# 16TH ANNUAL SYMPOSIUM Clinical & Pharmaceutical Solutions through Analysis

Where Technology and Solutions Meet



# **Connecting Patients and Subject Numbers through Analysis**

October 7 -10, 2013 Sheraton Bucks County Langhorne, PA

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## 2013 Program Chair

Shane Needham Alturas Analytics

## Distinguished Lecturer

Richard Kibbey Yale University

## **Plenary Speakers**

Ola Saad Genentech

Ellie Guardino Genentech

## **Keynote Speakers**

Nathan Yates University of Pittsburgh

> Gary Valaskovic New Objective

## **Poster Session Chairs**

Helene Cardasis Thermo Scientific

Matthew Szapacs GlaxoSmithKline

Tracie Williams Centers for Disease Control and Prevention

> Sean Yu *Merck*

#### **Vendor Session Chairs**

Mark Hayward *Revlon* 

Matthew Szapacs GlaxoSmithKline

Nicole Donnelly PharmaCadence

# General Information

## History

This annual meeting began in 1998 and was the first industry-led event to complement academic-based meetings and address the specific needs of industry researchers. The program highlights current industry trends and relevant topics. The broad-based support has allowed the meeting to evolve into a premier industry-led event that is dedicated to promoting awareness of issues and needs associated with research and development.

## Goals

The goal of CPSA is to provide in-depth review of innovative technology and industry practices through open discussion of industry-related issues and needs. The program will highlight speakers and sessions that provide real-world experiences with new technologies and critical insights into current issues and future needs. Education and specialized training are the foundation of all CPSA events.

## Format

The meeting features a unique format to allow scientists to openly share their comprehensive perspectives on industry-related issues and needs. First-hand experiences with specific applications and technologies are openly discussed.

## Symposia Feature

Industry Issues & Needs · Analysis Strategies · Performance Benchmarks

## **Roundtables Feature**

Commercial Technology · Mainstream Applications · Analysis Trends

## **Colloquium Series**

The CPSA Colloquium Series is held in parallel to the Symposia sessions on Tuesday, October 8 and Wednesday, October 9. This year the Colloquium Series will feature sessions on "Rapid Turn-Around Time of Bioanalytical Data" and "Regulations and Emerging Technology in the Clinical Sciences: The Impact on Research, Patients and Physicians." The goal of these sessions will be to provide attendees with an opportunity to:

- Further enhance the specialized training from the CPSA short courses; and
- Provide focus on industrial activities related to regulatory issues and industrial workflows

## **Short Courses Feature**

Practical Industry Applications · Fundamentals Real-World Examples · Emerging Methods and Techniques

CPSA attracts sponsors, thought leaders, and participants who are dedicated to the spirit of cooperation to achieve common goals.

## **Imagination needed!**

#### COURSE 1

## Colloquium on LC-MS Method Development: Fundamentals, New Technologies, and Advanced Methods

Instructor: Shane Needham, Alturas Analytics

This practical course on HPLC method development for LC-MS is a tutorial on LC-MS/MS in the bioanalytical and clinical laboratory. As a conduit for learning, a major portion of the course will feature a step-wise method development approach and tutorial on how to develop LC-MS/MS methods based on compound structure. The course will emphasize the importance of HPLC when interfaced with mass spectrometry including the HPLC and SPE separation of undetected matrix components (a major cause for ion suppression!), isomers and labile metabolites. Much of the course is geared towards development of HPLC methods for LC-MS in a regulated guantitative bioanalysis laboratory for both pharmaceutical and clinical applications. Seven experts will present their recent experiences with fundamentals, new technologies and advanced methods. This colloquium will feature a dynamic format where the latest technology in HPLC column chemistries, tools for microsampling, MFLC, UPLC of large molecules and tools for gaining extra selectivity with HPLC-MS/MS are openly discussed. A significant time will be devoted to answering questions from the audience about their specific issues, needs and requirements.

