AAPS Update

AAPS—YOUR FORMULA FOR SUCCESS!

July 2006

AAPS Workshop on Real World Applications of PAT and QbD in Drug Process Development and Approval Workshop

September 11-12, 2006
Hyatt Regency Crystal City, Crystal City, VA

Goals and Objectives

The Food and Drug Administration took a proactive approach to bring a scientific and risk-based framework founded on pharmaceutical process understanding, which is essential for prediction of product quality attributes. As a result of this proactive approach, PAT and QbD initiatives gained momentum amongst the pharmaceutical scientists. However, there seems to be little clarity on how to implement the concepts of PAT and QbD in real world applications, to get drug applications approved by the agency. Although many events (in the form of symposiums and workshops, etc) has been organized to address these issues, we believe none of the programs were directed at showing case examples of PAT and QbD in new drug applications and the feedback for streamlining the process. Industry is eager to understand the risk/benefits and specially return on investments by applying PAT and QbD. This workshop is geared to provide discussion on these topics.

For more information and to register, please visit **www.aapspharmaceutica.com/meetings**

AAPS Workshop on Challenges in Developing Fixed-dose Combination Oral Solid Dose Products

September 13-14, 2006
Hyatt Regency Crystal City, Crystal City, VA

Goals and Objectives

Combination products are becoming increasingly important, both as new products and as line extensions of approved products for synergistic therapeutic effects and/or to improve patient compliance. Oral solid dosage form comprises the vast majority of pharmaceutical dosage forms. Developing combination oral solid dose products presents a set of unique challenges arising from stability, process development and mechanical properties of the constituents. Given the growing number of combination products in development pipelines, and the meager amount of published information on the challenges in developing these products, there is a need for a forum for elucidating and discussing these challenges and means to address them.

- To provide an in-depth discussion of the formula tion, process development, and stability challenges in developing fixed-dose combination products of oral solid dosage forms, both as new products or as line extensions of approved products
- To discuss approaches for addressing the complexities in co-formulating chemically incompatible drugs, and drugs with different mechanical proper ties in a single unit dose, and the associated processing and biopharmaceutic challenges with case studies from industry
- Discuss registration of combination products with industry and regulatory perspective
- Present marketing and intellectual property considerations in developing combination products,/li>
- The objective of the workshop is to provide a comprehensive overview of the challenges in developing and registering combination products and practical approaches in addressing some of the formulation and process development challenges.

For more information and to register, please visit **www.aapspharmaceutica.com/meetings**

Plan Now for the 2006 AAPS Annual Meeting and Exposition

Plan ahead to join over 8,500 pharmaceutical scientists from every corner of the globe who will be promoting breakthrough research and technologies, networking with colleagues, and improving their professional edge at the 2006 AAPS Annual Meeting and Exposition, October 29 - November 2, 2006 at the Henry B. Gonzalez Convention Center, San Antonio, TX. More than 550 companies are expected to showcase the latest equipment, technical developments, publications and other services for the pharmaceutical scientist. Find both new and current suppliers of the equipment, services and techniques you need for your most pressing needs. An Exhibit Guide will be available on site for all attendees and will feature detailed descriptions of exhibiting company's contact information, products and services, plus an index of the companies by product category. This guide to the Exposition will also serve as a valuable reference after the meeting.
Visit **www.aapspharmaceutica.com** for details.

Continued

2nd Joint AAPS/AAVPT/CRS Workshop on Collaboration in the Research and Development of Veterinary Pharmaceuticals

October 27-29, 2006
Henry B. Gonzalez Convention Center
San Antonio, Texas

The number of people employed in the animal health industry, regulatory and the related scientific researcher are relatively small and few meetings dedicated to animal medicinal product development occur. This meeting brings together pharmaceutical and veterinary scientists to share development issues and bridge the gap between these two fields. The meeting provides educational opportunities for scientists to broaden their understanding of animal health product development, and as a forum for open discussion. The final session of this workshop will focus on the new field of *in-vitro in-vivo* correlation for veterinary species; this will be a springboard for future meetings and debates on this topic.

Goals and Objectives

- To bring together pharmaceutical scientists and veterinary pharmacologists to discuss areas of mutual interest.
- To provide a forum in which research, current issues and future objectives and directions in veterinary medicine can be presented and discussed.
- To disseminate information to promote and further enhance the interdisciplinary approach to animal health product research and development.

For more information and to register, please visit **www.aapspharmaceutica.com/meetings**

AAPS Workshop on Applications of Ion Chromatography in Pharmaceutical Drug Analysis

October 27-29, 2006
Henry B. Gonzalez Convention Center
San Antonio, Texas

Although there is already a strong interest in the biotechnology industry for IC, the interest in this pharmaceutical area is still growing and is expected to grow steadily over the next few years. Several factors, including the potential of being complementary to the conventional forms of HPLC such as RP or NP, orthogonal to techniques of metal ion analysis such as ICP and AA, a safer and low cost operation for not having to use organic solvents, and expiration of certain key patents held by the innovator company a few years ago has opened the potential of rapidly increasing application of IC in pharmaceutical drug analysis. The number of USP monographs that include IC-based procedures is low but is increasing steadily. USP plans to have a new general information chapter on Ion Chromatography and at least one more general chapter on an IC-based procedure. Given all these key factors, the timing of this meeting will be ideal for pharmaceutical industry to discuss the technology and explore its potential for application in drug analysis.

Goals and Objectives

Since its introduction in 1975, ion chromatography (IC) has become an important analytical methodology in a number of diverse applications in pharmaceutical, biotechnology, and environmental industries. Although IC based procedures are cited only in a handful of regulatory submissions and USP monographs, many more IC methods have been successfully developed and validated for pharmaceutical and drug analysis, and many more methods are being included in regulatory submissions and as well as in USP monographs. Ion chromatography has been successfully applied in the determinations of active and inactive ingredients, including excipients, degradation products, and impurities relevant to the pharmaceutical analyses, and also extensively used in the biotechnology industry for the determinations of amino acids, peptides, proteins, glycoproteins, and carbohydrates. The technique is complimentary to the more commonly used reversed-phase and normal-phase HPLC, AA and ICP techniques. Unlike reversed-phased HPLC, the IC methods generally employ dilute acids, alkalis or salt solutions as eluents with little or no organic solvents, and as such are safer and cost effective. Furthermore, with the expiration of key patents a few years ago, IC instruments and components are now available from several instrumentation companies, thereby making its widespread applications in the pharmaceutical area possible. For more information and to register, please visit **www.aapspharmaceutica.com/meetings**

Upcoming AAPS Meetings

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

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AAPS Workshop on Real World Applications of PAT and QbD in Drug Process Development and Approval
Hyatt Crystal City, Arlington, VA

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▶October 28, 2006
AAPS Workshop on Application of Ion Chromatography in Pharmaceutical Drug Analysis
Henry B. Gonzalez Convention Center, San Antonio, TX

▶October 29-November 2, 2006
2006 AAPS Annual Meeting and Exposition
Henry B. Gonzalez Convention Center, San Antonio, TX

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