



U.S. Pharmacopeia
The Standard of QualitySM

USP Annual Scientific Meeting 2006

Excipients

Track Manager:

Catherine Sheehan, Director, Excipients, USP

Track Description:

Due to recent advances in drug manufacturing, formulation, and delivery vehicles, excipients have assumed a significant role in the pharmaceutical industry. They can no longer be viewed as inactive ingredients. Careful selection and knowledge of the physical and chemical properties of an excipient can have a major impact on the final dosage form in today's global environment. This track will focus on excipient performance-related issues that may affect performance of the finished dosage form, and recent concerns regarding additives and impurities in excipients. It will also focus on recent advances in the development of new excipient technologies as well as drug excipient interactions. The track presents an opportunity to interact with USP experts and staff, FDA, industry, and academic experts and discuss the science of excipients and related issues.

The track should be of interest to finished drug and pharmaceutical excipient manufacturers; anyone involved in pharmaceutical research and development, quality control, quality assurance, and procurement; and middle and upper management leaders involved in setting objectives and goals for the pharmaceutical industry now and in the future.

Planning Committee:

- Gregory E. Amidon, Ph.D., Chair, Excipients General Chapters Expert Committee and Research Fellow, Pfizer, Inc.
- Lawrence H. Block, Ph.D., Chair, Excipients Monograph 2 Expert Committee and Professor of Pharmaceutics, Duquesne University
- Harry G. Brittain, Ph.D., Member, Excipients General Chapters Expert Committee and Director, Center for Pharmaceutical Physics
- Zak T. Chowhan, Ph.D., Chair, Excipients Monograph 1 Expert Committee and Independent Pharmaceutical Development Consultant
- Ashok V. Katdare, Ph.D., Vice Chair, Excipients Monograph 1 Expert Committee and Head, Formulation Development, Technology Transfer and CMC Management, NeuroMolecular Pharmaceuticals
- Garnet E. Peck, Ph.D., Member, Excipient: General Chapters and Professor Emeritus, Purdue University
- David R. Schoneker, Colorcon, IPEC-Americas
- Rajendra Uppoor, R.Ph., M.Pharm., Ph.D., Food and Drug Administration

Speakers:

- Moji Christianah Adeyeye, Ph.D. Professor of Pharmaceutics and Pharmaceutical Technology, School of Pharmacy, Duquesne University
- Gregory E. Amidon, Ph.D., Chair, Excipients General Chapters Expert Committee and Research Fellow, Pfizer, Inc.
- Lawrence H. Block, Ph.D., Chair, Excipients Monograph 2 Expert Committee and Professor, Division of Pharmaceutical Sciences, Mylan School of Pharmacy, Duquesne University
- Harry G. Brittain, Ph.D., Member, Excipients General Chapters Expert Committee and Institute Director, Center for Pharmaceutical Physics
- Zak T. Chowhan, Ph.D., Chair, Excipients Monograph 1 Expert Committee and Independent Pharmaceutical Development Consultant
- Hendrik De Jong, Ph.D., Vice-chair, International Pharmaceutical Excipients Council – Europe (IPEC)
- Ashok V. Katdare, Ph.D., Vice Chair, Excipients Monograph 1 Expert Committee and Head, Formulation Development, Technology Transfer and CMC Management, NeuroMolecular Pharmaceuticals
- Bogdan Kurtyka, Ph.D., Independent Consultant
- Richard C. Moreton Ph.D. Vice-Chair, Excipients Monograph 2 Expert Committee and Vice President, Pharmaceutical Sciences Idenix Pharmaceuticals, Inc
- David R. Schoneker, Member, USP Convention, Director of Global Regulatory Affairs, Colorcon, and Chair-Elect, International Pharmaceutical Excipients Council (IPEC)–Americas
- Rajendra Uppoor, R.Ph., M.Pharm., Ph.D., Food and Drug Administration

SESSION I & II Performance Related Tests in Excipients

Wednesday, September 27, 2006 (1:00–3:00 p.m. and 3:30–5:30 p.m.)

