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AAPS Connection

American Association of Pharmaceutical Scientists August 2013

AAPS Workshop On Inhaled Drug Products: Current Practices and the Future of In Vitro Testing Technologies And Regulation

September 9–10, 2013
USP Meetings Center
Rockville, MD.

Summary/Description

This workshop will provide a thorough update of various in vitro testing procedures and upcoming technologies for Orally Inhaled and Nasal Drug Product (OINDP).

Three sessions are considered for this workshop:

- Statistical techniques
- Aerosol characterization procedures
- Combination product development strategies

All topics were selected by a panel of subject matter experts (SMEs) from the AAPS Inhalation and Nasal Technology Focus Group, International Pharmaceutical Aerosol Consortium on Regulation and Science, United States Pharmacopeial Convention (USP), and the United States Food and Drug Administration. These topics will provide valuable feedback to industry and academia on the regulatory landscape and the pipeline of OINDPs in the US and world market. Proceedings should be published as a white paper in a peer-reviewed journal by participating organizations. Proceedings should be available at the INTFG AAPS website for future access to AAPS members and workshop attendees.

Goals and Objectives

- Learn the current regulatory developments and future perspectives of statistical approaches and aerosol characterization techniques for OINDPs.
- Learn the current developments and future perspectives of USP chapters related to OINDPs.
- Learn the current developments and future perspectives of combination product development.

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

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 a major concern 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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