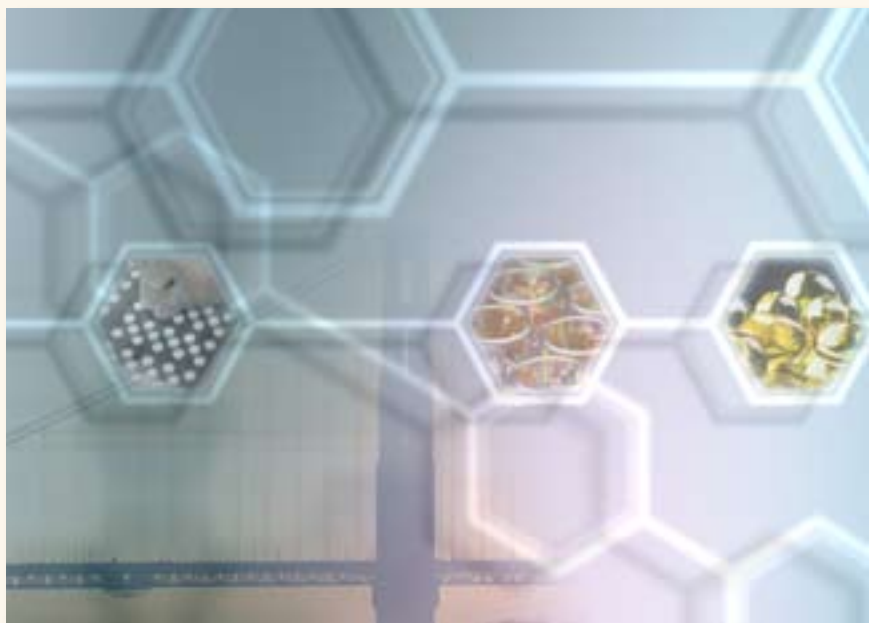


aaps WORKSHOP

Drug Discovery Strategies and Critical Issues for Clinical Candidate Selection

Co-sponsored with



**May 19 – 21, 2008
South San Francisco
Conference Center
South San Francisco, CA**



aaps

**American Association of
Pharmaceutical Scientists**

Goals & Objectives

The discovery and development of quality drug leads and clinical candidates, that will eventually become novel drugs, remains a significant challenge to pharmaceutical scientists. It is increasingly clear that integration of drug-like properties into the early stages of drug discovery is advantageous to efficient and effective drug development. Critical issues of compound selection and quality, safety, pharmacokinetics and formulation will be addressed. Symposia and speakers have been selected to enhance our collective knowledge on the discovery and development of novel lead molecules that have drug-like properties and can successfully lead to clinical development candidates. Key areas of focus will include state-of-the-art techniques to mine SAR, identify promising lead compounds, study drug-like properties of leads as they progress through optimization, screen for early safety concerns, and novel approaches to early formulation. The discussions will be targeted toward academic and industrial scientists from the disciplines of medicinal chemistry, biology, pharmacology, DMPK, toxicology, and formulation. This conference on Drug Discovery Strategies will provide a forum for pharmaceutical scientists to exchange ideas on the state-of-the-art techniques to study drug discovery, enhance knowledge about the relative importance of drug-like properties, and provide an opportunity to learn the cutting edge science in this area through sessions by invited speakers.

Planning Committee Members

Michael J. Hageman, Ph.D., Bristol-Myers Squibb Company, **Co-chair**

Jeffrey Silverman, Ph.D., Sunesis Pharmaceuticals, Inc., **Co-chair**

Bruce Car, Ph.D., Bristol-Myers Squibb Company

Tim Carlson, Ph.D., Amgen Inc.

E. F. "Gene" Fiese, Ph.D., Pharmaceutics Consultant

Michael Silber, Ph.D., University of California, San Francisco

Stefan Steyn, Ph.D., Pfizer Inc.

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

Workshop Agenda

Sunday, May 18

5:00 pm – 7:00 pm

Registration

Monday, May 19

7:00 am – 5:30 pm

Registration

8:00 am

Welcome and Opening Remarks

Jeffrey Silverman, Ph.D.
Sunesis Pharmaceuticals, Inc.

Michael J. Hageman, Ph.D.
Bristol-Myers Squibb Company

8:30 am

Keynote Address

Innovative Preclinical Strategies to Increasing Productivity in Drug R&D: Finding Medicines

Michael Silber, Ph.D.
University of California,
San Francisco

9:30 am -12:00 pm

TRACK A – Critical Issues for Candidate Selection - API Synthesis and Characterization

Moderator
E. F. “Gene” Fiese, Ph.D.
Pharmaceutics Consultant

9:30 am

Candidate Nomination to GMP API Supplies: Issues and Challenges

Thomas C. Crawford, Ph.D.
Tempo Pharmaceuticals, Inc.