Session leader: Gregory E. Amidon, Ph.D.

Session speaker(s): Gregory E. Amidon, Ph.D.
Hendrik De Jong, Ph.D.
Rajendra Uppoor, R.Ph., M.Pharm., Ph.D.
Richard C. Moreton, Ph.D.

Session format: Roundtable discussion

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Session description: The first speaker will provide a USP Compendial perspective highlighting the current work of USP Excipients General Chapter Expert Committee. He will follow-up on the key findings of the USP Performance testing survey from USP's 2005 Annual Scientific Meeting as well as USP's plan to publish a stimulus article describing their work on a General Information Chapter for excipient-performance testing. The second speaker will cover the Ph. Eur's Functionality –related characteristics (FRCs).

Pharmaceutical excipients play a critical role as components in almost all drug products that patients use or consume to maintain their health, or treat illnesses. Excipients with desirable physical and chemical properties are scientifically chosen for use in the formulation of drug products, based on the properties of active pharmaceutical ingredient(s), finished end-product drug dosage form or delivery system, route of administration, and the manufacturing processes used to make them. Tests performed on excipients to determine their suitability for intended use are part of the "Quality by Design" approach that should be employed in drug product development, current and proposed tests, along with a few case studies, will be presented and discussed during this session.

SESSION III **Additives and Impurities in Excipients**
Thursday, September 28, 2006 (8:00 a.m.–12:00 noon)

Session leader: Ashok V. Katdare, Ph.D.

Session speaker(s): Ashok V. Katdare, Ph.D.
David R. Schoneker
Richard C. Moreton Ph.D.

Session format: Roundtable discussion

Session description: This session will provide an opportunity to discuss the current compendial/industry perspectives regarding additives and impurities in excipients, how harmonization of excipient monographs maybe impacted by a lack of a harmonized definition for additives in excipients and key concerns relating to impurities in excipients.

SESSION IV **Development of New Excipient Technologies**
Thursday, September 28, 2006 (1:30 p.m.–5:30 p.m)

Session leader: Zak T. Chowhan, Ph.D.

Session speaker(s): Zak T. Chowhan, Ph.D.
Lawrence H. Block, Ph.D.
Bogdan Kurtyka, Ph.D.
Harry G. Brittain, Ph.D.

Session format: Roundtable discussion

Session description: Current standards may not adequately characterize macromolecular or polymeric excipients. As part of USP's ongoing effort to define these materials and decrease the likelihood of excipient inequivalence, new test methodologies need to be developed and utilized. This first and second speaker will provide an overview of *emerging excipient characterization technologies*. Emphasis will be placed on chromatographic and rheological methods that will facilitate this objective. An overview of the USP's expert committees' efforts to that end will be presented. Anticipated revisions to the current USP chapter on viscosity <911> and the development of new USP chapters on non-Newtonian rheology <912> and on viscoelasticity <913> are expected to provide additional guidance for excipient manufacturers and users. The third speaker will provide an overview on NIR technologies as it applies to the excipient industry. The fourth speaker will provide an overview on Raman Spectroscopy and the USP General Information In-Process Revision Chapter <1120> Raman Spectroscopy *PF 32(4)*.

SESSION V **Drug/Excipient Interactions**
Friday, September 29, 2006 **(8:30 a.m. –10:30 a.m.)**

Session leader: Harry G. Brittain, Ph.D. Excipient General Chapter member

Session speaker(s): Harry G. Brittain, Ph.D.
 Moji Christianah Adeyeye, Ph.D.

Session format: Roundtable discussion

Session description: The first speaker will cover the types of physical and chemical reactions that would be ordinarily encountered between drugs and excipients. The second speaker will cover methods for the study of such reactions. After the break, the speakers will lead a discussion on the scope of topics covered in the lectures, as well as responding to questions.