

# AAPS Annual Meeting Event Descriptions

**Short Course:** A 7½-hour course on a specific topic held pre or post meeting. Short courses are tutorial and interactive. Attendance is limited to 85 to ensure an interactive environment. All speakers are invited by the event organizer. Number of speakers should be limited to 3-6 per day. Speakers are required to provide handouts of their presentation for distribution to the attendees. Speakers are not required to submit an abstract, but must provide a biography. A sample submission can be found below:

Session Title: Recent Advances in Drug Substance and Drug Product CMC Information Requirements

Description/Purpose/Impact: This proposed short course is targeted to better understand current drug substance and drug product requirements that are expected in an IND, NDA and/or CTD submissions for marketing authorization. Presentations will include current "recommendations" on drug substance and drug product CMC information, per the draft FDA drug substance (forthcoming) and drug product Guidances, along with industry and FDA perspectives. Overall, this short course should help in gaining alignment among industry and FDA in our efforts to streamline drug development and accelerate review times.

A draft Guidance on Drug Substance Chemistry, Manufacturing and Controls (DS-CMC) Information is expected during 2003. For drug products, FDA has issued a draft Guidance on Drug Product Chemistry, Manufacturing and Controls (DP-CMC) Information that, when finalized, will be the primary content Guidance for NDA and ANDA applications submitted in the Common Technical Document (CTD) format. Several companies and PhRMA commented on the extent of information expected in Quality sections including pharmaceutical development, critical process controls, batch analyses data, executed manufacturing batch documentation, control of excipients and drug product, characterization of impurities, and justification of specifications.

The objective of this proposed short course would be for scientists to understand FDA's expectations and gain alignment on the value of presenting any new drug substance and drug product CMC information, as recommended in the FDA draft Guidances. Overall, this short course should help in gaining alignment among industry and FDA in our efforts to streamline drug development and accelerate review times.

This proposed short course is targeted to better understand drug substance and drug product information that need to be obtained prior to submission of an IND and an NDA for marketing authorization. Comprehensive information on drug substance and drug product based on scientific development from an industry perspective and regulatory requirements from an FDA perspective will be presented.

Proposed Speaker Drug Substance: Application of newly proposed CMC requirements for NMEs, Dr. Chuck Hoiberg (Pfizer)

Proposed Speaker Drug Substance: "Proposed" drug substance CMC requirements, Speaker TBD

Proposed Speaker Drug Product: Will the "newly" proposed CMC requirements streamline submissions? Dr. Sanjay Sehgal (P&G Pharmaceuticals)

Proposed Speaker: Recent advances in drug substance and drug product characterization, Mr. Richard Poska (Abbott Labs.)

Proposed Speaker: Drug Product: "Proposed" drug product CMC requirements, Speaker TBD

Proposed Speaker: Developing DP Stability Strategies for Global Submissions, Dr. Nirdosh Jagota (Wyeth)

Proposed Speaker: Pre And Post-Approval Manufacturing Changes: Do They Need To Be Qualified By BA/BE Studies? Vijay Tammara (Wyeth)

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**Symposia:** A 2½-hour program on a specific topic with 2-3 invited speakers and 1-2 speakers selected from contributed papers, for a total of 5 speakers or 4 speakers with a panel discussion. Speakers' presentations will be a maximum of 25 minutes and 5 minutes Q&A. Speakers are invited by the event organizer. Speakers' abstracts are not screened and submitted separately from the contributed papers process. AAPS staff will request all speaker biographies and abstracts. A sample submission can be found below:

Session Title: Building Quality During Pharmaceutical Manufacturing: Regulatory CMC

Perspective Description/Purpose/Impact: In August 2002, FDA launched an initiative to improve the way drug product quality is regulated "Pharmaceutical cGMPs for the 21st Century: A Risk-Based Approach". This initiative by the FDA represents the first "major" reassessment of the good manufacturing practices (GMPs) since the last major re-write of CFR 210/211. This initiative is based on the principle that unleashing analytical technologies is the most effective way to manage risk and streamline the quality regulatory process. Consequently, this initiative has a broad reach that extends across the drug quality regulatory spectrum.

The objective of this proposed symposium is to further develop an understanding of the progress made by FDA in defining the "risk-based scientific approach" to GMPs, drug review, and drug approval processes. In addition, industry will provide their perspective on how these initiatives, including the application of process analytical technologies, have helped build quality during pharmaceutical manufacturing and resulted in streamlining drug development processes.