10:10 am

Physical-chemical Characterization of API

E. F. “Gene” Fiese, Ph.D.
Pharmaceutics Consultant

10:50 am

Exploratory Development Strategies and Tactics in the Selection of Drug Form

George J. Quallich, Ph.D.
Pfizer Inc.

11:30 am

Panel Discussion

9:30 am -12:00 pm

TRACK B – Tools for Drug Discovery – Assisting Lead Selection Screening and SAR

Moderator
Michael J. Hageman, Ph.D.
Bristol-Myers Squibb Company

9:30 am

Implications of Promiscuous Molecules in Lead Selection and SAR

Brian Shoichet, Ph.D.
University of California, San Francisco

10:10 am

Leveraging ADME Screens to Choose Better Leads

Debra Luffer-Atlas, Ph.D.
Eli Lilly and Company

10:50 am

Mining SAR with a Functional Group Approach

Steve Johnson, Ph.D.
Bristol-Myers Squibb Company

11:30 am

Panel Discussion

12:00 pm – 1:00 pm

Lunch with Posters & Exhibits

Complimentary to all attendees

1:30 pm – 4:40 pm

TRACK A – Critical Issues for Candidate Selection-Formulation Design Strategies

Moderator
Michael J. Hageman, Ph.D.
Bristol-Myers Squibb Company

1:30 pm

Assessment and Characterization of Colloids in the Discovery Setting

Roy J. Haskell, Ph.D.
Bristol-Myers Squibb Company

2:10 pm

Role of Supersaturation in Enhancing Biological Exposure in Preclinical Models

Ping Gao, Ph.D.
Abbott

2:50 pm

Formulation Strategies for Animal DMPK, Pharmacology and Toxicology Evaluation

Jim Wesley, Ph.D.
Eli Lilly and Company

3:30 pm

Linking of Physical-chemical Characteristics with Formulation Strategies and “First in Human” Formulations

Gregory E. Amidon, Ph.D.
University of Michigan

Workshop Agenda

4:10 pm

Panel Discussion

1:30 pm - 4:40 pm

TRACK B – Tools for Drug Discovery/Tools for Guiding Lead Optimization of DMPK

Moderator

Michael Silber, Ph.D.
University of California,
San Francisco

1:30 pm

Small Molecule Discovery in the Modern World

Mike Varney, Ph.D.
Genentech, Inc.

2:10 pm

Optimizing CYP Inhibition Assays for Assessing Drug-drug Interaction Potential in Drug Discovery and Lead Optimization

Larry Wienkers, Ph.D.
Amgen Inc.

2:50 pm

Approaches to Minimize the Bioactivation Potential of 11-Beta HSD Inhibitors in Lead Optimization

Deepak Dalvie, Ph.D.
Pfizer Inc.

3:30 pm

Trials and Tribulation in the Discovery of a Cathepsin K Inhibitor

Deborah A. Nicolls-Griffith, Ph.D.
Merck and Company

4:10 pm

Panel Discussion

5:00 pm – 7:00 pm

Reception with Posters & Exhibits

Tuesday, May 20

8:00 am - 11:10 am

TRACK A - Critical Issues for Candidate Selection - Characterization of ADME Properties

Moderator

Jeffrey Silverman, Ph.D.
Sunesis Pharmaceuticals, Inc.

8:00 am

Characterization of Metabolites: Implications for Drug Discovery and Development

Gary L. Skiles, Ph.D.
Amgen Inc.

8:40 am

Implications of Efflux Transporters During Lead Optimization

Thomas J. Raub, Ph.D.
Eli Lilly and Company

9:20 am

Adding Value to the Discovery Process Through the Application of Pharmacokinetic/ Pharmacodynamic Principles

George Tonn, Ph.D.
Amgen Inc.

10:00 am

Whole-body, Micro- autoradiography, MALDI-MS, NanoSIMS, Cryo-Imaging, and PET: Integrated Approaches for Studying Tissue Distribution, Metabolism, and Transport of Biologicals across Tissue Compartments

Alfred Lordi, M.S.
QPS, Pharmaceutical Services

10:40 am

Panel Discussion

8:00 am -11:30 am

TRACK B – Tools for Drug Discovery- Advances in Analytical Technologies

Moderator

Tim Carlson, Ph.D.
Amgen Inc.

