

## EAS Short Courses at-a-Glance

*Please use the links to navigate to the course description*

Pricing for 2010 Short Courses is \$475 / \$675 before / after Oct. 15, 2010 for a one-day course and \$675 / \$975 before / after Oct. 15, 2010 for a two-day course; in addition to the Full Conferee registration fee. Courses are subject to changes.

<b>Date</b>	<b>Course #</b>	<b>Course Title</b>	<b>Instructor</b>
(November 14-15)	E10-01	Practical Gas Chromatography: Packed and Capillary Columns	Dr. Eugene Barry Dr. Mary Kaiser
(November 14-15)	E10-02	LC/MS: Theory, Instruments, and Applications	Dr. Guodong Chen Mr. Michael Balogh Dr. Ragu Ramanathan Dr. Birendra Praminik
(November 14)	E10-03	Modern HPLC Method Development in Pharmaceutical Analysis	Dr. Michael Dong Dr. Henrik Rasmussen
(November 14)	E10-04	Anatomy of Modern Reversed-Phase Columns: Understanding Their Role in HPLC	Dr. Brian Bidlingmeyer Dr. Richard Henry
(November 14)	E10-05	Chemometrics without Equations	Dr. Donald Dahlberg Dr. Barry Wise
(November 14)	E10-06	Enhanced Productivity by Design in the Analytical Laboratory: Design of Experiments for Analytical Chemists	Dr. Zenaida Otero Gephardt
(November 14)	E10-07	Physical Characterization and Analytical Test of Pharmaceutical Solids	Dr. Steve Byrn Dr. Sean Chen
(November 14)	E10-08	Effective Laboratory Audits and Inspections	Mr. Ken Christie
(November 14)	E10-09	Two Dimensional (2-D) Correlation Spectroscopy	Dr. Isao Noda
(November 14)	E10-10	High-Throughput Drug Analysis by LC/MS	Dr. Perry G. Wang
(November 14)	E10-11	Advanced Excel II: Write Your Own Functions and Macros	Dr. Robert de Levie
(November 15-16)	E10-12	Putting Organic Chemistry into Perspective - A Review of Sophomore Organic Chemistry	Dr. John Sowa
(November 15)	E10-13	Practical Enantiomeric Separations	Dr. Daniel Armstrong
(November 15)	E10-14	Modern HPLC for DMPK, Bioanalytical, and Analytical Development Scientists: Essentials, Best Practices, and Recent Developments	Dr. Michael Dong Dr. Anne-Francoise Aubry
(November 15)	E10-15	Laboratory Data Analysis Using EXCEL®: New Uses for a Familiar Tool	Dr. Zenaida Otero Gephardt
(November 15)	E10-16	Detection and Characterization of Drug Metabolites in Drug Discovery and Development	Dr. Donglu Zhang Dr. Mingshe Zhu
(November 15)	E10-17	The Chemistry of Drug Degradation	Dr. Karen Alsante Dr. Dinos Santafianos
(November 15)	E10-18	Analytical Laboratory Techniques for Pharmaceutical Chemists	Dr. Merlin Bicking
(November 15)	E10-19	Infrared Spectral (IR) Interpretation I	Dr. Brian Smith
(November 16)	E10-20	Infrared Spectral (IR) Interpretation II	Dr. Brian Smith
(November 15-16)	E10-21	Infrared Spectral (IR) Interpretation I + II (combined course)	Dr. Brian Smith
(November 16)	E10-22	The Role of Chromatography in the Analysis and Characterization of Protein Therapeutic Drugs	Mr. C. David Carr
(November 16-17)	E10-23	The Analysis and Characterization of Protein Therapeutic Drugs	Mr. C. David Carr
(November 16)	E10-24	Interpretation of Mass Spectra with Practical Solutions to Problems	Dr. Birendra Pramanik Dr. Mike Lee
(November 16)	E10-25	Data Analysis for Improved Productivity in the Analytical Laboratory	Dr. Zenaida Otero Gephardt
(November 16)	E10-26	Drug Development Process for Chemists	Dr. Michael Dong
(November 16)	E10-27	Introduction to Near-Infrared Spectroscopy: Applications in the Pharmaceutical Industry	Dr. Emil Ciurczak
(November 16)	E10-28	Critical cGMP and ICH Guidances for Analytical Laboratories	Ms. Kim Huynh-Ba Dr. Linda Ng
(November 16)	E10-29	Sample Preparation: The Chemistry Behind the Techniques	Dr. Douglas Raynie Dr. Merlin Bicking
(November 16)	E10-30	How to Create a More Effective Lab Safety Program	Dr. James A. Kaufman

## EAS Short Courses at-a-Glance

(November 17-18)	E10-31	Quantitative Analysis for Chromatographers	Dr. Harold McNair Dr. Gregory Slack Dr. Nicholas Snow
(November 17-18)	E10-32	Troubleshooting Chromatographic Systems	Dr. Merlin Bicking Dr. Douglas Raynie
(November 17-18)	E10-33	PLAstics-State of the Art Techniques Important in Cleaning their Surfaces	Dr. Yvonne Shashoua Ms. Kathrine Segel
(November 17-18)	E10-34	How to Develop Validated HPLC Methods: Rational Design with Practical Statistics and Troubleshooting	Dr. Brian Bidlingmeyer Dr. Stanley Deming
(November 17)	E10-35	Practical Headspace Gas Chromatography	Dr. Mary Ellen McNally Dr. Thomas Brettell
(November 17)	E10-36	Impurities and Degradants Identification: Strategies for Structure Elucidation via Chromatography, MS and NMR	Dr. Thomas Sharp Dr. Brian Marquez Mr. Todd C. Zelesky
(November 17)	E10-37	Laser Desorption Mass Spectrometry and Other MS Techniques for Identifying Trace Impurities in Biocompatibility Testing	Dr. Kevin Owens Dr. William Erb
(November 17)	E10-38	Leachables and Extractables in Pharmaceutical Development	Dr. Daniel Norwood Mr. James Mullis
(November 17)	E10-39	Supercritical Fluid Chromatography for the Pharmaceutical Industry	Dr. Larry Taylor Mr. Larry Miller
(November 17)	E10-40	Metrology in the Analytical Laboratory	Dr. Jerry Messman
(November 18)	E10-41	Dissolution: A Rational Approach to Developing and Validating Methods for a Variety of Purposes	Mr. Gregory Martin
(November 18)	E10-42	Application of Mass Spectrometry for Characterizing and Profiling Impurities/Degradation Products and Potential Genotoxic Impurities of Drug Substances and Drug Products	Dr. Nagella Nukuna
(November 18)	E10-43	Practical Solutions to Characterization of Protein Therapeutics Using Mass Spectrometry	Dr. Guodong Chen Dr. Li Tao Dr. Ragu Ramanathan
(November 18)	E10-44	Fundamentals of Microbiology for Chemists	Dr. Anthony Cundell
(November 18)	E10-45	Practical Introduction to Raman Spectroscopy	Dr. Frederick Long
(November 18)	E10-46	Authoring High Quality Technical Reports	Mr. Gregory Cuppan
(November 18)	E10-47	Theory and Practice of Ultra High-Pressure Liquid Chromatography (UHPLC)	Dr. Michael Swartz



## EAS Short Courses

EAS Short Courses emphasize practical and economical problem-solving topics which will include material that you can take home and immediately apply to your daily work. Various topics will be offered at the 2010 EAS. These courses will be taught by a group of distinguished instructors, who are well recognized in their fields.

Please visit [www.EAS.org](http://www.EAS.org) for latest information about short courses; pricing is listed on page 4.

