

Who Should Attend

Industrial, government, and academic professionals from research and development, quality assurance and regulatory affairs who have responsibility for development and oversight of stable pharmaceutical dosage forms.

Goals and Objectives

The role of stability in today's pharmaceutical development process and ongoing manufacturing environment is increasingly complex. Development and quality scientists are faced with many challenges including how to develop methodologies that predict stability, assessing stability for increasingly complex drug products, the role of QbD, diverse regulations in world-wide markets, and the continuous pressure to reduce costs. This workshop will bring together scientists and regulators from around the world to discuss current requirements, and best practices to address these challenges:

- stability by design and using predictive tools to develop stable pharmaceutical products;
- stability strategies and factors in design/formulation for drug device combinations;
- regulatory harmonization of world-wide stability requirements - WHO Stability Guideline, emerging markets, globalization;
- stability strategies for protein and biotech products;
- applications of new technologies to stability evaluation; and
- case studies.

Session Tracks

There will be four session tracks

- Day 1 All-Day Single Track: Stability by Design Using Predictive Tools
- Day 2 Morning Single Track: Stability Strategies for Drug Device Combinations
- Day 2 Afternoon Track 1: Regulatory Harmonization of World-Wide Stability Requirements (Small Molecule Focus)
- Day 2 Afternoon Track 2: Stability Strategies for Protein and Biotech Products

Conference Speakers and Presentations

- Steven Baertshi, Ph.D., Eli Lilly and Company: **Predicting Drug Degradation via In Cerebro Knowledge: A Fresh Look at Degradation Pathways**
- Jeffrey Hofer, Ph.D., Eli Lilly and Company: **Stability Studies - How They are Integral to Design Space Definition and Product Monitoring**
- Tom Schulz, Ph.D., Johnson & Johnson: **Minimizing Stability Programs for Products**
- Emily Schacter, Ph.D., U.S. Food and Drug Administration (*invited*): **Regulatory Perspective on Stability Requirements for Biogenics**
- Sabine Kopp, Ph.D., World Health Organization (*invited*): **Update on WHO 2008 Stability Guidance**

Programming Committee

Abbie Gentry, Ph.D., McNeil Consumer Healthcare, **Co-chair**

Dilip Choudhury, Ph.D., Allergan, Inc., **Co-chair**

Mark Alasandro, Ph.D., Merck

Steven Baertschi, Ph.D., Eli Lilly and Company

Stephen Colgan, Ph.D., Pfizer

Frank Diana, Ph.D., Endo Pharmaceuticals

Kim Huynh-Ba, M.Sc., Pharmalytik

Karen Lucas, Johnson & Johnson

Nanda Subbaro, Ph.D., Biologics Consulting

Saji Thomas, M.S., Par Pharmaceutical

Paula Youngberg Webb, M.Sc., Baxter Healthcare

Manuel Zahn, Ph.D., 3R Consultants

Melvin H. Weinswig, Ph.D., University of Wisconsin-Madison,

Continuing Education

Continuing Education



The University of Wisconsin, an approved provider of continuing pharmaceutical education, will offer continuing education credits.

Workshop Fees

Save by registering early!

August 26, 2009 or Before

| | |
|---------------------|---------|
| AAPS Member | \$1,140 |
| Non-member | \$1,510 |
| Government | \$450 |
| Student Member..... | \$70 |

Registration rates include two full days of programming with coffee breaks, two lunches, and one reception at the end of the first day. Registration fee does not include breakfast.

REGISTER ON LINE at
www.aapspharmaceutica.com/StabilityTrends

Hotel Accommodations

Discounted AAPS rates!

Gaylord National Resort & Convention Center

201 Waterfront Street
National Harbor, MD, USA 20745
www.gaylordnational.com
Reservations Phone: +1 301-965-2000

Online Reservations:

<http://www.gaylordnational.com/X-AMPH9>

Single/Double Rate: \$189.00
Triple Rate: \$209.00

Room rates include facilities fee but do not include 16% tax

Check In: 3:00 pm
Check Out: 12:00 pm

Reserve your hotel room early!

To make reservations, simply reserve your hotel online at <http://www.gaylordnational.com/X-AMPH9>.

Or call the reservation number, +1 301-965-2322 and be sure to mention the *AAPS Workshop on Current Trends in Stability – Challenges with Today's New Products* or Group Code X-AMPH9 to receive the discounted room rates.

Rooms are assigned on a first-come, first-served basis.

Reservations should be made by Wednesday, September 2, 2009. After September 2, 2009, all reservations will be accepted on a hotel room and rate-available basis only. Make your reservations quickly – space is limited.

Advertising Opportunity

Increase your visibility! Advertise in the final program and deliver your message to top pharmaceutical scientists. Limited space is available and ad space must be reserved no later than **September 3, 2009.**

The Townsend Group
Dan Cooper, National Sales Manager
Phone: + 1 301-215-6710
Fax: + 1 301-215-7704
Email: advertising@aaps.org
Deadline: September 3, 2009

Upcoming Meetings

For a complete list of upcoming meetings, please visit www.aapspharmaceutica.com/meetings

REGISTER TODAY!
www.aapspharmaceutica.com/StabilityTrends




American Association of
Pharmaceutical Scientists

2107 Wilson Blvd., Suite 700
Arlington, VA 22201-3042, USA

Non-Profit Org
US Postage
PAID
Merrifield, VA
Permit No. 1502

 **aaps**[®] WORKSHOP

Current Trends in Stability– Challenges with Today's New Products

Co-sponsored with 

September 24 - 25, 2009
Gaylord National Resort &
Convention Center
National Harbor, MD, USA