8:00 am

Application of LTQ-Orbitrap Mass Spectrometry for Metabolite Identification

Ji Ma, Ph.D.
Amgen Inc.

8:40 am

Novel LC/MS Approaches for Higher Throughput Screening of Reactive Metabolites in Lead Optimization

Mingshe Zhu, Ph.D.
Bristol-Myers Squibb Company

9:20 am

Accelerator MS and Microdosing for Human Metabolism, PK, and Target Confirmation

John Vogel, Ph.D.
Vitalea Science

10:00 am

Impact of Affinity Mass Spectrometry on Antibody-drug Conjugate Development

Keyang Xu, Ph.D.
Genentech, Inc.

10:40 am

Panel Discussion

11:30 am – 1:00 pm

Lunch with Posters & Exhibits

1:00 pm - 4:20 pm

TRACK A – Critical Issues for Candidate Selection-Characterization of Toxicology Properties in Candidates

Moderator

Bruce Car, Ph.D.

Bristol-Myers Squibb Company

1:00 pm

Addressing Metabolite Related Toxicology Concerns in Early Development

William G. Humphreys, Ph.D.

Bristol-Myers Squibb Company

1:40 pm

Safety and Cardiovascular Toxicology

Derek Leishman, Ph.D.

Eli Lilly and Company

2:20 pm

Mechanistic and Target Based Toxicology

Kyle L. Kolaja, Ph.D.

Roche

3:10 pm

Strategies, Logistics and Organizational Impact for Improved Toxicological Properties

Bruce Car, Ph.D.

Bristol-Myers Squibb Company

3:50 pm

Panel Discussion

1:00 pm - 4:20 pm

TRACK B – Tools for Drug Discovery- Advances with In Silico Methods

Moderator

Stefan Steyn, Ph.D.

Pfizer Inc.

1:00 pm

***In Silico* Drug Design Strategies**

Stefan Steyn, Ph.D.

Pfizer Inc.

1:40 pm

Integration of *In Silico* Models in Drug Design

Hua Gao, Ph.D.

Pfizer Inc.

2:20 pm

Computational Toxicology: New Methods and Models

Sean Ekins, Ph.D.

Arnold Consultancy and Technology

3:10 pm

Turning Uncertain, Multivariate Data into Effective Decisions

Matthew Segall, Ph.D.

BioFocus DPI

3:50 pm

Panel Discussion

Wednesday, May 21

8:00 am – 12:00 pm

Preclinical Data to Predict Developability

Moderator

Lan Xiao, Ph.D.

Bristol-Myers Squibb Company

8:00 am

Predicting the Human Dosage Regimen from Preclinical Data – How Confident are We?

Mario Monshouwer, Ph.D.

Roche

8:50 am

Predicting Human Toxicity from Preclinical Tools – Reality or Myth?

Donna Dambach, Ph.D.

Genetech, Inc.

9:40 am

Predicting Human Metabolism - Are We There Yet?

Debra Luffer-Atlas, Ph.D.

Eli Lilly and Company

10:30 am

Specialized Formulations Enhancing Oral Exposure During Lead Optimization–Converse to Formulation Developability?

Michael J. Hageman, Ph.D.

Bristol-Myers Squibb Company

11:20 am

Invoking Prodrugs as Part of the Lead Optimization Strategy – Should We?

Reza Oliyaji, Ph.D.

Gilead Sciences, Inc.

11:50 am

Closing Remarks

Jeffrey Silverman, Ph.D.

Sunesis Pharmaceuticals, Inc.

Meeting Information

Workshop Fees

Save by registering early!

April 18 or Before

AAPS Member	\$1,090
Non-member	\$1,445
Government, Member	\$450
Government, Non-member.....	\$500
AAPS Member, Student	\$ 70

After April 18

AAPS Member	\$1,275
Non-member	\$1,580
Government, Member	\$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 Policy

All refund requests must be made in writing. 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 April 28, 2008. Submit cancellation requests in writing to:

Fax: (703) 243-5582

Email: registration@aaps.org

Deadline: April 28, 2008

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: 1.7 CEUs (17 credit hours)

Program Number: 073-999-08-055-L04P

Fee: \$50, payable with registration

Call for Papers

The Contributed Paper Abstract submission process is now open. Log onto <http://abstracts.aapspharmaceutica.com/DDS> to submit your abstract. The deadline for submitting abstracts is April 2, 2008. Abstracts must be structured under the headings: Purpose, Methods, Results, and Conclusions or they will not be considered. Acceptance notifications and presentation schedules will be sent via e-mail. Please note that we must have a minimum of ten posters in order to have a poster session.

