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AAPS Connection

American Association of Pharmaceutical Scientists February 2013

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 Meetings Center
Rockville, MD

Overview

Over the last decade, pharmaceutical materials science has established itself as the foundation for Quality-by-Design (QBD) product development, and significant advances in the application of materials science have been made to understand the functionality of excipients and active pharmaceutical ingredients 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 multilayer 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 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, powder flow measurement. This conference will provide formulation scientists with 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 a QbD approach.

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

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

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

Background

Drug transporter-related research has grown exponentially in the last few years driven particularly by the emergence of the U.S. Food and Drug Administration (FDA) critical path transporter white paper and subsequent draft guidance from the FDA, European Medicines Agency, and Prescription Drug Marketing Act. Although considerable progress has been made over the past 15 years, the field of drug transport continues to evolve, particularly with respect to clinical translation of in vitro/preclinical data (*Nat Rev Drug Discovery, 2010*), understanding of systemic/tissue drug exposure implications, toxicity/disease pathogenesis, and the interplay between transporters and metabolism.

Goals and Objectives

The 2013 AAPS Workshop on Drug Transporters 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 effective transporter assays and emerging transporters and transporter sciences;
- the importance of understanding intracellular concentrations of drug and metabolites;
- transporters in translational medicine;
- an FDA-led session on regulatory perspectives on transporter-mediated drug-drug development evaluation during drug development, followed by an industry case study discussion forum.concentrations of drug and metabolites;
- transporters in translational medicine.

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

AAPS Workshop on Biorelevant In Vitro Performance Testing of Orally Administered Dosage Forms

March 18–19, 2013
Bethesda North Marriott Conference Center
Bethesda, MD

Summary/Description

Biorelevant in vitro performance testing of orally administered dosage forms has become an important tool for the assessment of drug product in vivo behavior. Biorelevant dissolution/release testing is useful for the evaluation of formulation and food effects on plasma levels and intralumenal dosage form performance after administration of oral drug products. Biorelevant testing has been utilized to decrease the number of in vivo studies required during the drug development process and to mitigate the risk related to in vivo bioequivalence studies. Data on the lumenal environment, its simulation and biorelevant in vitro performance testing methodologies that can be applied during product development will be presented and discussed. Case studies from industry will describe the application of biorelevant testing methodologies for formulation design, selection and development. Presentations from the FDA and EMA will discuss the use of biorelevant testing in the evaluation of a drug's performance.

Goals and Objectives

- Present the lumenal environment and its simulation and discuss advantages and issues of current methodologies for evaluating the intralumenal performance of orally administered drug products and its impact on plasma levels.
- Using case studies, discuss the use of biorelevant media for formulation selection and optimization during product development.
- Using case studies, discuss the review and utility of biorelevant dissolution studies to assess product performance attributes.
- Present and discuss the ability of current biorelevant dissolution methods to predict in vivo performance to generate successful in vitro–in vivo correlations (IVIVC) for oral formulations.
- Discuss the efforts to improve the in vivo predictability of biorelevant tests.
- Summarize current thinking of regulatory agencies on biorelevant performance testing.
- Provide opportunities to participants to interact with workshop speakers and others in panel discussions.
- Prepare a workshop summary report (a white paper) that can serve as an industry reference regarding the applications of biorelevant in vitro performance testing during product design and development.

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

Upcoming AAPS Meetings

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

- **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 Meetings 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.
- **March 18-19, 2013**
  AAPS Workshop on Biorelevant In Vitro Performance Testing of Orally Administered Dosage Forms
  Bethesda North Marriott Conference Center Bethesda, MD.
- **May 18, 2013**
  AAPS Workshop on Bioanalysis of Antibody Drug Conjugates
  Sheraton San Diego Hotel and Marina, San Diego
- **May 18-19, 2013**
  AAPS Workshop on Biologic Drugs: Recent Developments 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