

# aaps WORKSHOP

## Pharmaceutical Stability Testing to Support Global Markets

Co-sponsored with  **CHPA**  
CONSUMER HEALTHCARE  
PRODUCTS ASSOCIATION  **GPhA** &   
GENERIC PHARMACEUTICAL ASSOCIATION



September 10-12, 2007  
Bethesda North Marriott Hotel  
and Conference Center  
Bethesda, MD



American Association of  
Pharmaceutical Scientists

## Background

Stability is a critical quality attribute of all pharmaceutical products and therefore stability testing is a crucial component of drug development process. Companies rely on the stability data to establish an expiry for marketed pharmaceutical products. Many guidelines have been developed around this arena; however, many issues are continually raised and challenge our practices. Recently, the U.S. Food and Drug Administration withdrew their Stability Guidance; and ICH withdrew Q1F guidelines on storage requirements for Zone III and IV, leading manufacturers to search for the right choice of stability storage conditions for global submission. This meeting will provide a forum to discuss several technical issues that impact global submission and provide a framework for developing an effective and science-based stability program. It is comprised of several sessions organized in dual tracks to explore different stability related challenges, such as monitoring impurities, evaluating shipping excursions, setting specifications, estimating expiry, stability testing of OTCs and Generics. Discussion will also include solid state physical stability of drug substance that has a significant effect on both chemical stability and bioavailability of the drug products, and new issues such as stability of split tablets, repackaged products, and genotoxic impurities. As some companies are turning to Contract Research Organizations for their analytical testing, managing development of a project virtually also imposes technical as well as organizational challenges. This meeting will benefit scientists and managers having responsibilities in a variety of functions relating to drug development, including process development, formulation and analytical development, stability, regulatory affairs and production.

## Goals & Objectives

This workshop will provide the regulatory perspective of stability testing and globally position the stability program for 21<sup>st</sup> century through

- introducing regulatory initiatives on global stability submission;
- highlighting stability testing in challenging storage environments such as ASEAN or the Caribbean;
- exploring the concept of Quality by Design as it applies to stability testing;
- understanding stability challenges of biologics, generics, OTCs, nutraceuticals, lyophilization and other new product technologies;
- setting specifications for drug substances as well as various types of drug products;
- exploring concerns on changes of stability profiles such as repackaged products and split tablets;
- discussing safety and toxicology concerns of emerging impurities;
- understanding solid state physicochemical characteristics on product stability;
- developing stability protocols to support temperature excursion during shipping;
- assessing impurities, excipient compatibility and degradation products in development;
- leveraging stability data to expedite regulatory approval, and
- effectively utilizing Contract Research Organization resources under out-sourced paradigm

## Planning Committee Members

Kim Huynh-Ba, M.Sc., Pharmalytik C.S., **Co-chair**

Saji K. Thomas, M.Sc., Par Pharmaceutical, Inc., **Co-chair**

Mark S. Alasandro, Ph.D., Merck & Company, Inc.

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

Nicholas Cappuccino, Ph.D., Watson Pharmaceuticals

Dilip R. Choudhury, Ph.D., Scios Inc.

Abbie E. Gentry, Ph.D., McNeil Consumer Healthcare

Yushen Guo, Ph.D., Sanofi-Aventis

Mansoor Khan, Ph.D., U.S. Food and Drug Administration

Karen L. Lucas, B.S., Johnson and Johnson Consumer Groups

Prabu Nambiar, Ph.D., Cubist Pharmaceuticals

Nanda K. Subbarao, Ph.D., Sun Pharmaceuticals

Thirunellai G. Venkateswaran, Ph.D., Wyeth Research

Paula J. Youngberg Webb, M.Sc., Baxter Healthcare

Manuel Zahn, Ph.D., AstraZeneca

Melvin H. Weinswig, Ph.D., University of Wisconsin-Madison, **Continuing Education, AAPS**

# Workshop Agenda

## Sunday, September 9

5:00 pm – 7:00 pm

Registration

## Monday, September 10

7:00 am – 5:30 pm

Registration & Continental Breakfast

8:00 am – 9:45 am

**General Session A: Stability Testing in the 21<sup>st</sup> Century**

8:00 am

**Opening Remarks**

Saji K. Thomas, M.Sc.

Par Pharmaceutical

8:15 am

**Regulatory Perspectives on Product Stability**

Gary Buehler, Ph.D.

U.S. Food and Drug Administration

8:45 am

**The Concept of Quality-by-Design**

Ajaz Hussain, Ph.D.