### Practical Gas Chromatography: Packed and Capillary Columns (Dr. Robert Grob Memorial Course)

**Two-Day Course E10-01, Sunday and Monday, November 14 and 15, 2010, 8:30am – 5:30pm**

Dr. Eugene F. Barry, University of Massachusetts Lowell, Lowell, MA

Dr. Mary A. Kaiser, DuPont Company, Wilmington, DE

#### COURSE DESCRIPTION

This course presents the fundamentals of gas chromatography with an emphasis on practical applications for users and method developers. Topics to be covered include theoretical considerations, use of computer searches for literature references and methods of analysis, modern instrumentation, including inlet, column, and detector technology, and the applications of these to effective qualitative and quantitative analysis. The theoretical portion of the course will focus on using the fundamental understanding of the chromatographic process (limited number of equations and comparisons to extractions and distillations) to assist in obtaining a desired separation quality and run time. Modern instrumentation including split, splitless, on-column, and programmed-temperature inlets and electronic pressure control will be discussed. The proper selection of capillary columns to solve practical problems will be described, although the utility of modern packed columns will be briefly discussed. An emphasis will also be placed on detectors, including TCD, FID, ECD and GC/MS. Finally all this will be applied to practical problems in qualitative and quantitative analysis.

#### WHO SHOULD ATTEND

This course represents a balanced blend of pertinent information and underlying theory for successful practice of gas chromatography. Individuals working in the area of gas chromatography, beginners and those desiring to update their knowledge of the technique will find this course to be meaningful and useful. The Instructors of this Short Course will welcome Questions and Problems pertinent to the subject material covered in the course prior to the Meeting. These Questions & Problems will be answered in a Question & Answer Session at the end of the Course. Email your inquiries to either of the two Instructors: Dr. Eugene F. Barry: [Eugene\\_Barry@uml.edu](mailto:Eugene_Barry@uml.edu) or Dr. Mary A. Kaiser: [Mary.A.Kaiser@usa.dupont.com](mailto:Mary.A.Kaiser@usa.dupont.com).

#### TOPICS

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| <ul style="list-style-type: none"> <li>▶ Theory and Basics               <ul style="list-style-type: none"> <li>• Evolution of chromatography</li> <li>• IUPAC nomenclature</li> <li>• Similarities to extractions &amp; distillations</li> <li>• Theory of gas chromatography-Plate and Rate Theories</li> <li>• Effect of changing conditions on peak separations</li> </ul> </li> <li>▶ Inlets/mobile Phases               <ul style="list-style-type: none"> <li>• Injection modes &amp; mobile phases</li> <li>• Instrumental requirements for packed and capillary columns</li> <li>• Capillary column inlets (split, splitless, on- column, direct injection, electronic pressure control)</li> <li>• Programmed-temperature vaporizer, large volume injections.</li> <li>• Packed column inlets /column selection</li> <li>• Classification and selection of stationary liquid phases and adsorbents</li> <li>• Capacity and analysis time</li> </ul> </li> </ul> | <ul style="list-style-type: none"> <li>▶ Capillary Column               <ul style="list-style-type: none"> <li>• Capillary column selection</li> <li>• Chromatographic parameters affecting column                   <ul style="list-style-type: none"> <li>• performance</li> </ul> </li> <li>• Effect of capillary column ID, film thickness, length &amp; choice of carrier gas on resolution</li> <li>• Capillary column rinsing, rejuvenation, care and maintenance</li> </ul> </li> <li>▶ Detectors               <ul style="list-style-type: none"> <li>• Fundamentals of detector responses</li> <li>• Types of detectors</li> <li>• Detectors used for various analysis</li> </ul> </li> <li>▶ Computer Assistance in Gas Chromatography               <ul style="list-style-type: none"> <li>• Internet guidance</li> <li>• Software for prediction and optimization of separations</li> </ul> </li> <li>▶ Qualitative and Quantitative Analysis               <ul style="list-style-type: none"> <li>• Qualitative analysis</li> <li>• Quantitative analysis methods</li> </ul> </li> </ul> |
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\*NOTE: This course covers gas chromatography, not the technique of gas chromatography-mass-spectrometry (GC-MS). Modern Practice of Gas Chromatography; 4th Edition, Robert L. Grob and Eugene F. Barry, Eds.; John Wiley & Sons: New York, 2004. ISBN 0-471-22983-0

### ABOUT THE INSTRUCTORS

**Dr. Eugene F. Barry** is Professor of Chemistry and Chairman of the Chemistry Department at the University of Massachusetts Lowell. He received his B.S. in Chemistry from Villanova University (1967) and a Ph.D. in Analytical Chemistry from the University of Rhode Island (1970). In collaboration with the late Robert L. Grob, he is co-editor of *Modern Practice of Gas Chromatography*, Fourth Edition and co-author of the book, *Columns for Gas Chromatography: Performance and Selection*, both published by John Wiley. He has taught at the Pittsburgh Conference and the Eastern Analytical Symposium. During his tenure at the University of Massachusetts Lowell, Dr. Barry has taught a wide variety of courses in Analytical Chemistry, including graduate level courses in chromatography and separation methods, his primary area of research. His current research interests include GC-MS, computer-assisted optimization of separations by capillary GC, high-speed gas chromatography, enhanced oil recovery in addition to geological and oceanic sequestration of carbon dioxide and the determination of organics in challenging matrices, such as cement and concrete. He is author of over 100 research publications and several patents.

**Dr. Mary A. Kaiser** is a Senior Research Fellow in DuPont's Corporate Center for Analytical Sciences in Wilmington, Delaware. She received the Ph.D. under the direction of Dr. Robert L. Grob from Villanova University. She has over years of analytical science experience in industry. She co-authored a book on environmental analysis using GC and LC and has published over 55 papers and given over 95 technical presentations. She taught at the University of Delaware, the Society of Environmental Toxicology and Chemistry, the Chromatography Forum of the Delaware Valley, the Pittsburgh Conference and the Eastern Analytical Symposium. She served as President of the Chromatography Forum of the Delaware Valley, FACSS governing board chair, chair of the Division of Analytical Chemistry, American Chemical Society and President of EAS. She was awarded the Villanova University Founders Award, the Chromatography Forum of the Delaware Valley Award, the ACS Division of Analytical Chemistry service award, and the Delaware Section ACS award.

This course is dedicated to the late Dr. Robert Grob in honor to his years of service to academics, industry, the GC community and Eastern Analytical Symposium.

### **LC/MS: Theory, Instruments and Applications**

***Two-Day Course E10-02, Sunday and Monday, November 14 and 15, 2010, 8:30am – 5:30pm***

Dr. Guodong Chen, Bristol-Myers Squibb, Princeton, NJ

Mr. Michael Balogh, Waters Corporation, Milford, MA

Dr. Ragu Ramanathan, Bristol-Myers Squibb, Princeton, NJ

Dr. Birendra N. Pramanik, Merck & Co., Kenilworth, NJ

### COURSE DESCRIPTION

This course is designed to be an introduction to the theory and practical implementation of LC/MS and LC/MS/MS technology in the laboratory. It emphasizes problem-solving skills with examples encountered in industrial and academic research including characterization of trace level drug substance impurities and degradation products, identification of drug metabolites, and the analysis of natural products and bio-molecules. The interpretation of mass spectra will be illustrated with practical examples. In addition, structure determination of proteins and peptides will be presented. This course will focus on atmospheric pressure ionization interfaces including electrospray and atmospheric pressure chemical ionization, and will survey the various mass analyzer options. This course will address issues regarding the coupling of capillary HPLC, microbore HPLC, and standard 4.6 mm chromatography. A thorough coverage of approaches toward method development for both qualitative and quantitative analysis of pharmaceutical products and biopolymers will provide a good starting point for understanding the practical issues facing implementation of LC/MS in the laboratory. Furthermore, an overview of the current state-of-the-art of automating the LC/MS laboratory including the interfacing of automated sample preparation devices will be provided. Finally, this course will cover technological advancement in biological mass spectrometry combined with separation techniques for analyzing proteins and peptides.

