

AAPS Update

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December 2007

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 C_{max} 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 CrystalCity 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 compile and 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/meetings

Continued

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2008 AAPS National Biotechnology Conference

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

AAPS is pleased to announce that the 2008 AAPS National Biotechnology Conference will take place June 22–25, 2008, at the Metro Toronto Convention Centre in Toronto,

Canada. Attendees can enjoy a week of pharmaceutical biotechnology programming at the 2008 AAPS National Biotechnology Conference.

Participants can join in three days of conference programming consisting of a Plenary Session, Symposia, Roundtables and Sunrise Sessions. Some of the sessions that encompass the full program include Plant-based Biologics, Storage and Shipment of Biologics, Quality by Design, Inhibitors, Immunogenicity and Gene Therapy. The conference concludes by offering attendees the opportunity to attend one of four AAPS sponsored short courses, all of which are certain to engage you interest.

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.

If you have any questions about the program or registration procedures, please contact the AAPS office, (703) 243-2800, or, you can send an email to meetings@aaps.org.

The 2008 AAPS National Biotechnology Conference is designed to provide a complete educational event allowing each and every attendee the ability to customize their experience. Biotechnology is the cutting edge and AAPS is there with you.

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
 Hyatt Regency Crystal City, Arlington, VA

▶ 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

