

# AAPS Connection

American Association of Pharmaceutical Scientists

October 2013

## Put AAPS to Work for You Today!



### AAPS 2013 Membership Fees

Regular Member	Student/Postdoc	Retired
\$165.00	\$40.00	\$60
*eSubscribers \$65		

- Continue learning by attending AAPS Workshops and Short Courses.
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- Subscription to the *AAPS Newsmagazine*, AAPS's flagship publication.
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- AAPS member discounts on meeting and conference registrations.
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- Admission to the AAPS Member Directory.
- Membership in up to two AAPS Sections of your choice at no extra cost.
- Access to explore the latest emerging research via *AAPS Press*.
- Involvement in leadership opportunities by volunteering to serve on an AAPS committee.

## Benefits at Your Fingertips

- Participate in AAPS Focus Groups, Discussion Groups, and Student Chapters.
- Gain access of funding and recognition through AAPS Awards, Fellowships, Grants, and Travelships.
- Meet the best in the field at the AAPS Annual Meeting and Exposition.
- Provoke discussion across disciplines by attending the AAPS National Biotechnology Conference.

Join or Renew at <http://www.aaps.org/tojoin/>

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\*eSubscribers are ineligible for conference and meeting discounts, cannot purchase subscriptions to print editions of the journals at the member rate, and do not have full voting rights in the Association. eSubscribers also receive free access to archived AAPS webinars beginning thirty days after the session has been recorded.

## 2013 AAPS Annual Meeting and Exposition

November 10–14, 2013

Henry B. Gonzalez Convention Center  
San Antonio, TX



### AAPS Regular Member SAVINGS at Registration

Early Registration fees	On-site fees
\$355.00	\$310.00

Discounts are available for groups, and for the student, government, and academic categories.

## Register Today!

Register today for full access to the 2013 AAPS Annual Meeting and Exposition, including scientific sessions, general sessions, poster sessions, the AAPS 2013

Exposition Hall (including Career Center), and more.

For more information visit [www.aaps.org/annualmeeting](http://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



### AAPS Regular Member SAVINGS at Registration

Advanced fees  
\$420.00

On-site fees  
\$355.00

### 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](http://www.aaps.org/RSCS).

## AAPS Workshop on Developing a Biopharmaceuticals Risk Assessment Road Map

November 9–10, 2013

Henry B. Gonzalez Convention Center

San Antonio, TX



### AAPS Regular Member SAVINGS at Registration

Advanced fees  
\$590.00

On-site fees  
\$375.00

### 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 biopharmaceuticals 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 a QbD/systems approach to drug development starts with patient needs, indication, mechanism of action of the API, and characteristics to build the target effect profile, which may incorporate PK characteristics. This approach 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 biopharmaceuticals 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 biopharmaceuticals 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](http://www.aaps.org/Biopharm).

## 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



### AAPS Regular Member SAVINGS at Registration

Advanced fees  
\$360.00

On-site fees  
\$375.00

### 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 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 (non-bioerodible or bioerodible), current state and challenges, case studies.

- Regulatory perspective on ocular drug delivery.

For more information visit [www.aaps.org/Ocular](http://www.aaps.org/Ocular).

## AAPS Fellows Webinar

### Save the Date!

AAPS has a strong commitment to the recognition of select AAPS members through their designation as AAPS Fellows. The primary criterion for election to Fellow status is professional excellence in the fields relevant to the mission of AAPS. Election to Fellow status thus will be based on the individual's documented sustained level of superior and distinguished professional achievement and contributions in a relevant field. AAPS will be hosting a 1 h 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.

Visit [www.aaps.org/About\\_AAPS/Fellows](http://www.aaps.org/About_AAPS/Fellows).



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