### WHO SHOULD ATTEND

This course is designed for practicing LC/MS chemists (new users, chromatographers, analytical chemists, protein chemists, and laboratory managers).

### TOPICS

- ▶ Introductions to Liquid Chromatography (LC) / Mass Spectrometry (MS)
- History
- Instrument overview: sector, ion trap and TOF

- ▶ Introductory Theory
  - Ionization
  - Electron ionization (EI)
  - Atmospheric pressure ionization API (ESI, APCI)

- ▶ Mass Analyzers
  - Quadrupoles
  - Magnetic sectors
  - Ion trap
  - Ion cycotron resonance (ICR)
  - Time-of-flight
  - Orbitrap
- ▶ LC/MS Method Development
  - Issues
  - Electrospray ionization (ESI)
  - Atmospheric pressure chemical ionization (APCI)
- ▶ Automation and High Throughput Sample Analysis
  - Sample preparation
  - Development of high-throughput chromatography
- ▶ Tandem Mass Spectrometry (MS/MS) and LC/MS/MS
  - ▶ Sample Preparation for LC/MS
  - ▶ Application in Drug Metabolism
  - ▶ Applications—Small Molecules, Pharmaceuticals,
  - ▶ Natural Products (Structure Elucidation, Identification and Quantitation)
  - ▶ Applications—Proteins and Peptides
    - Protein characterization and structural problems
    - Non-covalent interactions and drug discovery process
    - Proteomic

### ABOUT THE INSTRUCTORS

**Dr. Guodong Chen** (Course Director) has extensive pharmaceutical research experience in major pharmaceutical companies, including Eli Lilly and Co., Schering-Plough (now Merck & Co.) and Bristol-Myers Squibb. He is currently heading a mass spectrometry group at Bristol-Myers Squibb's Princeton site, providing mass spectrometric/analytical support to drug discovery and development programs in small molecule pharmaceuticals and biologics. He is the author and/or co-author of over 50 research publications covering the broad area of mass spectrometry and analytical chemistry. He authored/co-authored nine book chapters. He has over 55 presentations at conferences and academic institutes. He also organized/chaired scientific sessions at various forums, including major sessions on mass spectrometry of small molecule pharmaceuticals and biologics at Eastern Analytical Symposium, Pittsburgh Conference on Analytical Chemistry and Applied Spectroscopy, American Society for Mass Spectrometry (ASMS) conference and American Chemical Society (ACS) conference. Dr. Chen was the Chairperson of the North Jersey Section of ACS Mass Spectrometry Discussion Group (2004) and in 2006, he received Early Career Award in Mass Spectrometry. He was an invited Analytical Chemistry Program Chair for ACS MARM Conference (2005) and elected President of Chinese American Chemical Society-Tri State (2007). He serves as founding coordinator for ASMS Protein Therapeutics Interest Group (2009-2011). Dr. Chen was a recipient of Schering-Plough President's Award for Discovery, the highest scientific award at Schering-Plough. He received his Ph.D. in Analytical Chemistry/Mass Spectrometry from Purdue University under the direction of Professor R. Graham Cooks.

**Mr. Michael Balogh** is the principal scientist and LC/MS Technology Development Manager in Waters Strategic Business Development Group. His work over the past 20 years has appeared in the *Journal of Nuclear Medicine*, *Journal of Chromatography*, *Analytical Chemistry*, *LCGC*, and *Rapid Communications in Mass Spectrometry* among others. Since 1995, Michael has been the chair and co-organizer of LC/MS interests for the American Society for Mass Spectrometry (ASMS). He has taught courses in LC/MS fundamentals and practice and has been an invited speaker at the British Mass Spec Society and Australian/New Zealand Mass Spec Society, and has been appointed to the scientific advisory board for *LCGC* magazine and *PharmaGenomics*. His current interests involve multi-mode ionization for mass spectrometry, an area where he has developed patented technology.

**Dr. Ragu Ramanathan** received a B.Sc. in Chemistry from the University of Southern Mississippi and a Ph.D. in Physical Chemistry/Mass Spectrometry from the University of Florida. His graduate research focused on coupling of electrospray ionization (ESI) to Fourier transform ion cyclotron resonance (FTICR) mass spectrometer. After spending three years as a postdoctoral research fellow with Professor Michael L. Gross at the Washington University, St. Louis, Missouri, Dr. Ramanathan managed the Center for Advanced Mass Spectrometry at the Analytical Bio-Chemistry Laboratories, Columbia, Missouri. In 1998, Dr. Ramanathan joined Schering-Plough Research Institute's (now Merck) Drug Metabolism and Pharmacokinetics (DMPK) Department and completed his tenure as a senior principal scientist in 2008. While at Schering-Plough, Dr. Ramanathan was involved in the application of LC/MS for profiling and characterization of metabolites of drug candidates in the preclinical development and clinical stages. Dr. Ramanathan was with Pfizer Global Research and Development from 1999 to 2002 as a group leader of the Ann Arbor site biotransformation group. Dr. Ramanathan is currently an associate director at the Bristol-Myers Squibb, Co. and is responsible for elucidating biotransformation pathways of development drug candidates. Dr. Ramanathan's accomplishments include 35 peer-reviewed papers, 10 book chapters, a book entitled "Mass Spectrometry in Drug Metabolism and Pharmacokinetics" and over 60 oral/poster presentations. He also served as a chairperson for the North Jersey ACS Mass Spectrometry Discussion Group and as a chairman for DMPK sessions of the American Society for Mass Spectrometry and Eastern Analytical Symposium meetings.

**Dr. Birendra N. Pramanik** has been working for Schering-Plough Research Institute (now Merck & Co.) in the area of mass spectrometry since 1980. He is currently a Distinguished Fellow. He has developed a strong mass spectrometry program to support projects from chemical research, chemical development, biology and biotechnology using a wide range of MS techniques (FAB, ESI, APCI, MALDI, LC/MS, LC/MS/MS, and HRMS). He has published over 130 research papers in mass spectrometry, including chapters in books. Dr. Pramanik is a co-editor of a book on Applied Electrospray Mass Spectrometry (Marcel Dekker, Inc., New York, 2002). He has been an invited speaker at national and international meetings. He has served as a chairperson for the North Jersey ACS Mass Spectrometry group and as chairman for major sessions of the American Society of Mass Spectrometry meetings. He received his Ph.D. in Organic Chemistry under Professor Ajay K. Bose from Stevens Institute of Technology in 1977.

## Modern HPLC Method Development in Pharmaceutical Analysis

**One-Day Course E10-03, Sunday, November 14, 2010, 8:30am – 5:30pm**

Dr. Michael W. Dong, Genentech, Small Molecule Analytical Chemistry, S. San Francisco, CA  
Dr. Henrik T. Rasmussen, Johnson & Johnson Pharmaceutical Research & Development, LLC, Raritan, NJ

### COURSE DESCRIPTION

This is a one-day HPLC method development course at an intermediate/advanced level. The course reviews relevant concepts, best practices and tricks-of-the-trade to help the attendees to become more successful in developing difficult ICH-compliant stability-indicating HPLC methods for pharmaceuticals (small-molecule drug substances and products). The focus is on methods for new chemical entities, complex molecules with one or more chiral centers, and drug products with multiple APIs. Though case studies are taken from pharmaceutical analysis, concepts presented in this course would be useful to attendees from other industries.