Sandoz

9:15 am

**Positioning Stability Program for 21<sup>st</sup> Century**

Nirdosh Jagota, Ph.D.

Wyeth Research

9:45 am

**Coffee Break**

10:05 am – 5:30 pm

**Concurrent Tracks (See pages 4-5)**

12:00 pm – 1:00 pm

**Lunch**

Complimentary to all attendees

5:00 pm

**Reception**

## Tuesday, September 11

7:00 am – 5:30 pm

Registration

8:00 am – 9:45 am

**General Session B: Global Stability Testing Requirements**

Moderator

Kim Huynh-Ba, M.Sc.

Pharmalytik

8:15 am

**Current International Harmonization Efforts**

Capt. Justina A. Molzon, M.S., Pharm.D., J. D.

U.S. Food and Drug Administration

8:45 am

**Update on the WHO Stability Guideline**

Sabine Kopp, Ph.D., *invited*

World Health Organization, (Switzerland)

9:15 am

**Leveraging Stability for Tropical Countries**

Vipul Doshi, Ph.D.

Sun Pharmaceuticals, India

9:45 am

**Coffee Break**

10:05 am – 5:30 pm

**Concurrent Tracks (See pages 6-7)**

12:00 pm – 1:00 pm

**Lunch**

Complimentary to all attendees

## Wednesday, September 12

7:00 am – 12:00 pm

Registration

8:00 am – 12:00 pm

**General Session C: Future Trends in Stability Testing**

Moderator

Kim Huynh-Ba, M.Sc.

Pharmalytik

8:00 am – 8:15 am

**Introduction**

Kim Huynh-Ba, M.Sc.

Pharmalytik

(Continued on page 8)

## Concurrent Tracks

10:05am – 12:00pm

### Track A1: Quality by Design (QbD) and Stability Testing

Moderator

Mark S. Alasandro, Ph.D.

Merck and Company, Inc.

**10:10 am**

#### Stability Model Based on QbD

Bob H. Seevers, Ph.D.

Eli Lilly and Company

**10:40 am**

#### ICH Q8 and Q9 – A Review

Thirunellai G. Venkateswaran, Ph.D.

Wyeth Research

**11:10 am**

#### Quality By Design of Analytical Methods

Jianmei Kochling, Ph.D.

Vertex Pharmaceuticals, Inc.

Mark G. Schweitzer, Ph.D.

Abbott Laboratories

**11:40 am**

#### Panel Discussion

### Track A2: Stability Challenges of Biologics

Moderator

Dilip R. Choudhury, Ph.D.

Scios Inc.

**10:10am**

#### Stability Evaluation of Therapeutic Proteins – An Overview

Dilip R. Choudhury, Ph.D.

Scios Inc.

**10:40 am**

#### Qualification of Reference Standards for Therapeutic Proteins

Speaker to be Announced

**11:10 am**

#### Evaluation of Impurities/ Degradation Products in Biopharmaceuticals

David Lin, Ph.D., *invited*

Biologics Consulting Group, Inc.

**11:40 am**

#### Panel Discussion

**12:00 pm – 1:00 pm**

#### Lunch

Complimentary to all attendees

## Concurrent

1:00pm -

### Track B1: Strategies for Setting Global Stability Specifications

Moderator

Abbie E. Gentry, Ph.D.

McNeil Consumer Healthcare

**1:05 pm**

#### Setting Specifications for Drug Substances

Jon V. Beaman, Ph.D.

Pfizer PGRD, United Kingdom

**1:35 pm**

#### Setting Specifications for Drug Products

Abbie E. Gentry, Ph.D.

McNeil Consumer Healthcare

**2:05 pm**

#### Setting Specifications for Biologics

Timothy L. Schofield, M.Sc.

Merck and Company, Inc.

## nt Tracks

- 2:35pm

### **Track B2: Stability Challenges of Generic Pharmaceutical Products**

Moderator

Karen L. Lucas, B.Sc.

Johnson & Johnson Consumer Groups

**1:05 pm**

### **Regulatory Requirements for Stability Testing of Generics**

Gary Buehler, Ph.D.

U.S. Food and Drug Administration

**1:35 pm**

### **Stability Testing of Generics: Industry View**

Nicholas Cappuccino, Ph.D.

Watson Pharmaceuticals

**2:05 pm**

### **Flexible Pharmacopeial Monographs**

Karen A. Russo, Ph.D.

U.S. Pharmacopeia

**2:35 pm**

### **Coffee Break**

## Concurrent Tracks

2:55pm – 5:30pm

### **Track C1: Strategies for Setting Global Stability Specifications (cont'd)**

Moderator

Frank J. Diana, Ph.D.

