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AAPS Connection

American Association of Pharmaceutical Scientists June 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 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 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 ePosters

AAPS has initiated a new ePosters viewing service. Posters presented at future AAPS Annual Meetings and AAPS National Biotechnology Conferences will be available for viewing after each meeting has taken place. Viewing is limited to AAPS members as well as non-members and exhibitor attendees of specific meetings.

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