51st Annual Land O’Lakes Pharmaceutical Analysis Conference

“Challenges for the Analytical Laboratory: Today and Tomorrow”

August 1-5, 2011
Devil’s Head Resort and Conference Center
Merrimac, WI

http://ce.pharmacy.wisc.edu/courseinfo/2011AugustLOL
Program Overview and Objectives
The 51st Annual Pharmaceutical Analysis Conference is intended to serve as an opportunity for pharmaceutical scientists to learn of the analytical development and specification strategies in early development. In addition, new methodologies for analytical procedures will be discussed as well as assisting in developing a procedure to manage an analytical laboratory. Upon completion of this conference learners will be able to:

1. Describe the various selection criteria for new development compounds.
2. List the analytical development and specification strategies in early development.
3. Discuss the need for risk management procedures in a QbD world.
4. Recognize newer analytical techniques to assist the analyst in today's and tomorrow's challenges.

Who Should Attend
This conference is targeted to those scientists involved with formulation, quality control and traditional pharmaceutical analysis. Topics are applicable to all levels of individuals from entry level BS through experienced PhD's.

Location & Travel
The conference will be conducted at Devil's Head Resort and Conference Center in Merrimac, Wisconsin (www.devilsheadresort.com). Merrimac is approximately 40 minutes from Madison. The conference atmosphere offers an informal setting for interaction and networking with industrial peers.

For those registrants flying into Madison, bus transportation to the venue will be available on Monday afternoon, with return service on Friday morning.

Shuttle Bus Service to and from the Dane County Regional Airport - On Monday and Friday Only!
* Monday 1:30 and 4:30 PM Airport to Devil's Head
* Friday 10:45 AM Devil's Head to Airport
* $20.00/person one-way

Registration & Fees

<table>
<thead>
<tr>
<th>Registration Fee</th>
<th>$1,250.00</th>
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<tbody>
<tr>
<td>Lodging &amp; Meals (single accommodations)</td>
<td>$625.00</td>
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<tr>
<td>Total</td>
<td>$1,875.00</td>
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<tr>
<td>Register prior to 7/8/2011</td>
<td>- $150.00</td>
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<tr>
<td>EARLY REGISTRATION</td>
<td>$1,725.00</td>
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NOTE: All accommodations at Devil’s Head for conference registrants will be processed through Extension Services in Pharmacy. Fees are based on single accommodations. Additional fees will be assessed for both lodging and meals in the event more than one person occupies a room.
Lodging & Meals
Registration includes four nights’ single accommodations at Devil’s Head Resort and Conference Center and all meals from Monday’s dinner through breakfast on Friday.

Enrollment Deadline / Limits
To insure maximum interaction between registrants and program faculty, enrollment for the August 2011 LOL Conference will be limited. Therefore, it is suggested that you register as soon as possible. Please note that there is an early registration discount for applications received prior to July 8. In the event that you register and at a later date find you are unable to attend, a refund less a $50 administrative fee will be provided OR a replacement from your company may be accepted provided that advance request and approval of this replacement by Extension Services in Pharmacy is received along with a $50 change fee. No refunds will be provided after July 8 as a firm commitment of all funds is necessary by this date.

Networking Activities
In addition to the educational benefits of this program, the conference is designed to provide registrants with a relaxing environment to meet and share ideas with colleagues with similar interests and network for future collaborative effort. To this end, Devil’s Head Resort offers a variety of activities including tennis, indoor and outdoor swimming pools, mountain biking, nature trails and two golf courses.

If you should have questions or require more information, please contact:

Melvin Weinswig, Ph.D.
Conference Director
Extension Services in Pharmacy
777 Highland Avenue
Madison, WI 53705
(608) 262-3130 (608) 262-2431 FAX
Program Outline

Monday, August 1
Afternoon - Registration
6:00 PM  Reception/Dinner

Tuesday, August 2
Morning
7:00 AM  Breakfast

8:25 AM  Award of Excellence:
Dennis Runser, Ph.D.
TMI Regulatory Compliance Consulting
Overland Park, KS

Moderator: Timothy Wozniak, Ph.D. (Chairperson)
Research Fellow
Eli Lilly & Company
Indianapolis, IN

8:30 AM  Physical – Chemical Selection Criteria for New Development Compounds (What kinds of criteria?)
Peter Wuelfing
Merck & Co. Inc.
West Point, PA

9:15 AM  Strategies for Qualitative and Quantitative Analysis of Solid Forms-Case Studies
Gerald D. Danzer, Ph.D.
Section Manager, Global Analytical R&D
Abbott Laboratories
Abbott Park, IL

10:00 AM  Break

Analytical Development and Specification Strategies in Early Development

10:20 AM  Case Study #1: Early Development Strategies
Michael A. Coutant, Ph.D.
Senior Principal Scientist
Pfizer Global Research & Development
Groton, CT