### WHO SHOULD ATTEND

This course is intended for analysts, managers, regulators and researchers using HPLC in the pharmaceutical laboratory (or other industries). At least two (2) years of practical hands-on experience is suggested as a prerequisite.

### TOPICS

- ▶ Course Introduction/Overview
- ▶ Key Concepts and Modern Trends in HPLC Method Development
  - Common-sense but often-neglected corollaries in HPLC separations
  - Practical concepts ( $k'$ ,  $\alpha$ ,  $n$ ,  $R_s$ ,  $V_M$ , peak volume,  $H$ ,  $dp$ , method orthogonality), and mobile phase parameters (organic modifiers, pH)
  - Column fundamentals and selection
  - UV detector fundamentals and wavelength selection
  - Important instrumental considerations: system dispersion and dwell volume
  - Modern trends in method development
- ▶ ICH Guidelines
  - ICH guidelines Q2A, Q2B, Q3A, Q3B and interpretation
- ▶ The Traditional Method Development Approach and Case Studies
  - Defining method types/goals and gathering pertinent sample / analyte information
  - Scouting gradient and getting the first chromatogram
  - Method fine-tuning and optimization (Solvent strength/type, pH, buffer/additive, F, T,  $t_G$ , column screening)
  - Demonstrating method specificity and stability-indicating capability (how to conduct rapid forced degradation studies)
  - Use of simulation software to facilitate selectivity tuning and column optimization
- Final method adjustments for ICH compliance methods (peak shape, LOQ, analysis time)
- Case studies for NCEs, complex formulations and drug products with multiple APIs
- ▶ Phase Appropriate Method Development and Validation
  - Forced decomposition studies
  - Development of orthogonal methods
  - Progressive validation strategies
- ▶ The 3-Prong Approach and Tools for Efficient Method Development
  - Road map for efficient method development - the 3-prong approach (Generic IPC gradients, Fast LC isocratic, multi-segment gradients)
  - Automated column and mobile phase screening systems
  - Case study on method support for molecules with multiple chiral centers using achiral and chiral methods to assess and control starting materials, intermediates and final APIs
- ▶ Method Robustness Testing
  - Critical control parameters for HPLC
  - Use of Experimental designs for establishing Robustness
- ▶ New Developments in HPLC
  - HILIC, monolith, sub-3  $\mu\text{m}$  and sub-2  $\mu\text{m}$  packing, fused core particles, ultra high-pressure LC, high-temperature LC, parallel analysis, Lab-on-a-chip

### RECOMMENDED TEXT

1. L. R. Snyder, J. J. Kirkland & J. L. Glajch, *Practical HPLC Method Development, 2nd Ed.*, Wiley-Interscience, NY, 1997.
2. M. W. Dong, *Modern HPLC for Practicing Scientists*, Wiley, New Jersey, June 2006.
3. S. Ahuja and H. Rasmussen (ed.), *HPLC Method Development for Pharmaceuticals*, Academic Press, 2007.

### ABOUT THE INSTRUCTORS

**Dr. Michael W. Dong** (Lead instructor) is a Senior Scientist at Genentech, Small Molecule Drug Discovery, South San Francisco, CA. His research interests are in Fast LC, ultra-high-pressure LC, rapid HPLC method development and chiral separations. He was formerly Research Director at Synomics Pharmaceutical Services, Research Fellow/Group Leader at Purdue Pharma, Senior Staff Scientist at Applied Biosystems / Perkin-Elmer, and section-head in Hoechst Celanese. He holds a B.Sc. in Chemistry from Brooklyn College and a Ph.D. in Analytical Chemistry from City University of New York Graduate Center. He has conducted numerous HPLC training courses at national meetings (ACS, PittCon, EAS, AAPS) on advanced HPLC, Fast LC / HTS, stability testing and HPLC method development. He pioneered Fast LC and has over 80 publications in chromatography, pharm analysis and analytical chemistry. He authored a best-seller in chromatography – “Modern HPLC for Practicing Scientists”, Wiley, 2006 and co-edited Handbook of Pharmaceutical Analysis by HPLC, Elsevier/Academic Press, 2005.

**Dr. Henrik T. Rasmussen** is a Scientific Fellow II at Vertex Pharmaceuticals Inc., in Cambridge, MA. He is currently responsible for the Analytical Development of several Phase I and Phase II compounds, including development of phase appropriate HPLC methods. He holds a B.S. in Chemistry (Magna Cum Laude) from Delaware Valley College of Science and Agriculture and a Ph.D. in Analytical Chemistry from Virginia Tech. His current research interests focus on means of improving accuracy, precision, and robustness of HPLC methods, on systematic approaches for achieving orthogonal chemical separations, and on the use of experimental designs and automation. He has (co-)authored over 20 publications and book chapters, has presented over 30 (invited) papers and posters at international symposia, and has taught numerous HPLC short courses. Dr. Rasmussen served as President of the 2003 Eastern Analytical Symposium and Exposition.

## Anatomy of Modern Reversed- Phase Columns: Understanding Their Role in HPLC

**One-Day Course E10-04, Sunday, November 14, 2010, 8:30am – 5:30pm**

Dr. Brian A. Bidlingmeyer, Agilent Technologies, Inc., Wilmington, DE  
Dr. Richard A. Henry, Penn State University, State College, PA

### COURSE DESCRIPTION

The heart of any HPLC system is the column. Understanding the reversed-phase column contributes greatly to successful separations and rugged HPLC methods. This short course treats the column as the center of the system and focuses on how the column is made, how it contributes to the system and how it is used successfully. Approximately half of the column course will focus on the “nuts and bolts” and will cover topics such as particle size, pore size, the base particle (silica, polymer, hybrid, others), surface chemistries, hardware and geometries. The other half will discuss choosing a column and stationary phase for the task at hand, development of a rugged method, column troubleshooting, and proper column care and use.

### WHO SHOULD ATTEND

This one-day course will benefit analysts, managers, regulators, and researchers, who perform HPLC and evaluate data related to pharmaceutical and other products. It will be particularly useful to those who develop or desire to develop their own HPLC methods. The course was designed for analytical chemists, biochemists and others who have some experience in HPLC. To get the most out of the course, it is highly recommended that you have at least one year of HPLC operating experience.

### TOPICS

- ▶ Overview of HPLC and role of the column
  - Terminology- Principles of sample retention and resolution (what makes up a column)
  - Types of column backbones
- ▶ How silica is made
- ▶ How silica is bonded
- ▶ How the column is used
- ▶ How to choose the best column and stationary phase for different solutes
- ▶ What changes in UHPLC columns
- ▶ Role of mobile phase, including temperature and viscosity
- ▶ Modes and method development- emphasis on RP
- ▶ Troubleshooting the separation and the column
- ▶ Care and use for long column life
- ▶ General questions from attendees

### ABOUT THE INSTRUCTORS

**Dr. Brian A. Bidlingmeyer** is employed by Agilent Technologies in Wilmington, DE. He is an accomplished separation scientist who has work experience in the chemical, pharmaceutical and instrumentation industries. He has published 2 books and more than 80 papers. Brian is the Chairman-elect of the Separations Science Subdivision of the American Chemical Society's Analytical Division and is active in the ASTM committee concerning chromatographic practices. He has made significant contributions to the practice and understanding of modern HPLC and has received numerous awards including the Heinrich Emmanuel Merck Prize for contributions to analytical chemistry, the International Ion Chromatography Award for contributions to that area, and an IR 100 Award for a new method for amino acid analysis (Pico Tag Method). He is presently an associate editor of the *Journal of Chromatographic Science*.

