aaps WORKSHOP

Pharmaceutical Stability Testing to Support Global Markets

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

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

aaps
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 21st 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 21st 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 21st 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)

Monday, September 10

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

Concurre
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 Instiute 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 Carribbean
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 Gatlin, 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

Concurre
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

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 3rd 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

10:10 am
Survey Results of Stability Practices
Jeff Medwid, Ph.D.
JM Pharmaceutical Consulting

10:30 am
Summary of Workshop Sessions

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: @experient-inc.com

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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
Student/Post-doc Membership Fee: $30

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
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
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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

June 24-27, 2007
2007 AAPS National Biotechnology Conference
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 10, 2007
AAPS Workshop on Stress Testing and Degradation Chemistry
San Diego Convention Center
San Diego, CA

November 10, 2007
AAPS Workshop on Enzyme- and Transporter-based Drug Interations: Progress and Future
Co-sponsored by ISSX
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 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 or call (703) 243-2800 or toll free (877) 998-AAPS (2277).

aaps Registration Form

AAPS Workshop on Pharmaceutical Stability Testing to Support Global Markets

September 10-12, 2007
Bethesda North Marriott Hotel and Conference Center • Bethesda, MD
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Registration Information (Please print or type)

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❑ The information above is new or has changed.

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Registration Fees (Choose One)

	8-10-07 or Before	After 8-10-07
AAPS Member	❑ $1050	❑ $1260
Non-member	❑ $1450	❑ $1570
Government, Member	❑ $450	❑ $525
Government, Non-Member	❑ $500	❑ $575
AAPS Member, Student	❑ $70	❑ $80

Additional Fees

Become an AAPS Member today and check the AAPS Member rate to save.

Continuing Education	❑ $30 (CEW)
AAPS Membership	❑ $135 (RM)
AAPS Full-time Grad/Undergrad Student Membership*	❑ $30 (ST)
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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.

Signature _____ Date _____

Please choose one track per session time:

Monday, 9-10-07

10:05am	1:00pm	2:55pm
❑ Track A1	❑ Track B1	❑ Track C1
❑ Track A2	❑ Track B2	❑ Track C2

Tuesday, 9-11-07

10:05am	1:00pm	2:55pm
❑ Track D1	❑ Track E1	❑ Track F1
❑ Track D2	❑ Track E2	❑ Track F2

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Toll Free: (866) 229-2386 in U.S. and Canada

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Business Information

Primary Business/Industry (Check only one)

A ❑ Academia
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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.

Payment Method

AAPS does not accept government training forms or purchase orders.
Federal tax ID: 52-1444968

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Pharmaceutical Stability Testing to Support Global Markets

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