11:10 AM  Case Study #2:
Terry Tougas
Boehringer-Ingelheim
Ridgefield, CT
Tuesday, August 2 (continued)

Afternoon
12:10 PM  Lunch

Moderator:  Russell Hertzler, Ph.D.
            Section Manager, Global Analytical R&D
            Abbott Laboratories
            Abbott Park, IL

1:00 PM  Workshop – Analytical Development and Specification Strategies in Early Development
          Michael A. Coutant, Ph.D.
          Senior Principal Scientist
          Pfizer Global Research & Development
          Groton, CT

          Russell Hertzler, Ph.D.
          Abbott Laboratories
          Abbott Park, IL

          Terry Tougas
          Boehringer-Ingelheim
          Ridgefield, CT

          Tim Wozniak
          Lilly Research Laboratories
          Indianapolis, IN

Evening
6:00 PM  Dinner

Moderator:  Galen Radebaugh, Ph.D.
            Principal
            Black River PharmSci Solutions
            Chester, NJ

7:30 PM  Sensitive Analytical Methods for Genotoxic Compounds
          Richard Thompson
          Novartis Pharmaceuticals Corporation
          East Hanover, NJ
**Wednesday, August 3**

**Morning**

7:00 AM  Breakfast

Moderator:  Louis W. Yu, Ph.D.
Senior Vice President
Perrigo
Allegan, MI

8:30 AM  Materials Assessments as part of QbD
Joseph Kushner, IV, Ph.D.
Principal Scientist, Pharmaceutical Development
Pfizer Worldwide Research and Development
Groton, CT

9:20 AM  Trace Impurities & Allergen Testing in Ingredients, Products & Containers

Industry Perspective
Scott K. Christiansen
PBM Nutritionals (A Perrigo Company)
Georgia, VT

Government Perspective
R.D. Satzger, Ph.D.
FDA – Forensic Chemistry Center
Director, Organics Branch
Cincinnati, OH

10:00 AM  Break

10:30 AM  Predictive modeling tools: Gastro Plus
Yi Gao
Abbott Laboratories
Abbott Park, IL

11:20 AM  Case Study: Analytical Challenges Associated with Combination Products
Walter Wasylaschuk
Merck & Co., Inc.
West Point, PA

12:10 PM  Lunch

**Afternoon**

1:00 PM  Optional Golf Tournament or Dells Boat Tour
Wednesday, August 3 (continued)
Evening
6:00 PM   Dinner
7:30 PM   Exhibitors and Poster Sessions

Thursday, August 4

Morning
7:00 AM   Breakfast

Moderator:  Mark Mowery  
Merck & Co., Inc.  
West Point, PA

8:30 AM   Analytical Analysis of Synthetic Peptide Oligonucleotide Purifications: Understanding Yield and Purity Definitions  
Michael McGinley  
Phenomenex  
Torrance, CA

9:20 AM   Get the Most out of Your ridiculously Expensive Detector: Interesting Quantitative NMR Applications  
Andreas Kaerner, Ph.D.  
Eli Lilly & Company  
Lilly Corporate Center  
Indianapolis, IN

10:00 AM   Break

10:30 AM   Elemental Impurities  
Nancy Lewen  
Principal Scientist  
Bristol-Myers Squibb, R&D  
Analytical and Bioanalytical Development  
Supervisor of the Atomic Spectroscopy Laboratory  
New Brunswick, NJ

11:15 AM   Cutting Edge Trends in Separation Techniques - Use of Super Heated Water to do Separation  
John G. Dorsey, Ph.D.  
Florida State University  
Tallahassee, FL

12:00 PM   Lunch

Moderator:  Peter Rahn  
Phenomenex  
Torrance, CA
Thursday, August 4 (continued)

Afternoon
1:00 PM  Workshop

Preparing for the Future: Why Peptides and Oligonucleotides are Like Small Molecules from an Analytical Perspective

Using Mass Spectrometry to Characterize Therapeutic Oligonucleotides
Mark Hail
Novatia, LLC, Monmouth Junction, NJ

Analytical Aspects of Developing a Peptide Therapeutic
Martin Robatille

Evening
6:00 PM  Dinner

Moderator: Christianna Strohbeck, Ph.D.
Assoc. Director, Global Regulatory Affairs CMC
Johnson & Johnson Pharmaceutical R&D
Raritan, NJ

7:15 PM  Delivering Medicines in the Third World: A Case Study
Rosario LoBrutto, Ph.D.
Project Leader
Novartis Pharmaceuticals Corporation
East Hanover, NJ

7:50 PM  The role of the FDA Forensic Analysis Center Plays in assuring Public Safety
R.D. Satzger, Ph.D.
FDA – Forensic Chemistry Center
Director, Organics Branch, Cincinnati, OH

Friday, August 5

Morning
7:00 AM  Breakfast

Moderator: Ramaswamy Murari
Forest Research Institute, Inc.
Jersey City, NJ

8:30 AM  Hot topics in Compendial Science (Spectral Libraries, Packaging, etc.)
Todd Cecil
U.S. Pharmacopeia
Rockville, MD
Call for Posters
Submission Deadline: July 5, 2011
Annual Meeting Registration Deadline: July 8, 2011
(Meeting registration is required for poster presenters.)