Questions should be sent to abstracts@aaps.org

Submission deadline: April 2, 2008

Exhibit Opportunities

Do not miss your chance to reach a specialized and focused group of scientists involved with activities at the Drug Discovery and Development Interface! Companies providing services or instrumentation used for the discovery and development of drug candidates including formulation, quality, and safety assessment, pharmacokinetic and pharmacodynamic assessments are invited to exhibit. Limited space is available for \$1,500 on a first-come, first-served basis. All exhibitors will receive one full complimentary registration, including luncheons. Exhibits will be two days only – May 19 and 20, 2008.

For more information about exhibiting and sponsorship opportunities, contact
Heather Horan, Associate Exposition Manager
Phone: (703) 248-4785
HoranH@aaps.org

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 **April 28, 2008**.

The Townsend Group
Kim Kelemen, National Advertising Director
Phone: (301) 215-6710
Fax: (301) 215-7704
Email: advertising@aaps.org
Deadline: April 28, 2008.

Become an AAPS Member and Save

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 keep 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: \$140
Student/Post-doc Membership Fee: \$30

Hotel Accommodations

Discounted AAPS rates available!

Embassy Suites Hotel
250 Gateway Boulevard
South San Francisco, CA 94080

Phone: (650) 589-3400

Single Rate: \$139
Double Rate: \$139

4:00 pm Check-in
12:00 pm Check-out

The Embassy Suites Hotel is a full-service, all-suite hotel that offers a full cook-to-order breakfast, nightly manager's cocktail reception, complimentary self parking, and shuttle service to and from the San Francisco International Airport.

Reserve your space early! Rooms are assigned on a first-come, first-served basis. When you call the hotel directly, tell the reservation agent you are participating in this workshop to receive the AAPS rate. **Reservations should be made by April 28, 2008.** After April 28, 2008, all reservations will be accepted on a space and rate-available basis only. Make your reservations quickly – space is limited.

The Embassy Suites will provide a shuttle to the South San Francisco Conference Center both in the morning and afternoon from Monday, May 19 through Wednesday, May 21.

Travel

AAPS encourages all attendees to make their travel reservations through the official AAPS travel agent, Carlson Wagonlit Travel. Please contact them directly to make your arrangements.

Carlson Wagonlit Travel
Phone: (866) 412-7957 in the U.S.
Phone: (304) 876-8635 outside the U.S.
9:00 am – 5:30 pm, Monday – Thursday (EST)
9:30 am – 4:00 pm, Friday (EST)

Upcoming Meetings

April 28-29, 2008

The AAPS Workshop on Demonstrating Disease-modifying Effects for the Treatment of Parkinson's Disease: Drug Development and Regulatory Issues

Co-sponsored with the U.S. Food & Drug Administration, The Michael J. Fox Foundation for Parkinson's Research and the Parkinson's Study Group

The Hyatt Regency Crystal City
Arlington, VA

April 28-30, 2008

AAPS Workshop on the Role of Dissolution in QbD and Drug Product Life Cycle

Co-sponsored with the U.S. Food & Drug Administration and U.S. Pharmacopeia

The Hyatt Regency Crystal City
Arlington, VA

June 22-25, 2008

2008 AAPS National Biotechnology Conference

Co-sponsored with BIOTECCanada

Metro Toronto Convention Centre
Toronto, Canada



September 10-12, 2008

DIA/AAPS Workshop on Immunogenicity of Therapeutic Proteins

Bethesda Marriott, Bethesda, MD

November 16-20, 2008

2008 AAPS Annual Meeting and Exposition

Georgia World Congress Center
Atlanta, GA



Visit AAPS Pharmaceutica for up-to-date meeting information at www.aapspharmaceutica.com/glp or call (703) 243-2800 or toll free (877) 998-AAPS.

MARK YOUR CALENDARS TODAY!



2008 AAPS Annual Meeting and Exposition

November 16–20, 2008

Georgia World Congress Center
Atlanta, GA



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American Association of
Pharmaceutical Scientists

FOR UP-TO-DATE INFORMATION, LOG ON TO: www.aapspharmaceutica.com/annualmeeting



2008 AAPS National Biotechnology Conference

Advancing Health Through
Innovations in Biotherapeutics



FEATURING:

- Plenary Session
- Symposia
- Roundtables
- Posters
- Exhibits
- Advertising and Sponsorship Opportunities
- Career Center

Mark Your Calendars!

