AAPS Update

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January 2008

2008 Arden Conference: Particle and Powder Technologies for Solid Dosage Forms

February 3–8, 2008
The Thayer Hotel
West Point, NY

Background

This program is designed to provide fundamental understanding and latest technologies on particle and powder for pharmaceutical scientists engaged in solid dosage formulations. It will also give an overview of fundamental principles for particle and powders. Detailed presentations will cover nanoparticles and particle engineering for novel drug delivery, as well as characterization and modeling of powder flow and powder compaction for traditional solid dosage forms. Each topic will include lectures from experts in the field followed by in-depth group discussion and case studies in which participants are eager to participate. Attendees are encouraged to bring examples of current problems from their laboratories to share with participants, as well as past successes and failures.

Goals and Objectives

This program will provide fundamental understanding and latest update on particle and powder technologies for pharmaceutical scientists engaged in solid dosage formulations. Day one of the program will focus on particles and particle engineering in terms of formation, chemical and physical characterization. Day two is designed to provide in-depth review on simulation and characterization of powder flow, content uniformity, optimization of pharmaceutical products and processes. Day three will review characterization of granulation, mechanism and simulation of powder compaction. Day four will cover enabling technologies for particle and powders, such as supercritical fluid processing, self-assembled macromolecular nanoshells, nanosuspensions particle toxicology and the final day will be devoted to QbD with engineering precision from both industrial and regulatory perspectives.

Case studies and workshops will also be provided everyday to engage participation from the attendees.

For more information, please visit
www.aapspharmaceutica.com/ardenhouse

AAPS Workshop on Current Topics in GLP Bioanalysis: Assay Reproducibility for Incurred Samples — Implications of Crystal City Recommendations

February 7–8, 2008
Hyatt Regency Crystal City
Arlington, VA

Background

The FDA has been particularly concerned recently about adequately establishing the specific method validation parameter assay reproducibility for quantitative methods that support both pharmacokinetics and bioequivalence. The Division of Scientific Investigations reports that

- During inspections the investigators found large inconsistencies between original and repeated results from acceptable runs;
- During validation inter-day precision and accuracy was less than 6% but original and repeated Cmax values differed by 30–80%;
- In an effort to verify the PK and BE data to support the FDA review process DSI has focused on data integrity;
- They suggest pursuing a moderate approach to testing paradigms;
- They suggest that incurred sample re-analysis is a reasonable step to document reproducibility.

Goals and Objectives

This workshop will present a forum for discussing what various companies and laboratories have done to implement the recommendations of the Crystal City III paper on assay reproducibility for both small and large molecules. Speakers will give an overview of various practices and the breakout sessions will allow the sharing and compiling of various techniques that have been used since the issuance of the paper. The workshop will distribute recommendations for implementing the assessment of reproducibility in incurred samples. This workshop will allow practitioners to gather, share information on their strategies to deal with the issues raised by the Crystal City III white paper, and learn how other groups and companies are handling this proposal.

For more information, please visit
www.aapspharmaceutica.com/glp

Continued

2008 AAPS National Biotechnology Conference

June 22–25, 2008
Metro Toronto Convention Centre
Toronto, Canada

At the 2008 AAPS National Biotechnology Conference attendees can enjoy a week of pharmaceutical biotechnology programming.

This conference will also feature a fully operational Career Center, including job postings, a résumé database, and interview facilities. Additionally, a full Exposition Hall will be hosting major companies. The call for papers submission has been released; check the NBC website, **www.aapspharmaceutica.com/nationalbiotech**, for further details regarding topics and submission deadlines.

AAPS Workshop on Drug Discovery Strategies and Critical Issues for Clinical Candidates

Spring 2008
Location TBD

Goals and Objectives

The Strategies for Preclinical Drug Discovery and Delivery Interface Workshop is intended to introduce those people who are less familiar with pre-clinical evaluations, which lead to drug-like molecules, an opportunity to get introduced to those disciplines prior to the main meeting.

The discovery and development of quality drug leads and clinical candidates, which will eventually become novel drugs to address un-met medical needs, remains a significant challenge to pharmaceutical scientists. It is increasingly clear that integration of drug-like properties into the early stages of drug discovery is advantageous to efficient and effective drug development. This meeting will examine the critical issues of compound selection and quality, safety, pharmacokinetics and formulation.

For more information, please visit
www.aapspharmaceutica.com/meetings

AAPS Workshop on Role of Dissolution on QbD and Drug Product Life Cycle

Spring 2008
Washington, DC Metro Area

Dissolution testing continues to be one of the critical tests that support drug and product development through commercialization. There is a need to better understand the objectives behind the dissolution test and the role it plays during different stages of product development. QbD concepts and science-based risk assessment (ICHQ8-10) require industry and regulatory agencies to re-examine the current approaches to dissolution method develop-ment. In this emerging context of QbD, dissolution may serve as a more important role in some cases; while in others, if other critical parameters are more relevant, dissolution may not be needed as a test. This workshop is aimed at exploring the dissolution test in QbD environment in the 21st century.

Goals and Objectives

At this workshop we will:

- explore Quality by Design (QbD) as it applies to dissolution testing;
- demonstrate why dissolution testing methods and specifications are clinically relevant (*IVIVC/IVIVR*);
- explain the role of dissolution in assessing drug release from novel and modified release dosage forms;
- show the relevance of dissolution through various stages of product development;
- highlight other diagnostics which may complement the dissolution test; and
- illustrate recent advances in dissolution technology.

For more information, please visit
www.aapspharmaceutica.com/meetings

Upcoming AAPS Meetings

Log onto **www.aapspharmaceutica.com/meetings** for details.

▶February 3-8, 2008
2008 Arden Conference: Particle and Powder Technologies for Solid Dosage Forms
The Thayer Hotel, West Point, NY

▶February 7-8, 2008
AAPS Workshop on Current Topics in GLP Bioanalysis: Assay Reproducibility for Incurred Samples—Implications of Crystal City Recommendations
Co-sponsored with the AAPS Contract Research Organization Focus Group (CRO), and the AAPS Ligand Binding Assays Bioanalytical Focus Group
Hyatt Regency Crystal City, Arlington, VA

▶Spring 2008
AAPS Workshop on Drug Discovery Strategies and Critical Issues for Clinical Candidates
TBD

▶Spring 2008
AAPS Workshop on Role of Dissolution on QbD and Drug Product Life Cycle
Washington, DC Metro Area

▶June 22-25, 2008
2008 AAPS National Biotechnology Conference
Metro Toronto Convention Centre, Toronto, Canada

▶November 16-20, 2008
2008 AAPS Annual Meeting and Exposition
Georgia World Congress Center, Atlanta, GA

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