**Dr. Richard A. Henry** received his B.S. degree in Chemistry from Juniata College in 1963 and Ph.D. in Analytical Chemistry from The Pennsylvania State University in 1966. After a postdoctoral year in separations at Purdue University with Professor L. B. Rogers, he joined DuPont at the Experimental Station in Wilmington, DE and became one of the first employees of the Analytical Instrument Products Division. Dick worked closely with Dr. Jack Kirkland and others in the development of HPLC columns and packing materials until about 1973. After about 10 years on the west coast with Spectra-Physics, he joined the Penn State University chemistry faculty and became Director of Analytical Laboratories where he taught Instrumental Analysis to chemistry majors. He also founded Keystone Scientific, Inc. in 1985 to develop and market HPLC columns and related separation technology. He retired from both Penn State University and Keystone Scientific in 2002, and remains active teaching short courses on separation technology and as a consultant. Dick has research interests in

separation mechanisms and all applications of the latest HPLC column technology. He has special interest in the rapidly growing fields of UHPLC, chiral HPLC, LC-MS, and multidimensional separation methods. He served two terms as Chairman of the ACS Subdivision on Separations (1998-2002) and has also served on its Executive Committee.

## Chemometrics without Equations

### **One-Day Course E10-05, Sunday, November 14, 2010, 8:30am – 5:30pm**

Dr. Donald Dahlberg, Lebanon Valley College (Emeritus), Campbelltown, PA  
Dr. Barry M. Wise, Eigenvector Research, Manson, VA

#### **COURSE DESCRIPTION**

This course concentrates on two areas of chemometrics: (1) exploratory data analysis and pattern recognition, and (2) regression. Participants learn to apply techniques such as principal-component analysis (PCA), principal-components regression (PCR), and partial least squares (PLS) regression safely. Examples include problems drawn from process monitoring and quality control, predicting product properties, and others. This course will finish with a short section on how to apply these models for on-line predictions, multivariate statistical process control and inferential sensing.

#### **WHO SHOULD ATTEND**

This course on Chemometrics Without Equations (or Hardly Any) is designed for those who wish to explore the problem-solving power of chemometric tools, but are discouraged by the high level of mathematics found in many software manuals and texts. Course emphasis is on proper application and interpretation of chemometric methods as applied to real-life problems. The objective is to teach in the simplest way possible so that participants will be better chemometrics practitioners and managers.

#### **TOPICS**

- ▶ Introduction
  - What is chemometrics
  - Resources
- ▶ Pattern Recognition Motivation
  - What is pattern recognition
  - Relevant measurements
  - Some statistical definitions
- ▶ Principal-component Analysis
  - What is PCA
  - Scores and loadings
  - Interpretation
  - Supervised and unsupervised pattern recognition
  - Examples
- ▶ Regression
  - What is regression
  - Classical least squares (CLS)
  - Inverse least squares (ILS)
  - Principal components regression (PCR)
  - Partial least squares regression (PLS)
  - Examples
- ▶ On-line Application
  - Clients and servers
  - Available technologies (COM, ActiveX, etc.)
  - Using MATLAB and PLS\_Toolbox on line
- ▶ Summary

#### **ABOUT THE INSTRUCTORS**

**Dr. Donald Dahlberg** (Course Director) is Professor Emeritus of Chemistry at Lebanon Valley College. Dr. Dahlberg earned a B.S. in Chemistry from the University of Washington and a Ph.D. in Physical Chemistry from Cornell University. After decades of doing research in the area of Physical Organic Chemistry, he got involved in Chemometrics while on sabbatical in 1988 at the Center for Process Analytical Chemistry at the University of Washington. There he learned chemometrics in the Bruce Kowalski group (co-founder of chemometrics). Upon returning to LVC, he taught chemometrics to undergraduate students for over a decade. Although retired from the classroom, he continues to do consulting and supervises undergraduate research in industrial chemometrics. Dr. Dahlberg wrote and teaches this course so that those not fluent in matrix algebra can take advantage of the powerful tool of chemometrics.

**Dr. Barry M. Wise**, PLS\_Toolbox creator and co-founder of Eigenvector Research, holds a doctorate in Chemical Engineering and has experience in a wide variety of applications spanning chemical process monitoring, modeling and analytical instrument development. He has extensive teaching experience, having presented over 50 chemometrics courses. Dr. Wise has also taught MATLAB and SIMULINK for The MathWorks, Inc.

## Enhanced Productivity by Design in the Analytical Laboratory: Design of Experiments for Analytical Chemists

### **One-Day Course E10-06, Sunday, November 14, 2010, 8:30am – 5:30pm**

Dr. Zenaida Otero Gephardt, Rowan University, Glassboro, NJ

**COURSE DESCRIPTION**

Experimentation in the analytical laboratory can be expensive and labor intensive. This is especially true for complex and highly regulated analyses. Optimization of experimental design techniques offers the advantage of minimizing the number of experiments required in the laboratory. This improves the efficiency of the laboratory staff and reduces the cost of operation. Experimental design techniques often yield better data, and results that are more meaningful and easier to interpret. Many design techniques are simple to use and only require a calculator or spreadsheet software. Experimental design techniques allow laboratory staff to focus on experimental development and to mainstream laboratory operations. This course will provide participants with analysis tools they can immediately use in their laboratories including an introduction to available experimental design software.

**WHO SHOULD ATTEND**

Chemists and laboratory supervisors will benefit from this course. Researchers and technical personnel who design and carry out experiments will also benefit.

**TOPICS**

Interactive exercises and practical examples will be used throughout the course.

- ▶ Background and Introduction to Experimental Design Optimization
- ▶ Simple Optimization Techniques and Applications
- ▶ Identifying Key Variables Using Optimization Techniques and Applications
- ▶ Optimization Techniques for Complex Systems and Applications
- ▶ Optimization Techniques for Experiments with Mixtures and Applications

**ABOUT THE INSTRUCTOR**

**Dr. Zenaida Otero Gephardt** Dr. Zenaida Otero Gephardt is Associate Professor of Chemical Engineering at Rowan University (Glassboro, NJ) and consultant through Otero Keil Associates. Her research focuses on optimization, development and mathematical modeling of chemical processes and laboratory techniques. She has developed statistical models and experimental designs for a wide range of chemical processes including high pressure, supercritical systems and multi-phase systems. Dr. Gephardt has worked with a wide range of system scales ranging from bench scale laboratory systems to large-scale industrial applications. Dr. Gephardt has over 12 years experience with analysis and optimization applications in the chemical process industry. She teaches on-site courses for industry and provides analysis and experimental design support. Dr. Gephardt holds a Ph.D. in chemical engineering from the University of Delaware and is a registered Professional Engineer in Delaware.

## Physical Characterization and Analytical Test of Pharmaceutical Solids

**One-Day Course E10-07, Sunday, November 14, 2010, 8:30am – 5:30pm**

Dr. Steve R. Byrn, Purdue University, West Lafayette, IN  
Dr. Xiaoming (Sean) Chen, OSI Pharmaceuticals, Inc, Cedar Knolls, NJ

**COURSE DESCRIPTION**

Physical characterization and analytical test of pharmaceutical solids are essential for drug research and development. Solid characteristics such as polymorphism, formation of hydrate and solvate, and crystallinity have profound impact on the quality attributes of drug substances and drug products such as solubility, dissolution, bioavailability, processability, and stability. Characterization of those solid state properties is critical for selection and manufacture of desirable solid forms for development. This short course presents some essential knowledge for pharmaceutical solids. It also introduces methods of analysis at solid state such as X-Ray powder diffraction, differential scanning calorimetry, thermogravimetric analysis, microscopy, infrared spectroscopy, Raman spectroscopy, and solid state NMR. Applications of those techniques in the final form selection of drug substances and the mixture analysis of drug products are discussed.