#### COURSE 2

## Targeted Metabolomics: The Art & Science of Measuring Drug Efficacy

Instructors: Mark Hayward, Active Ingredient Technologies; Ken Lewis, OpAns

Integrated HPLC and MS approaches for high throughput analysis have become standard practice in a pre-clinical drug discovery setting. Successful support strategies often provide a blend of high throughput methodologies with appropriate resources (tools and personnel). This course will target the "bread and butter" functions of discovery medicinal chemistry support. Real-world experiences with method development and analytical support will be discussed.

#### COURSE 3

## Analysis of Peptides Peptides and Proteins: Sample Prep to Identification and Quantitation

Instructors: Nalini Sadagopan, Agilent Technologies; Gary Valaskovic, New Objective; Nathan Yates, University of Pittsburgh

Within the last decade, nanoscale liquid chromatography-tandem mass spectrometry (nLC-MS/MS) has revolutionized the identification of proteins and peptides in biological matrices. The technology has developed from being a purely qualitative tool for (global) proteomics to a quantitative method suitable for peptide/protein biomarker validation.

#### COURSE 4

## Assessment of Oral Bioavailability in Preclinical Species and Human: Impact of Physicochemical, Biopharmaceutical and Physiological Factors

#### Instructor: Ayman El-Kattan, Pfizer

Poor oral bioavailability is one of the leading causes of compound failure in preclinical and clinical development. Compounds with poor oral bioavailability have low plasma exposure and tend to demonstrate high inter-individual variability, which can limit their therapeutic application. Poor oral bioavailability in preclinical species does not necessarily translate into poor human oral bioavailability.













# **E CPSA**

Make plans to attend the 16th Annual Symposium on Clinical and Pharmaceutical Structure Analysis (CPSA 2013). This unique event is highly interactive. The program features updated perspectives and experiences on clinical and pharmaceutical structure analysis. Imagination and stimulating discussion are central to each CPSA function and session.



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## Call for Papers - Abstracts due September 1st

## **Abstract Submission Open**

Abstracts are being accepted for the 16th Annual CPSA USA Symposium on Clinical & Pharmaceutical Solutions through Analysis. Please submit your abstract on the CPSA USA website at www.cpsa-usa.com.

- · Abstracts must be received by September 1, 2013
- · Maximum length is 350 words

A sample abstract is available at www.cpsa-usa.com as a guide for correct format. Please visit the conference website for more information.

## Registration

To register for CPSA USA 2013, please download the registration form from the conference website at www.cpsa-usa.com. Submit by FAX (267-757-0463) or mail directly to Dr. Mike Lee at the address noted below. All fees are in US Dollars.

## **Conference Registration**

Early Registration:	Before June 28, 2013
Pre-Registration:	June 28 - September 20, 2013
On Site Registration:	After September 20, 2013

## **Payment Methods**

Check:	Make payable to Milestone Development Services (Must be drawn on US bank)
Credit Card:	American Express, MasterCard, Visa accepted.
Wire Transfer:	Contact info@milestonedevelopment.com for wire transfer instructions.
Cash:	Send the completed CPSA USA Registration Form to the CPSA office by fax (+1 267-757-0463) or mail directly to: Dr. Mike Lee Attn: CPSA USA P.O. Box 178,
	Newtown, PA 18940-0178, USA
Full payment is d	lue upon conference registration

#### **Hotel Registration**

A special CPSA room rate of \$129 per night is available at the Sheraton Bucks County Hotel when you book your room by September 10, 2013. Please call the Sheraton Hotel reservations department directly at 215-547-4100 and mention (code: CPSA/Milestone) to reserve with the CPSA room rate. Visit the Sheraton Bucks County Hotel website for more information (www.Sheraton.com/BucksCounty).

## **CPSA is User Friendly!**

CPSA attracts sponsors, thought leaders, and participants who are dedicated to the spirit of cooperation to achieve common goals. Imagination needed.

## CPSA - Where Technology and Solutions Meet!



## **CPSA Golf Outing**

Makefield Highlands Golf Club, Yardley, PA

The 5th Annual CPSA Open will take place on Monday, October 7th. Don't miss your tee time!

Contact Brad Coopersmith (brad\_coopersmith@waters.com), Ken Imitani (ken\_imitani@agilent.com), or Paul Corcoran (paul.corcoran@mkscientific. com) for more information and to sign-up to play.