Endo Pharmaceuticals

**3:00 pm**

### **Setting Specifications for Clinical Supplies**

Adam W. Grobin, Ph.D.

Eisai, Inc.

**3:30 pm**

### **Setting Tolerances for Instrument Qualification**

Horacio Pappa, Ph.D.

U.S. Pharmacopeia

**4:00 pm**

### **Investigating OOS Results**

Saji K. Thomas, M.Sc.

Par Pharmaceutical

**4:30 pm**

### **Panel Discussion**

### **Track C2: Stability Challenges of OTCs, Nutraceuticals and Combination Products**

Moderator

Nanda K. Subbarao, Ph.D.

Sun Pharmaceuticals

**3:00 pm**

### **Stability Design for Consumer Healthcare Products**

Karen L. Lucas, B.S.

Johnson and Johnson Consumer Groups

**3:30 pm**

### **Practical Challenges of Stability Testing on Nutraceutical Formulations**

Jairaj U. Mehta, R.Ph.

JM Pharma, LLC.

**4:00 pm**

### **Challenges of Drug/Devices Pharmaceutical Products**

Duu-Gong Wu, Ph.D.

PharmaNet

**4:30 pm**

### **Panel Discussion**

# Tuesday, September 11

## Concurrent Tracks

10:05am – 12:00pm

### Track D1: Stability Testing in Challenging Storage Environments

Moderator  
Manuel Zahn, Ph.D.  
AstraZeneca

10:10 am

#### The Challenge of Divers Climates: Adequate Stability Testing Conditions for India

Saranjit Singh, Ph.D.  
National Institute of Pharmaceutical Education and Research (NIPER), India

10:40 am

#### Development of a Regional Guideline for the Eastern Mediterranean Region

Abdel Aziz Saleh, Ph.D.  
World Health Organization, EMRO, Egypt

11:10 am

#### Stability Testing Requirements for South America, Central America and the Caribbean

Speaker to be Announced

11:40 am

#### Panel Discussion

### Track D2: Physicochemical Stability

Moderator  
Yushen Guo, Ph.D.  
Sanofi-Aventis

10:10 am

#### Physical Stability in Solid State

Stephen R. Byrn, Ph.D.  
Purdue University

10:40 am

#### Stability of Lyophilized Dosage Forms

Larry Gattlin, Ph.D.  
Pfizer Inc.

11:10 am

#### Excipient Compatibility

Tony Tong, Ph.D.  
Novartis Pharmaceuticals

11:40 am

#### Panel Discussion

12:00 pm – 1:00 pm

#### Lunch

Complimentary to all attendees

## Concurrent

1:00pm -

### Track E1: Stability Protocols to Support Temperature Excursions During Shipment

Moderator  
Manuel Zahn, Ph.D.  
AstraZeneca

1:05 pm

#### Temperature Monitoring During Shipment and Storage

Conny Axelsson, Ph.D.  
AstraZeneca, Sweden

1:35 pm

#### Interpretation of Monitoring Data

Manuel Zahn, Ph.D.  
AstraZeneca, Germany

2:05 pm

#### How to Calculate Product Expiry after Excursions

Timothy L. Schofield, M.Sc.  
Merck and Co., Inc.

(Continued from page 3)