**WHO SHOULD ATTEND**

This one-day course will benefit formulation scientists, process engineers, analysts, QA and QC managers, regulators, and researchers, who perform process development and manufacture of drug substances, develop formulation of drug products, conduct analytical testing and method development, set up stability program, and evaluate stability data of drug substances and products.

**TOPICS**

- ▶ Pharmaceutical Solids–Introduction
  - Polymorphs
  - Solvates and hydrates
  - Salt formation and co-crystal
  - Amorphous forms
- ▶ Methods of Analysis
  - Crystal packing, unit cell, X-ray powder diffraction
  - Differential scanning calorimetry and thermogravimetric analysis
  - Microscopy
  - Infrared spectroscopy and Raman spectroscopy
  - Solid-state NMR

### ABOUT THE INSTRUCTORS

**Dr. Stephen R. Byrn** is Charles B. Jordan Professor of Medicinal Chemistry in the School of Pharmacy, Purdue University, West Lafayette, Indiana. He is also Head of the Department of Industrial and Physical Pharmacy. He received his B.A. degree in Chemistry from DePauw University and his Ph.D. degree in Chemistry from the University of Illinois, Urbana. He did postdoctoral research at UCLA. His research focuses on solid state chemistry, polymorphism, stability, manufacturing science, quality by design, and medicinal chemistry. Dr. Byrn opened up the field of solid state chemistry of drugs with his research and books of that title (first edition, 1982, second edition, 2000). Dr. Byrn has founded and directed several programs at Purdue University including CAMP, the Center for AIDS Research, the Molecules to Market program, and Purdue's graduate programs in regulatory and quality compliance. He is also one of the founders and a member of the executive committee of NIPTE (National Institute for Pharmaceutical Technology and Education). He continues to be involved in educating scientists in solid state chemistry, methods of analysis, and regulatory science. Dr. Byrn has served as chair of the Pharmaceutical Sciences Advisory Committee to the FDA and Chair of the Drug Substances Technical Committee, Product Quality Research Initiative. Dr. Byrn has extensive experience as a consultant in the pharmaceutical industry and currently serves as Purdue's representative to the USP. Dr. Byrn is co-founder of SSCI, Inc. (Solid State Chemical Information) a cGMP research and information Company specializing in polymorphism, crystallization, analysis, problem solving and regulatory issues. SSCI, Inc. is now owned by Aptuit and Dr. Byrn serves as Head of the Aptuit Scientific Advisory Board. Dr. Byrn is also a technical founder of Andara now owned by Cyberkinetics, Inc. Andara specializes in devices and drugs for the treatment of spinal cord injury and CNS diseases.

**Dr. Xiaoming (Sean) Chen** received his Ph.D. in Industrial and Physical Pharmacy from Purdue University in 2000. He has worked as a project leader in discovery support and preformulation at Schering-Plough Research Institute for five years. He has contributed the nomination of five NCE for development and received one President Award, one Impact Award and Three Excellence Awards from Schering-Plough Research Institute. He has also worked in Exploratory Formulation group of Schering-Plough for three years, leading formulation development of two important line extension projects. Currently, Dr. Chen is a Senior Development Investigator in Pharmaceutical Development of OSI Pharmaceuticals. Dr. Chen is an expert in physical characterization of solids, crystal form and salt selection, and controlled release formulation. He has published over a dozen of papers in peer-reviewed journals. Dr. Chen is a member of AAPS and has served in PDD award committee for two years.

## Effective Laboratory Audits and Inspections

**New One-Day Course E10-08, Sunday, November 14, 2010, 8:30am – 5:00pm**

Mr. Ken Christie, VTS Consultants, Inc., Amherst, MA

### COURSE DESCRIPTION

A vital part of a quality system is the requirement for auditing of suppliers to assure their quality practices meet the expectations of one's company. In an attempt to reduce costs, companies today are increasingly outsourcing both needed services and expanding their dependency on suppliers. Laboratories, based on the data they provide that impacts the use of raw materials and components or the release of final products is an increasing area of focus during regulatory inspections. This course will help provide a template in terms of how to audit such suppliers, manufacturers and laboratories that many companies depend on. It will focus on current regulatory expectations and responsibilities for these audits, along with reviewing the main points to cover during the audit. The course will examine expectations as defined in 21 CFR 58, and ISO 17025. Auditing do's and don'ts will be covered and participants will be given a chance to raise questions regarding their current practices and procedures.

### WHO SHOULD ATTEND

This one-day course will benefit laboratory analysts, QA and QC managers, regulators, and manufacturers, who depend on various services or products that are performed or obtained by outside services or suppliers. Companies must remember that they are responsible for the quality of these services or components as they are the ones who are ultimately liable for the end product.

### TOPICS

- ▶ Regulatory Requirements and Guidelines.
  - Review of expectations as defined in 21 CFR 58.
  - Review of common industry practices as recommended by ISO 17025.
  - Discuss the main objectives for conducting audits.
- ▶ Preparing for Audits of Suppliers/Labs.
  - Learn how to prepare for conducting an audit and assembling the audit team.
  - Define the areas to be audited per a check list.
  - Review the main areas of focus and typical areas of deficiencies.
- ▶ Review Practices Required for an Effective Audit Program.
  - Review do's and don'ts during the audit.
  - Prepare final report and classifications of findings.
  - Discuss follow-up activities for marginally acceptable suppliers.
  - Discuss regulatory ramifications for non-acceptable suppliers.
- ▶ Interactive Exercises and Discussion - Participants will openly discuss questions associated with their current auditing practices or have questions answered regarding results.

### ABOUT THE INSTRUCTOR

**Mr. Kenneth Christie** has over 20 years of sterile manufacturing experience in the areas of Quality Assurance and Validation Management in the pharmaceutical and biotechnology industries. Mr. Christie is currently the Chief Operating Officer for VTS Consultants, Inc located in Amherst, MA. He is responsible for both business development planning and Validation and Regulatory Consulting services on a global basis. Specifically, his responsibilities include quality system auditing, GMP training, and serving as a subject matter expert for aseptic and solid dosage processing equipment, utilities, and systems.

Prior to joining VTS, Mr. Christie was the Validation Manager at Parke-Davis' Sterile Products Facility in Rochester, MI. While there, he was involved in the review and approval of all facility, equipment, and system commissioning/qualification activities. Additional responsibilities included routine interaction with the FDA and European inspectors, corporate management and third party contract-manufacturing representatives to defend validation practices and to assure regulatory compliance for the manufacture of aseptically produced products.

Mr. Christie is a speaker and trainer for several professional organizations in the US, Canada, Europe, and Asia and is a published author of several articles dealing with the challenges of aseptic processing. Additionally, Mr. Christie serves as a member of the ISPE Professional Certification (PCC) Commission Examination Development Committee (EDC), which is industry's first attempt to "certify" industry professionals based on proven regulatory knowledge. He possesses a BS degree in Biology from Shippensburg State University (PA) and an Executive MBA degree from Michigan State.