June 22-25, 2008
Metro Toronto Convention Centre
Toronto, Ontario Canada



For up-to-date information:
www.aapspharmaceutica.com/nationalbiotech

Registration Form

May 19 - 21, 2008

AAPS Workshop on Drug Discovery Strategies and Critical Issues for Clinical Candidate Selection

Co-sponsored with The European Federation for Pharmaceutical Sciences

Registration Information (Please print or type)

APS084

1 2 3 4 5 6

First Name _____ Middle Initial _____

Last (Family) Name _____ Nickname for Badge _____

Job Title _____ Organization _____

Address _____

City/State/Zip/Country _____

Phone _____ Fax _____

Email Address _____ Highest Academic Degree _____

Emergency Contact Name _____ Phone _____

- The information above is new or has changed.
- I will require special services in accordance with The Americans with Disabilities Act.

Meals

- Please check here if you would prefer vegetarian lunches

Registration Fees (Choose One)

04-18-08 or Before After 04-18-08

AAPS Member	<input type="checkbox"/> \$1,090	<input type="checkbox"/> \$1,275
Non-member	<input type="checkbox"/> \$1,445	<input type="checkbox"/> \$1,580
Government, Member	<input type="checkbox"/> \$450	<input type="checkbox"/> \$525
Government, Non-member	<input type="checkbox"/> \$500	<input type="checkbox"/> \$575
AAPS Member, Student	<input type="checkbox"/> \$70	<input type="checkbox"/> \$80

Additional Fees

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

Continuing Education	<input type="checkbox"/> \$50 (CE)
AAPS Membership	<input type="checkbox"/> \$140 (RM)
AAPS Full-time Graduate/Undergrad Student Member*	<input type="checkbox"/> \$30 (ST)

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 _____

Payment Method

AAPS does not accept government training forms or purchase orders.

Federal tax ID: 521444968

Check # (_____)

Payable to: AAPS/DDS Workshop
(U.S. dollars, drawn on a U.S. bank)

- Visa
- MasterCard
- AMEX
- Discover

It's easy to register!

Fax: (301) 694-5124
Credit card payments only

Web

www.aapspharmaceutica.com/DDS

Mail

AAPS/DDS
PO Box 590
Frederick, MD 21705

Overnight/Express Deliveries

AAPS/DDS
1888 N. Market Street
Frederick, MD 21701

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)

- A Academia
- B Analytical Testing Lab
- C Association
- D Biotechnology
- E Contract/Clinical Research
- F Cosmetics
- G Foods
- H Government
- I Manufacturing
- J Materials Manufacturing
- K Medical Devices/Diagnostics
- L Publications
- M Other _____

Purchasing Authority

(Check only one)

- A Authorize
- B Purchase
- C Recommend
- D Specify
- 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. Cancellations must be received in writing, via fax or email by **April 28, 2008**. All refunds, less an administrative fee, will be issued after the meeting has occurred.

Breakout Sessions

Please select one breakout session to attend from each time slot:

9:30 am – 12:00 pm Monday, May 19:

- Track A – Critical Issues for Candidate Selection – API Synthesis and Characterization
- Track B – Tools for Drug Discovery – Assisting Lead Selection Screening and SAR

1:30 pm – 4:40 pm Monday, May 19:

- Track A – Critical Issues for Candidate Selection – Formulation Design Strategies
- Track B – Tools for Drug Discovery/Tools for Guiding Lead Optimization of DMPK

8:00 am – 11:10 am Tuesday, May 20:

- Track A – Critical Issues for Candidate Selection – Characterization of ADME Properties
 - Track B – Tools for Drug Discovery – Advances in Analytical Technologies
- #### 1:00 pm – 4:20 pm Tuesday, May 20:
- Track A – Critical Issues for Candidate Selection – Characterization of Toxicology Properties in Candidates
 - Track B – Tools for Drug Discovery – Advances with *In Silico* Methods

Register online or visit www.aapspharmaceutica.com/DDS for details

Card Number _____ Expiration Date (Required) _____

Cardholder Name _____

Amount Authorized to Charge _____

Authorized Signature (Required) _____

AAPS Workshop on Drug Discovery Strategies and Critical Issues for Clinical Candidate Selection

Co-sponsored with The European Federation for Pharmaceutical Sciences

Register Now! www.aapspharmaceutica.com/DDS



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Pharmaceutical Scientists**

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