## Wednesday, September 12

8:15 am

### Toxicology Considerations for Stability Program

David Jacobson-Kram, Ph.D., *invited*  
U.S. Food and Drug Administration

8:50 am

### Stability and Safety Concerns of Repackaged Products

Mansoor Khan, Ph.D.  
U.S. Food and Drug Administration

9:25 am

### Stability of Split Tablets

Vilayat Sayeed, Ph.D., *invited*  
U.S. Food and Drug Administration

## nt Tracks

- 2:35pm

### **Track E2: Assessment of Impurities and Degradation Products in Drug Development**

Moderator  
Thirunellai G. Venkateswaran, Ph.D.  
Wyeth Research

**1:05 pm**

### **Low Level Impurities in Drug Substances and Drug Products and the Analytical Challenges in Identification**

Ganapathy Mohan, Ph.D.  
Sanofi-Aventis

**1:35 pm**

### **Toxicological Evaluation of Genotoxic Impurities**

Speaker to be announced

**2:05 pm**

### **Forced Degradation & Real Time Stability**

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

**2:35 pm**

### **Coffee Break**

**10:10 am**

### **Survey Results of Stability Practices**

Jeff Medwid, Ph.D.  
JM Pharmaceutical Consulting

**10:30 am**

### **Summary of Workshop Sessions**

## Concurrent Tracks

2:55pm – 5:30pm

### **Track F1: Leveraging Stability Data to Expedite Regulatory Approval**

Moderator  
Paula J. Youngberg Webb, M.Sc.  
Baxter Healthcare

**3:00 pm**

### **Optimizing Stability Data Package to Facilitate NDA/ MAA Approval**

Frank J. Diana, Ph.D.  
Endo Pharmaceuticals

**3:30 pm**

### **Maximize Data for Post Approval Changes**

Paula J. Youngberg Webb, M.Sc.  
Baxter Healthcare

**4:00 pm**

### **Use of Statistics to Establish A Stability Trend – Matrixing**

Earl Nordbrock, Ph.D.  
Nordbrock Consulting

**4:30 pm**

### **Panel Discussion**

### **Track F2: Outsourcing Stability Testing**

Moderator  
Prabu Nambiar, Ph.D.  
Cubist Pharmaceuticals

**3:00 pm**

### **Development and Maintenance of Relationships with 3<sup>rd</sup> Party Analytical Labs**

Jon V. Beaman, Ph.D.  
Pfizer PGRD, United Kingdom

**3:30 pm**

### **Strategies for Ensuring Regulatory and cGMP Compliance of Outsourced Stability Programs**

Eda Ross Montgomery, Ph.D.  
Vertex Pharmaceuticals, Inc.

**4:00 pm**

### **Outsourcing Analytical Testing – A Tool for Resource and Risk Management**

Michael D. Barron, M.B.A.  
Cardinal Health

**4:30 pm**

### **Panel Discussion**

**11:30 am**

### **Summary of Workshop–Hot Topic**

Kim Huynh-Ba, M.Sc.  
Pharmalytik

**12:00 pm**

### **Conclusion and Adjournment**

# Meeting Information

## Continuing Education

The University of Wisconsin, an approved provider of continuing pharmaceutical education, offers continuing education credits. The fee must be paid at the time of registration or on-site. Continuing education credits will not be available after the meeting has occurred.

**Earn: 2.0 CEUs (20 credit hours)**  
**Program Number: 073-999-07-081-L04**  
**Fee: \$30, payable with registration**

## Workshop Fees

Save by registering early!

### August 10 or Before

AAPS Member .....	\$ 1,050
Non-member .....	\$1,450
Government, Member .....	\$450
Government, Non-Member.....	\$500
AAPS Member, Student .....	\$70

### After August 10

AAPS Member .....	\$1,260
Non-member .....	\$1,570
Government.....	\$525
Government, Non-Member.....	\$575
AAPS Member, Student .....	\$80

For registration to be processed, the appropriate fee must be received with your registration form. Registration forms without payment will be considered received on the date the payment arrives.

## Cancellation/Substitution Policy

All refund requests must be made in writing on or before **August 17, 2007**. Refunds will be issued minus an administrative fee (\$180 for registrants/\$50 government registrants/\$15 student registrants). Registrant substitutions from the same company may be submitted in writing at any time without penalty. If the membership status of the substitute differs from that of the original registrant, a refund or additional charge

may apply. All refunds will be issued after the meeting has occurred. No refunds will be issued for requests received after **August 17, 2007**. Submit cancellation requests in writing.

**Fax: (703) 243-5582**  
**Email: registration@aaps.org**  
**Deadline: August 17, 2007**

Registration confirmations are sent via email within 5-10 business days of receipt. To insure receipt of email, please place the following sender on your "safe sender" list:  
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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 **August 3, 2007**.

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Save money on this AAPS workshop by taking advantage of AAPS membership. Membership gives you the competitive edge you need to advance your career and keeps you up-to-date on the latest in pharmaceutical research. Continue your professional development and take advantage of AAPS membership! Use the registration form to indicate your membership choice and send in payment with your registration fees.

**Phone: (703) 243-2800**  
**Email: membership@aaps.org**  
**Regular Membership Fee: \$135**  
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## Hotel Accommodations

Discounted AAPS rates!

Bethesda North Marriott Hotel and Conference Center

Bethesda, MD

Toll Free: (800) 228-9290

Toll Call: (301) 822-9200

Single Rate: \$194.00

Double Rate: \$194.00

Room rates do not include applicable taxes.

3:00 pm Check-in

12:00 pm Check-out

Reserve your space early! Rooms are assigned on a first-come, first-served basis. Reservations should be made by **August 20, 2007**. After August 20, all reservations will be accepted on a space and rate-available basis only.

Make your reservations quickly – space is limited!