## **Two-Dimensional Correlation Spectroscopy**

**One-Day Course E10-09, Sunday, November 14, 2010, 8:30am – 5:30pm**

Dr. Isao Noda, Procter & Gamble Company, West Chester, OH

### COURSE DESCRIPTION

Two-dimensional (2D) correlation spectroscopy is a relatively new addition to the field of optical spectroscopy. In 2D spectroscopy, a spectrum is obtained as a function of two independent spectral variables, such as wavenumbers. Peaks are spread over the second dimension, thereby simplifying the visualization of complex spectra consisting of many overlapped bands, and thus enhancing spectral resolution. Relationships among various spectral bands are characterized by the presence or absence of 2D cross peaks. The new correlation formalism provides a unified model-free path to the construction of useful 2D correlation spectra for wide ranges of spectral data, obtained by common electromagnetic probes (e.g., IR, Raman, NIR, UV, visible, fluorescence, x-ray, NMR, and so on) under various experimental conditions. In fact, this technique can also be extended to the analysis of data outside of spectroscopy, such as chromatography and microscopy. In this short course, an overview and detailed tutorial will be provided for this powerful and versatile technique with many application examples, including the study of synthetic polymers, bio-molecules, surfaces, and many other industrially important systems. The course includes the hands-on exercise of actual 2D correlation analysis by using free software.

### WHO SHOULD ATTEND

The course is intended for general audience with some basic technical background, including chemists, physicists, biologists, engineers, material scientists, and students at graduate or undergraduate level. Almost anyone who uses spectroscopic techniques in a part of their work will benefit from taking this course. Some basic mathematical tools, such as Fourier transform and correlation analysis, are used as a background, but no in-depth knowledge in mathematics is required.

### TOPICS

- ▶ Part 1. Basics
  - Introduction to 2D correlation spectroscopy
  - Background information to be a 2D spectroscopist
    - How to get started with 2D spectroscopy
    - Properties and interpretation of 2D correlation spectra
    - Computation and construction of 2D spectra
- ▶ Part 2. Case Studies of Application Examples
  - Phenomena studied include: chemical reactions, rheology and mechanical deformation, thermal effect such as melting and crystallization, electrochemistry, pressure induced effects, etc.
- Analytical probes used include: IR, NIR, Raman, fluorescence, NMR, and even chromatography.
- Systems analyzed include: synthetic and natural polymers, biomolecules, colloids and solutions, and many more.
- ▶ Part 3. Advanced Topics (optional)
  - Fundamental theory of 2D correlation analysis
  - New developments in 2D spectroscopy
- ▶ Part 4. Software Hands-on Tutorial
  - Demonstration of free 2D software

### RECOMMENDED TEXT

Although not an absolute requirement, the participant is strongly encouraged to obtain the textbook on the topic prior to attending the course.

I. Noda and Y. Ozaki, Two-Dimensional Correlation Spectroscopy — Applications in Vibrational and Optical Spectroscopy, Wiley: Chichester, UK, 2004.

### **ABOUT THE INSTRUCTOR**

**Dr. Isao Noda** was born in Tokyo, Japan. He came to the United States in 1969 and was graduated from Columbia University in the City of New York in 1974 with B.S. degree in chemical engineering. He also received his M.S. in bioengineering (1976), as well as M.Phil. (1978) and Ph.D. (1979) in chemical engineering from Columbia. In 1997 he received D.Sc. degree in chemistry from the University of Tokyo. He is currently a Research Fellow of the Procter and Gamble Company in Cincinnati, Ohio. His research interest is in the broad area of polymer science and spectroscopy. He is well known for the development of two-dimensional infrared (2D IR) correlation spectroscopy. He has also been actively involved in the research and development of a novel class of bio-based biodegradable plastics called Nodax™. He is a recipient of the 1991 William F. Meggers Award from the Society for Applied Spectroscopy and the 2002 Williams-Wright Award from the Coblenz Society. In 2002, he was appointed to the position of Honorary Adjunct Professor of the Department of Biological Science and Biotechnology at Tsinghua University in Beijing, China. He was selected as the 2005 Chemist of the Year by the Cincinnati Section of the American Chemical Society. He received the International Academic Cooperation and Exchange Medal in 2008 from the Chinese Chemical Society and Chinese Optical Society. Dr. Noda was the recipient of the 2009 New York Section of the Society for Applied Spectroscopy Gold Medal Award which was presented EAS.

## **High-Throughput Drug Analysis by LC/MS**

***New One-Day Course E10-10, Sunday, November 14, 2010, 8:30am – 5:30pm***

Dr. Perry G. Wang, US Food and Drug Administration, College Park, MD

### **COURSE DESCRIPTION**

The introduction of combinatorial chemistry technology has significantly increased the amount of compounds generated in pharmaceutical industry. Conventional analytical approaches simply cannot keep up. These circumstances have caused drug discovery and development to take on the shape of a bottleneck, like traffic through a toll booth. In order to break the bottleneck, a corresponding revolutionary improvement to the conventional methodology must happen.

High-throughput drug analysis is a new topic for drug discovery and development in the pharmaceutical industry. This one-day short course will mainly focus on the most recent significant advances of high-throughput sample preparation and drug analyses by LC/MS.

### **WHO SHOULD ATTEND**

This one-day course will benefit the scientists ranging from college students to professional in the fields of pharmaceuticals and biotechnology.

### **TOPICS**

- ▶ Overview
  - Introduction of high-throughput concept to pharmaceutical industry
  - Why do we need high-throughput analysis
  - The requirements for high-throughput analysis
  - Why do we use LC/MS or LC/MS/MS
- ▶ How to Develop a High-throughput LC/MS Method
  - The relationship of pKa and pH
  - MS analyzer selection and MS parameters optimization
  - HPLC,  $\mu$ HPLC and UHPLC
  - Solvent selection
  - Introduction of nanoelectrospray technology
  - Introduction of HPLC-Chip/MS system
  - Introduction of multiplexing systems
- ▶ High-throughput Sample Preparation
  - Protein precipitation
  - Liquid-liquid extraction
  - Solid phase extraction
  - Immobilized liquid extraction
  - Introduction to solid phase micro extraction
  - Disposable pipette extraction – DPX
- ▶ Special Topics
  - Monolithic chromatography for high-throughput analysis
  - Hydrophilic interaction liquid chromatography (HILIC) for biological samples
  - Ion suppression of biological samples
  - How to deal with urine samples

### **ABOUT THE INSTRUCTOR**

**Dr. Perry G. Wang** is a Chemist in the Office of Regulatory Science, Center for Food Safety and Applied Nutrition, US Food and Drug Administration (FDA). His interests include analytical method development and validation for drugs and constituents of foods and cosmetic products using advanced instrumentation. His expertise focuses on high throughput drug analysis by LC/MS/MS for the pharmaceutical industry.

Dr. Wang has authored more than 20 scientific publications. His most recent book entitled "High-Throughput Analysis in the Pharmaceutical Industry" was published by CRC Press in October 2008. He is currently editing three additional books, one entitled "Monolithic Chromatography and Its Modern Applications" with ILM Publications, which is scheduled for publication in April 2010; another one entitled "Hydrophilic Interaction Liquid Chromatography (HILIC) and Its Advanced Applications" with CRC Press, which will be published in July 2010; and the third one entitled "Combating Substandard and Counterfeit Pharmaceuticals: Challenges, Identification and Analysis" with ILM Publications, which is scheduled for publication in May 2011.

