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January 2007

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FDA Pharmaceutical Quality Initiatives—A Modern Risk-Based Approach

Co-sponsored by:
AAPS, FDA,
and ISPE



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 21st 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



New Release from AAPS Press

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



Edited by:

Ronald T. Borchardt, Ph.D., University of Kansas

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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.

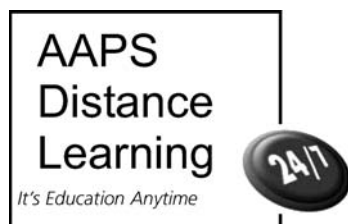
Optimizing the "Drug-like" Properties of Leads in Drug Discovery is an essential tool in the new understanding of drug discovery that outlines strategies and methodologies designed to guide pharmaceutical and biotechnology companies through the drug discovery and development process. This volume also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

List Price: \$189; AAPS Member price: \$141.75

Please contact: orders-ny@springer.com for further details.

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► January 21-26 2007

42nd Annual Pharmaceutical Technologies Arden Conference— Best Practices for Parenteral Dosage Forms: Formulation and Process Development, Package Selection, and Manufacturing
Thayer Hotel, West Point, NY

► February 28-March 2, 2007

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
North Bethesda, MD

► May 9-11, 2007

AAPS Workshop on Stability: Developing a Stability Program for the Global Market
Bethesda North Marriott Hotel & Conference Center
North Bethesda, MD

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Bethesda North Marriott Hotel & Conference Center
North Bethesda, MD

► June 24-27, 2007

AAPS 2007 National Biotechnology Conference
San Diego Convention Center, San Diego, CA



► November 12-16, 2007

2007 AAPS Annual Meeting and Exposition
San Diego Convention Center, San Diego, CA

