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AAPS Connection

American Association of Pharmaceutical Scientists November 2012

Be a Part of AAPS on LinkedIn

Over 14,300 professionals in the pharmaceutical sciences industry have joined the conversation on the official AAPS LinkedIn group. AAPS members and non-members from all over the world are able to interact with their peers and discuss the most prominent topics in the field.

Topics of conversation include white papers from the latest scientific meetings, reactions to FDA and EMA guidances, and break-through methods targeted at treating the world's most challenging diseases. The AAPS LinkedIn group provides a dynamic, online social avenue for you to have your voice heard on issues important to your work and to expand your professional network.

Members of the LinkedIn group can also engage in more targeted discussion by joining one or more of the 24 subgroups comprised from AAPS sections, focus groups, and discussion groups.

Join today to begin sharing your thoughts on the pharmaceutical sciences in a new and exciting way at **http://linkd.in/osnmRO**.

Tune In to the AAPS Social Media Channels: Facebook, Tweeter, LinkedIn, and YouTube

- Connect with colleagues and friends
- Receive the latest AAPS news and offerings
- Find job opportunities
- Discuss the latest discoveries and breakthroughs in the field
- Tweet from meetings and conferences
- Submit your AAPS-related photos and videos

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

December 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 the 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 de facto guidance to industry.

The 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 some time in 2012. This meeting is a proactive response to the above information.

Published online: 29 September 2012

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.**

48th Annual AAPS Arden Conference: Pharmaceutical Materials Science and Engineering—Mechanical Characterization and Predictive Tools for Rapid Drug Product Development

March 4–6, 2013
USP Meeting Center, Rockville, MD

Summary/Description

Over the last decade, pharmaceutical materials science has established itself as the foundation for QbD product development, and significant advances in the application of materials science have been made to understand the funtionality of excipients and API and how they influence the performance of formulations. Mathematical modeling can lend considerable insight and predictive ability to aid in development of difficult formulations, e.g., high drug loading, complex tablet shapes, or multi-layer tablets. Both qualitative insight as well as quantitative modeling and prediction are possible when accurate material properties are known and their combined influence in a multicomponent formulation can be understood theoretically and empirically.

The implementation of QbD in pharmaceutical tablet product development has been largely relying on statistical approach, i.e., design of experiments (DOE). Although useful in identifying a design space, DOE typically is resource intensive and does not provide mechanistic understanding of the performance of a formulation. A seamless integration between materials science and DOE is a key for truly achieving QbD in product development.

In this conference, key materials science and engineering principles applicable to tablet design will be covered, e.g., relationship between mechanical properties and compaction behavior, crystal and particle engineering for superior tableting performance, and powder flow measurement. This conference will provide formulation scientists both basic knowledge in materials science and advanced techniques that can be used to facilitate the design of tablet product.

Goals and Objectives

- Review fundamental mechanical properties of pharmaceutical solids and the methods to measure them.
- Review theoretical modeling of particle mixing and simulation tools of powder compaction.
- Apply mechanical properties in drug product development following quality by design (QbD) approach.

For more information visit
www.aaps.org/ArdenConference2013.

AAPS Workshop on Drug Transporters in ADME: From the Bench to the Bedside

March 17–20, 2013
Bethesda North Marriott Conference Center, Bethesda, MD

The AAPS Workshop on Drug Transporters 2013 will deliver cutting-edge science in a focused and state-of-the-art meeting.

Key areas of focus will include

- the impact of drug molecules on physiological processes mediated by transporters,
- regulation of transporter expression and function in health and disease,
- state-of-the-art sessions on (i) effective transporter assays and (ii) emerging transporters and transporter sciences,
- the importance of understanding intracellular concentrations of drug and metabolites,
- transporters in translational medicine, and
- FDA-led session on regulatory perspectives on transporter-mediated DDI evaluation during drug development followed by an industry case study discussion forum.

For more information visit
www.aaps.org/Transporters13.

Upcoming AAPS Meetings

Log onto **www.aaps.org/meetings** for details

- **December 2012**

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

Washington D.C. metro area

- **March 4-6, 2013**

48th Annual AAPS Arden Conference: Pharmaceutical Materials Science and Engineering—Mechanical Characterization and Predictive Tools for Rapid Drug Product Development

USP Meeting Center, Rockville, MD

- **March 17-20, 2013**

AAPS Workshop on Drug Transporters in ADME: From the Bench to the Bedside Conference

Bethesda North Marriott Conference Center
Bethesda, MD

- **May 18-19, 2013**

AAPS Workshop on Bioanalytical Considerations for Antibody-Drug Conjugate Development: From Discovery to Post-approval Commitments

Sheraton San Diego Hotel and Marina, San Diego, CA

- **May 18-19, 2013**

AAPS Workshop onParenteral Dosage Forms Containing Biologic Drugs—Basics and 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

- **November 10-14 , 2013**

2013 AAPS Annual Meeting and Exposition

Henry B. Gonzalez Convention Center, San Antonio, TX