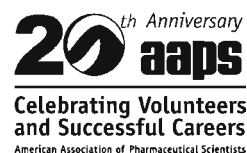


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November 2006

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FDA Pharmaceutical Quality Initiatives—A Modern Risk-Based Approach

Co-sponsored by:
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February 28–March 2, 2007

Bethesda North Marriott Hotel and Conference Center, North Bethesda, Maryland

Objectives:

- ▶ To explore FDA's quality initiatives and share progress made since the issuance of the Agency's 2004 report, "Pharmaceutical cGMPs for the 21st Century—A Risk-based Approach".
- ▶ To provide updates from the FDA's Council on Pharmaceutical Quality, with a focus on implementation challenges and remaining issues.
- ▶ To seek input and recommendations from stakeholders.

Abstract:

This workshop is a follow up to the PQRI/FDA Workshop on A Drug Quality System for the 21st Century held in April 2003. It is being planned under the auspices of the Council on Pharmaceutical Quality at FDA and is co-sponsored with the American Association of Pharmaceutical Scientists and the International Society of Pharmaceutical Engineers. The 2 1/2 day program is intended to present progress on FDA's pharmaceutical quality initiatives. Furthermore, the workshop will allow regulated industry, other stakeholders, and the public to comment on progress made and to provide input to facilitate implementation of a common vision for pharmaceutical manufacturing in the twenty-first century. Among topics to be addressed: pharmaceutical development; chemistry, manufacturing and controls (CMC); manufacturing and quality operations; good manufacturing practices (GMP); and quality systems and quality assurance.

For more information visit
www.aapspharmaceutica.com/FDAQualityInitiatives

Continued

New Release From AAPS Press

Optimizing the "Drug-Like" Properties of Leads in Drug Discovery



Edited by:

Ronald T. Borhardt, Ph.D., University of Kansas
Edward H. Kerns, M.S., Wyeth Research
Michael Hageman, Ph.D., Bristol-Meyers Squibb
Dhiren R. Thakker, Ph.D., University of North Carolina
James L. Stevens, Eli Lilly & Company

This title is the fourth volume of the AAPS series, *Biotechnology: Pharmaceutical Aspects*. Based on workshops organized by the American Association of Pharmaceutical Scientists in 2003 and 2004, *Optimizing the "Drug-Like" Properties of Leads in Drug Discovery* emphasizes the importance of the new shift of assessment in the area of profiling drug-like properties during drug discovery. This shift encompasses medicinal chemists now incorporating optimal drug-like properties into a structural lead, from the traditional position of fixing the undesirable drug-like properties of drug candidates by preclinical development scientists.

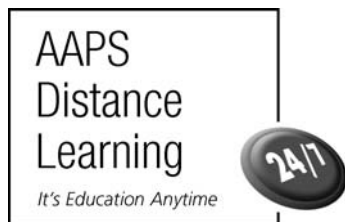
The primary concerns addressed in this crucial new volume is the recognition that the drug-like properties of structural hits, structural leads, and drug candidates are intrinsic properties of the molecules and that it is the medicinal chemist's responsibility to optimize not only the pharmacological properties but also the drug-like properties of these molecules.

Optimizing the "Drug-Like" Properties of Leads in Drug Discovery is an essential tool in the new understanding of drug discovery that outlines strategies and methodologies designed to guide pharmaceutical and biotechnology companies through the drug discovery and development process. This volume also places emphasis on advancing higher quality drug candidates into preclinical and clinical development, resulting in more efficacious and safer drugs.

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AAPS Workshop on FDA's Pharmaceutical Quality Initiatives—A Modern Risk-based Approach
Co-sponsored with AAPS, FDA, and ISPE
Bethesda North Marriott Hotel & Conference Center
Bethesda, MD

► March 5-6, 2007

AAPS Workshop on Effective Utilization of Lipid-based Systems to Enhance the Delivery of Poorly Soluble Drugs: Physicochemical, Biopharmaceutical and Product Development Considerations
Bethesda North Marriott Hotel & Conference Center
North Bethesda, MD

► March 5-7, 2007

AAPS Workshop on Drug Transporters in ADME: From Bench to the Bedside
Bethesda North Marriott Hotel & Conference Center
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► November 12-16, 2007

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