career Center, please go to careers.aaps.org.

AAPS-FDA Fifth Bioanalytical Workshop: Quantitative Bioanalytical Methods Validation and Implementation

Fall 2012
Washington, D.C

The draft Food and Drug Administration (FDA) Guidance on Bioanalytical Method Validation has the potential to have significant impact on the bioanalytical community and thereby all pharmaceutical and biotechnology companies and the contract research organizations (CROs) that support them.

Four previous conferences (1999, 2000, 2006, and 2007) between the AAPS and FDA were very successful. Starting in 1990, the first meeting established a dialogue between industry and agency, which was then enhanced in subsequent meetings.

The bioanalytical and scientific needs that intersected with regulatory compliance and patient safety were freely discussed and debated to produce best practices and influence FDA in finalizing the first guidance in 2001. The other AAPS-FDA meetings subsequent to this resulted in white papers that have served as a defacto guidance to industry.

FDA has advised the industry that the agency is revising the 2001 guidance to incorporate the recent advances in bioanalysis and will be publishing a draft sometime in 2012. This meeting is a proactive response to the above informamaion.

Goals and Objectives

- To provide a forum for open discussion between industry and FDA around FDA's 2012 draft Revision to the Bioanalytical Method Validation Guidance
- To permit science-based industry perspectives to align and harmonize around the new proposals
- To understand the implications and reasoning behind the revisions and new aspects of the guidance
- To provide industry output to FDA

For more information, visit www.aaps.org/BMV.

2012 AAPS Workshop on Predicting and Monitoring Impurities in API and Drug Products: Analytical and Regulatory Issues

October 13–14, 2012
McCormick Place, Chicago

Goals and Objectives

Stability has long been recognized as critically important in the drug development process, affecting both the safety and efficacy of drugs. The ability to rapidly predict and assess the potential for stability and safety concerns is an important part of speeding the development of innovative drug therapies. This workshop will discuss the foundational aspects of building stability into the development process to enable predictability and assurance of safety and efficacy.

Innovative methodologies for development of effective stability control strategies will be presented. The workshop will provide participants a forum to discuss a comprehensive array of topics such as stress testing, chemical stability, predictive tools, excipient issues, physical stability concerns, genotoxic degradation products, in-use stability, analytical methodologies, and lean stability options. Issues related to global filing of new API and drug products, especially those in emerging markets, will also be explored.

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

2012 AAPS Workshop on Patient-centric Drug Delivery, Product Design, and Development: Meeting Requirements in Future Healthcare

October 13–14, 2012
McCormick Place, Chicago

Goals and Objectives

With the increasing focus on the overall therapeutic outcomes of a drug therapy, including patient's quality of life and patient populations with different needs, patient-centricity in drug product development, design, and manufacturing is becoming of prime importance. This accounts for specific age groups, like pediatrics and geriatrics, as well as patient populations in specific disease areas, like rheumatoid arthritis or Parkinson's disease, and the emerging concept of personalized medicine, due in part to the increase of diagnostics. With the increasing complexity of drug therapy, patient-centric drug delivery will play a key role in medication adherence and contribute substantially to the therapeutic outcome. Patient-centric drug product development and design is yet a new and challenging area that might impact the entire product life cycle and future drug development programs.

The scientific and technology advancements of the past decade have created a good base for patient-centric drug product development, design, manufacturing, and distribution, which will be discussed in this workshop. Workshop participants should leave the workshop with a clear understanding on the different aspects of patient-centric drug products and gain insight on the latest science and regulations.

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

2012 AAPS Workshop on 21st Century Oral Bioperformance Prediction and Testing

October 13–14, 2012
McCormick Place, Chicago

Goals and Objectives

The ability to predict the oral bioperformance of a formulation from a laboratory-based dissolution test is a long-term goal of the pharmaceutical scientist. The oral bioperformance of formulations, however, still remains a partially empirical art or mystery with dissolution testing at its core.

The 21st century is starting off differently. A more thorough and integrated view of the dosage form and how it interacts with the gastrointestinal tract is required.

Specific goals of this workshop are to present new ideas and approaches to the development of more physiologically relevant tests and approaches that accurately reflect *in vivo* oral bioperformance, including

- physiological factors influencing oral dosage form performance,
- key physicochemical principles impacting dissolution and bioavailability,
- dosage form design considerations,
- dissolution testing methodologies, and
- predictive tools of oral bioperformance.

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

Upcoming AAPS Meetings

Log onto www.aaps.org/meetings for details

- October 13-14, 2012
2012 AAPS Workshop on Predicting and Monitoring Impurities in API and Drug Products: Analytical and Regulatory Issues
McCormick Place, Chicago
- October 13-14, 2012
2012 AAPS Workshop on Patient-centric Drug Delivery, Product Design, and Development: Meeting Requirements in Future Healthcare
McCormick Place, Chicago
- October 13-14, 2012
2012 AAPS Workshop on 21st Century Oral Bioperformance Prediction and Testing
McCormick Place, Chicago
- October 14-18, 2012
2012 AAPS Annual Meeting and Exposition
McCormick Place, Chicago
- March 4-6, 2013
48th AAPS Annual Arden Conference: Pharmaceutical Materials Science and Engineering — Mechanical Characterization and Predictive Tools for Rapid Drug Product Development
USP, Rockville, Md.
- May 20-22, 2013
2013 AAPS National Biotechnology Conference
Sheraton San Diego and Marina, San Diego

