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AAPS Connection

American Association of Pharmaceutical Scientists September 2013

Keynote Speaker — 2013 AAPS Annual Meeting and Exposition

Rye Barcott, Social Entrepreneur and Veteran


Rye Barcott

Rye Barcott is author of *It Happened on the Way to War*, a memoir that Bono called "a wild ride" and *Reader's Digest* named one of the four best nonfiction titles of 2011. The book is about his experience co-founding Carolina for Kibera as a nongovernmental organization that uses a model of participatory development in Nairobi, Kenya, while serving simultaneously as a Rye Barcott United States Marine in Iraq, Bosnia, and the Horn of Africa. A *Time Magazine* "Hero of Global Health," Carolina for Kibera helps scale new ideas and technology by investing directly into young leaders in one of the largest and most volatile slums in the world.

For more information visit **www.aaps.org/annualmeeting**.

AAPS Workshop on Regulatory and Stability Control Strategies for Atypical Impurities, Including Leachables/Extractables and Metal Impurities

November 9–10, 2013
Henry B. Gonzalez Convention Center
San Antonio, TX

Summary/Description

The topics covered in this workshop will include

- Special considerations for biological product impurity control strategies.
- Discovering extractable and monitoring leachable impurities from container closure systems.
- Key considerations for testing metal impurities and satisfying USP requirements for metal impurities.
- Monitoring impurities in global submission.
- Extractables and leachables concerns from pharmaceutical packaging.
- Discovering and monitoring impurities from excipients and excipient interactions.
- Stability considerations of excipients.

Goals and Objectives

Monitoring and controlling impurities have been major concerns in the pharmaceutical industry. Many scientific forums have discussed traditional impurities in drug substances and drug products. However, they do not normally include the atypical impurities which could potentially affect the quality and safety of drug products. These impurities are not necessarily caused by the manufacturing process or degradation.

This workshop will discuss the impurities that originate from packaging components, container-closure systems, excipient interactions, or in biological products.

In addition, we'll also discuss the current limits proposed by ICH Q3D and USP General Chapters regarding metal impurities. Innovative methodologies for development of effective stability control strategies will be presented.

This workshop will provide participants a forum to discuss a comprehensive array of topics such as leachables, extractables, excipient impurities, impurities from biologics and non-NDA/ANDA products and metals impurities.

For more information visit **www.aaps.org/RSCS**.

AAPS Workshop on A New Vision for the Eye: Unmet Ocular Drug Delivery Needs

The First Structured Ocular Workshop To Ever Be Offered In The United States

November 10, 2013
Henry B. Gonzalez Convention Center
San Antonio, TX

Summary/Description

The purpose of the conference is to review the current landscape of ocular drugs, address existing clinical needs as well as critical delivery challenges and highlight the up-to-date development of ocular drug delivery with an ultimate goal of promoting the scientific understanding as well as clinical solutions for ocular diseases.

The following topics will be included in this workshop:

- Clinical experience and gaps/challenges with existing ocular drugs and delivery systems.
- Current and emerging drug delivery solutions (nonbioerodible or bioerodible), current state and challenges, case studies.
- Regulatory perspective on ocular drug delivery.

For more information visit **www.aaps.org/Ocular**.

AAPS Workshop on Developing a Biopharmaceutics Risk Assessment Road Map

November 9–10, 2013
Henry B. Gonzalez Convention Center
San Antonio, TX

Goals and Objectives

A significant impact of implementing the Quality by Design (QbD) paradigm is that it enables a systems approach, a continuum throughout drug development and lifecycle management. A biopharmaceutics risk assessment road map developed according to the desired drug delivery patterns facilitates development and communication of such linkages between the desired clinical outcome and the necessary product quality attributes as described in the Quality Target Product Profile (QTPP).

- Illustrating integration of QbD/systems approach to drug development, starting with patient needs, indication, mechanism of action of the API, and characteristics to build the target effect profile, which may incorporate PK characteristics, will demonstrate application of QbD throughout the lifecycle and promote methods that support the link between the patient needs and the product, as well as increase awareness of the available tools and methods and advance novel approaches.
- The biopharmaceutics risk assessment road map will provide information on "what's needed and how" and will provide guidance/direction depending on the level of complexity (less challenging development path vs. more challenging). Risk is considered as an integrated multidisciplinary risk.
- The biopharmaceutics risk assessment road map and the supporting methodology for each scenario will be discussed in the breakout sessions.

For more information visit **www.aaps.org/Biopharm**.

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AAPS Fellows Webinar Save the Date!

AAPS has a strong commitment to the recognition of select AAPS members through their designation as Fellow. The primary criterion for election to Fellow status is professional excellence in the fields relevant to the mission of AAPS. Election to Fellow thus will be based on the individual's documented sustained level of superior and distinguished professional achievement and contributions in a relevant field. In order to assure that only persons of the highest qualifications and distinction be elected to Fellow status, there must be focus and rigor in the nominating process. Therefore, AAPS will be hosting a 1 hour webinar on **Wednesday, December 11, 2013, 1:00 pm** (**Eastern Standard Time**).

The webinar will be based on how to develop a nomination package according to the Fellows Process outlined by the Fellows Committee. The nominator is responsible for assembling and submitting the completed nomination package, which must be received by the AAPS Office on Friday, March 14, 2014.

For more information visit www.aaps.org/About_AAPS/Fellows.

AAPS Connection **September 2013**
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