The Planning Committee invites interested parties to submit research poster abstracts for the 2011 Conference Poster Session on Wednesday, August 3, at the Devil’s Head Resort and Conference Center, Merrimac, Wisconsin. All abstracts must be submitted via email to the University of Wisconsin by Tuesday, July 5, 2011. Proposals will be reviewed and evaluated by a review panel of Planning Committee members. Acknowledgement of receipt will be sent by e-mail, as well as notification of the acceptance or rejection of abstracts to primary presenters by July 8. Please do not call the University of Wisconsin to find out the status of your abstract(s). To submit a poster for consideration, at least one author must be registered for the conference. If the poster is not accepted, authors have the right to cancel their registration by the registration deadline of July 8 and will receive a full refund. Any author present at the Conference must be registered for the entire Conference.

Research topics
The poster should be related to the objectives of the Conference and appropriate for Conference attendees. Abstracts should represent one of the following three types of research:

- “Completed Research” includes any research having analyzed results by the abstract deadline.
- “Work in Progress” includes any research having a methodology and implemented, with data collection ongoing, but whose results have not been analyzed by the abstract deadline.
- “Theoretical Models” are theory-based explanations for anticipated or observed phenomena, or events. Appropriate models for submission would include a novel model proposed by the abstract submitter, a new model derived from existing models, or a model from some other field being applied to pharmaceutical bioanalysis.
Additional 2011 Land O’Lakes Conferences

   June 6-10, 2011
   Merrimac, WI
   $1875 ($1725 prior to 5/6/11)
   http://ce.pharmacy.wisc.edu/courseinfo/2011JuneLOL

July Land O’Lakes Bioanalytical Conference: Agency and Industry Perspectives on Biomarkers, Bloodspots and Beyond
   July 11-15, 2011
   Merrimac, WI
   $1875 ($1725 prior to 6/20/11)
   http://ce.pharmacy.wisc.edu/courseinfo/2011JulyLOL

September Land O’Lakes Drug Metabolism/Applied Pharmacokinetics Conference
   September 12-16, 2011
   Merrimac, WI
   $1875 ($1725 prior to 8/29/2011)
   http://ce.pharmacy.wisc.edu/courseinfo/2011SeptemberLOL

For updated program information on this and other offerings, please visit our course catalog:

http://ce.pharmacy.wisc.edu

or contact Extension Services in Pharmacy
   by phone: (608) 262-3132
toll free: (877) 947-4255
or by email: cemail@pharmacy.wisc.edu
LAND O’LAKES REGISTRATION APPLICATION
August 1-5, 2011 • Merrimac, WI
http://ce.pharmacy.wisc.edu/courseinfo/2011AugustLOL

Name _________________________________________________________________
First      Last
Name of Company/Institution ________________________________________________
Home Mailing Address
Street _________________________________________________________________
City, State, Zip ___________________________________________________________
Daytime Phone ( ______ ) __________________________________________________

Email address* ___________________________________________________________
*An email address is required to receive confirmation materials. You will receive emails from ceadmin@pharmacy.wisc.edu. Please make sure your email filters do not block our messages. We do not sell or distribute your email address to other organizations or companies.

Registration Fee                         $1,250.00
Lodging & Meals (single accommodations) $625.00
TOTAL AMOUNT                     $1,875.00
Payment received prior to 7/8/2011 $ - 150.00
EARLY REGISTRATION                $1,725.00

Make checks payable to the UNIVERSITY OF WISCONSIN
*Credit card information (only those listed are accepted): [ ] MasterCard [ ] Visa [ ] American Express
Cardholder’s Name _______________________________________________________________
Card Number ___________________________________________________________________
Expiration Date ________________________
A confirmation email will be sent to your provided email address when we receive your registration.

Register via ONE of the following methods:
2. By phone at (608) 262-3132 or toll free at (877) 947-4255 with a credit card.
3. Fax the registration form to (608) 262-2431 with credit card information.
4. Mail the registration form with a check or credit card information.

Mail or fax this form and payment to:
LOL Conferences
Extension Services in Pharmacy
777 Highland Avenue
Madison, WI 53705
FAX (608) 262-2431
For general program information & all other questions, call (608) 262-3130 or (608) 262-3132.