## Travel and Transportation

Air/Train Travel

Discounted airfares are available for attendees traveling to/from the AAPS Workshop on Stability Testing to Support Global Markets. To take advantage of these discounts, call the official AAPS travel agency, Carlson Wagonlit, and mention this workshop. You may also call the airlines directly. Certain restrictions apply and seats are limited. Times are listed as Eastern Standard Time (EST).

**Carlson Wagonlit**

**Phone: (866) 412-7957 in the U.S.**

**Phone: (304) 876-8635 outside the U.S.**

**Email: [SiSmith@carlsonwagonlit.com](mailto:SiSmith@carlsonwagonlit.com)**

**9:00 am – 5:30 pm, Monday – Thursday**

**9:30 am – 4:00 pm, Friday**

# Upcoming Meetings

## May 21 - 23, 2007

### AAPS Workshop on BE, BCS, and Beyond

Co-sponsored with FDA

Bethesda North Marriott Hotel & Conference Center

North Bethesda, MD

## November 10, 2007

### AAPS Workshop on Stress Testing and Degradation Chemistry

San Diego Convention Center

San Diego, CA

## June 23-24, 2007

### AAPS Ligand Binding Assay (LBA) Training Course: Development and Validation of Quantitative Ligand Binding Assays

San Diego Marriott Hotel & Marina

San Diego, CA

## November 10, 2007

### AAPS Workshop on Enzyme- and Transporter-based Drug Interactions: Progress and Future

Co-sponsored by ISSX

San Diego Convention Center

San Diego, CA

## June 24-27, 2007

### 2007 AAPS National Biotechnology Conference

San Diego Convention Center

San Diego, CA

## November 10, 2007

### AAPS Workshop on Quantitative Pharmacology: A Roadmap for Rational, Model-based Drug Development

San Diego Convention Center

San Diego, CA

## November 9-10, 2007

### CRS Workshop on Development and Regulatory Challenges for Controlled Release Formulations

Co-sponsored with AAPS

San Diego Convention Center

San Diego, CA

## November 11-15, 2007

### 2007 AAPS Annual Meeting and Exposition

San Diego Convention Center

San Diego, CA

Visit AAPS Pharmaceutica for up-to-date meeting information at [www.aapspharmaceutica.com/meetings](http://www.aapspharmaceutica.com/meetings) or call (703) 243-2800 or toll free (877) 998-AAPS (2277).

## AAPS Workshop on Pharmaceutical Stability Testing to Support Global Markets

September 10-12, 2007

Bethesda North Marriott Hotel and Conference Center • Bethesda, MD

Co-sponsored with CHPA, EAS, GPhA, PhRMA

### Registration Information (Please print or type)

APP075 1 2 3 4 5 6

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### Registration Fees (Choose One)

	8-10-07 or Before	After 8-10-07
AAPS Member	<input type="checkbox"/> \$1050	<input type="checkbox"/> \$1260
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Government, Non-Member	<input type="checkbox"/> \$500	<input type="checkbox"/> \$575
AAPS Member, Student	<input type="checkbox"/> \$70	<input type="checkbox"/> \$80

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Continuing Education	<input type="checkbox"/> \$30 (CEW)
AAPS Membership	<input type="checkbox"/> \$135 (RM)
AAPS Full-time Grad/Undergrad Student Membership*	<input type="checkbox"/> \$30 (ST)
AAPS Postdoctoral Fellow Membership*	<input type="checkbox"/> \$30 (PD)

**Total Fees \$ \_\_\_\_\_ \$ \_\_\_\_\_**

\*The signature of your Dean or Department Chair is required below to certify your full-time status to be eligible for this fee.

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Signature Date

### Payment Method

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**Questions?**  
Meeting registration:  
Toll Free: (866) 229-2386 in U.S. and Canada

**General meeting:**  
(877) 998-AAPS (2277)

**Email:** Meetings@aaps.org

### Business Information Primary Business/Industry (Check only one)

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 E  None

Until you receive a confirmation letter, your registration is not complete. You should receive a confirmation by fax or email 5-10 business days after your payment is received. If not, call (301) 694-5243 or toll free at (866) 229-2386. Cancellations must be received in writing, via fax or e-mail by **August 17, 2007**. All refunds, less an administrative fee, will be issued after the meeting has occurred.

# Pharmaceutical Stability Testing to Support Global Markets

Co-sponsored with  **CHPA**  
CONSUMER HEALTHCARE  
PRODUCTS ASSOCIATION



**PhARMA**  
& **PhARMA**

Register Now! [www.aapspharmaceutica.com/Stability](http://www.aapspharmaceutica.com/Stability)



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