The proposed symposium is intended to provide an understanding of the progress made by FDA in defining the "risk-based scientific approach" to GMPs, drug review, and drug approval processes. Industry will provide their perspective on how these initiatives, including the application of PAT, have helped build quality during pharmaceutical manufacturing and resulted in streamlining drug development processes. There will at least one presentation from the FDA and three presentations from industry. The presentations will be followed by extensive panel discussions.

Proposed Speaker: Dr. Alton D. Johnson, Pfizer Inc. Title: Pharmaceutical Manufacturing: Impact of PATs in Building Product Quality

Proposed Speaker: Mr. William Skolfield, Procter & Gamble Pharma. Inc. Title: Role of Quality Assurance in Risk Management for PAI Readiness and Product Commercialization

Proposed Speaker: Dr. Nirdosh Jagota, Wyeth Title: Pharmaceutical Manufacturing: Regulatory CMC Considerations

Proposed Speaker: Dr. Ajaz Hussain, FDA Title: FDA Update "Pharmaceutical cGMPs for the 21st Century: Risk-Based Approach"

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**Roundtable:** A 2-hour program limited to a maximum of 85 attendees. This program is designed for small intimate groups and open discussions moderated by 1-2 people. Speakers for Roundtables are invited and should be limited to 1-3. Speakers are invited by the event organizer. Speaker abstracts and biographies are not required. A sample submission can be found below:

Session Title: Counterfeit Drug Initiative by the FDA - How can Industry Support!

Description/Purpose/Impact: Earlier this year, FDA Commissioner Mark McClellan unveiled the Agency's "Counterfeit Drug Initiative". FDA is identifying best practices to regulate wholesalers that market pharmaceutical products. FDA has set up a task force to look at agency's current plans to implement its final pedigree rule, as required under the Prescription Drug Marketing Act.

The task force will examine the use of new technologies to make counterfeiting drugs extremely difficult. The use of new technologies, such as radio frequency identification, counterfeit-resistant packaging, chemical taggants and other technologies will be studied. Pharmaceutical industry can play a major role in facilitating FDA's counterfeit drug initiative. In June 2004, PhRMA announced its own five-point program for combating counterfeiting of pharmaceutical products.

The proposed round table discussion is intended to discuss ways for combating counterfeiting and how industry can help facilitate FDA's initiative. There will at least one presentation from the FDA and one from industry.

Proposed Speaker: Industry speaker to be determined

Proposed Speaker: FDA speaker to be determined

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**Open Forum:** A 3½-hour program outside of core programming which requires an additional registration fee. These sessions are sponsored by a specific section at their discretion. There is no requirement for the number of speakers and session format. Abstracts and biographies not required.

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**Poster Podium:** A 2½-hour program whereby up to nine (9) contributed abstracts are selected and screened by the section screeners. Authors are asked to present their paper at the podium. Their paper will be displayed on a poster board inside the meeting room. All papers will address a specific topic. Authors will not be reimbursed for travel expenses and must pay a registration fee to attend the meeting.

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**Sunrise Session:** A 1-hour, 15 minute program whereby a lecture on a specific emerging scientific topic is given. The education lectures are held outside of core programming hours (7:00am – 8:15am). A sample submission can be found below:

Session Title: Sunrise School Overview of Drug Transporters in the Liver

Description: An understanding of hepatic transport is essential in our understanding of hepatic clearance and hepatobiliary elimination. Transporters expressed in the basolateral membrane of hepatocytes mediate the uptake of drugs and metabolites from blood into liver. Transporters in the canalicular membrane of hepatocytes belong to the ATP-binding cassette family and serve to pump drugs and metabolites against a steep concentration gradient from liver to bile. Hepatic transporter proteins are subject to genetic polymorphisms, drug-drug interactions, and drug- and disease-induced alterations of expression levels. These interactions and alterations may profoundly influence the fate of drugs. This overview is designed to provide a comprehensive description of hepatic transporters, significant drug substrates for these transporters, drug-drug interactions, and the variability in transporters due to genetic variability, gender, species, as well as the influence of disease on transport. Regulation of transport will be briefly introduced, as a second Sunrise School session is proposed to address this topic. The incorporation of transport into hepatic clearance models will also be discussed. Educational Goals: 1. The student will be familiar with the major organic anion and organic cation transporters

present in the basolateral (sinusoidal) and canalicular membranes of the liver<sup>2</sup>. The student will have an understanding of the influence of genetic variability, gender, species and disease on hepatic transporters.<sup>3</sup> The student will be able to provide clinical examples of drug-drug interactions involving hepatic transport.

Proposed Speaker: Marilyn Morris, University at Buffalo – Organic Cation Transporters

Proposed Speaker: K. Sandy Pang, University of Toronto – Organic Anion Transporters