He has prepared, organized and presided over symposia for the Pittsburg Conference (PittCon) since 2006. He has been an invited speaker since 2004 at international conferences including the PittCon; Federation of Analytical Chemistry and Spectroscopy Societies (FACSS); Beijing Conference and Exhibition on Instrumental Analysis (BCEIA) and International Symposium on Chemical Biology and Combinatorial Chemistry (ICCBC). He has been invited to teach short courses for the PittCon and the American Chemistry Society (ACS) Annual Meetings. His current research focuses on developing analytical methods for constituents of cosmetics and dietary supplements.

Dr. Wang received his B.S. degree in Chemistry from Shandong University. He earned his M.S. and Ph.D. degrees in Environmental Engineering from Oregon State University, in Corvallis, Oregon, USA.

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## Advanced Excel®: Write Your Own Functions and Macros

**One-Day Course E10-11: Sunday, November 14, 2010, 8:30am – 5:30pm**

Dr. Robert de Levie, Bowdoin College, Brunswick ME

### COURSE DESCRIPTION

The flexibility of EXCEL® is mostly due to its excellent facilities for writing, debugging, and using custom functions and macros. This allows you to write the precise programs you need to solve your problems, or to write programs that others in your organization or field can use. This course will emphasize the most error-prone aspects of such writing, which involves data output and, even more, data input. A set of MacroMorsels will also be provided to illustrate many of these points. You will also learn how to incorporate existing data processing routines, such as those of the Numerical Recipes by Press et al., into your EXCEL® functions and macros, and how to test and debug your routines.

This is a hands-on course, with about half of the time devoted to practical exercises. Students should bring their own laptop computers, and will be informed by the instructor what Microsoft or free software tools to load. Students will get copies of all PowerPoint slides, and therefore will be able to concentrate on what is said rather than on taking notes.

### WHO SHOULD ATTEND

The course may benefit industrial and academic researchers, who want to get the most out of EXCEL® data analysis, and their scientific supervisors.

### TOPICS

- ▶ Survey: functions, subroutines, and macros
- ▶ Practice session: write your own functions
- ▶ Survey: the structure of VBA
- ▶ Practice session: write your own macros
- ▶ Survey: testing and debugging
- ▶ Practice session: testing and debugging
- ▶ Survey: incorporating existing code
- ▶ Practice session: incorporating existing code

### ABOUT THE INSTRUCTOR

**Dr. Robert de Levie** is an emeritus professor of chemistry at Georgetown University, where he worked for 34 years. For ten of those was the US editor of the Journal of Electroanalytical Chemistry, and he chaired the 1976 Gordon Research Conference on Electrochemistry. He has published some 160 scientific papers as well as a number of books, of which the latest is Advanced Excel for Scientific Data Analysis, 2<sup>nd</sup> ed., Oxford University Press 2008. Now semi-retired, he lives in Maine, where he is associated with Bowdoin College.

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## Putting Organic Chemistry into Perspective – A Review of Sophomore Organic Chemistry

**Two-Day Course E10-12, November 15 and 16, 2010, 8:30am – 5:30pm**

Dr. John R. Sowa, Jr., Seton Hall University, South Orange, NJ

### COURSE DESCRIPTION

Putting Organic Chemistry into Perspective is a course that reviews the fundamentals of organic chemistry for analytical chemists. Often, the chemistry of organic compounds must be considered when choosing analytical strategies. We will review the essential tools needed for understanding organic chemistry and communicating with organic chemists.

### WHO SHOULD ATTEND

This is an organic chemistry course for analytical chemists. Analytical chemists dealing with organic compounds and communicating or working on projects with those who synthesize them will find this course very useful.

### TOPICS

- ▶ Acid-base Chemistry
- ▶ Functional Groups
- ▶ Nomenclature
- ▶ Structures of Pharmaceuticals
- ▶ Stereochemistry
- ▶ Fundamental Organic Reactions
- ▶ Principles of Organic Chemistry that are Relevant to Chromatography will also be Discussed

### ABOUT THE INSTRUCTOR

**Dr. John R. Sowa, Jr.**, is an associate professor at Seton Hall University. He received a B.S. from Manhattan College and a Ph.D. from Iowa State University. He has taught an expanded version of this course at a local pharmaceutical company. His research interests include organic synthesis via homogeneous and heterogeneous catalysis, asymmetric synthesis and organoboron chemistry.

## Practical Enantiomeric Separations

**One-Day Course E10-13, Monday, November 15, 2010, 8:30am – 5:30pm**

Dr. Daniel W. Armstrong, University of Texas, Arlington, TX

### COURSE DESCRIPTION

Chirality is an inherent property of all living things. Hence, enantiomers that have the same physical and chemical properties (except for the rotation of plane polarized light) in an isotropic environment tend to have different biological properties. Consequently, the analysis, isolation, use and production of enantiomers is of fundamental importance in many areas of science and technology. This course will provide a basic introduction and background to chirality and a survey the methodologies used in enantiomeric separations and analysis.

### WHO SHOULD ATTEND

This one-day course will benefit pharmaceutical scientists, organic chemists, analytical chemists, biochemists, food scientists, environmental scientists, regulators QU and QC managers. It is assumed that everyone attending this course has a good basic knowledge of organic chemistry and chromatography.

### TOPICS

- ▶ An Introduction to Chirality (History)
- ▶ Nomenclature
- ▶ Brief Survey of Classes of Chiral Selectors used in LC, CE and GC
- ▶ Macrocyclic Chiral Selectors
- ▶ Linear Natural Polymeric Selectors
- ▶ Synthetic Polymer Selectors
- ▶  $\pi$ -Complex Chiral Selectors
- ▶ Analyzing Real World Samples
- ▶ SFC Enantiomeric Separations
- ▶ Chiroptical Detectors
- ▶ GC Enantiomeric Separations
- ▶ Discussion, Questions and Answers

### ABOUT THE INSTRUCTOR

**Dr. Daniel W. Armstrong** is the Robert A. Welch Professor of Chemistry at the University of Texas at Arlington, TX. He received his B.S. (1972) from Washington and Lee University and his M.S. (1974) and Ph.D. degrees (1977) from Texas A&M University. He has over 420 publications including 22 book chapters, 1 book (*Use of Ordered Media in Chemical Separations*) and 8 patents. He has given over 410 invited seminars and colloquia worldwide. He is considered the "Father" of pseudophase (micelle and cyclodextrin-based) separations. He elucidated the first chiral recognition mechanism for cyclodextrins. He also first developed macrocyclic antibiotics as chiral selectors. He is one of the world's leading authorities on the theory, mechanism and use of enantioselective molecular interactions. Over 30 different LC and GC columns originally developed in his laboratories have been commercialized and/or copied worldwide. His work and columns were in part responsible for the chromatography and electrophoresis-lead revolution in chiral separations over the last two decades. This work provided the impetus for the FDA's regulatory changes regarding chiral drug development in 1992. More recently, he has developed rapid, high efficiency, microfluidic methods for analyzing microorganisms and colloidal particles. Dr. Armstrong also developed the most comprehensive solvation and characterization models for room temperature ionic liquids (RTILs) and pioneered their use in analytical chemistry.

## Modern HPLC for DMPK, Bioanalytical, and Analytical Development Scientists: Essentials, Best Practices, and Recent Developments

**One-Day Course E10-14, Monday, November 15, 2010, 8:30am – 5:30pm**

Dr. Michael W. Dong, Genentech, Small Molecule Analytical Chemistry, S. San Francisco, CA  
Dr. Anne-Françoise Aubry, Bristol-Myers Squibb, Princeton, NJ

### COURSE DESCRIPTION

This is a one-day HPLC course at an intermediate/advanced level for analysts, scientists and managers who want to improve skills in HPLC and LC/MS/MS analysis by learning advanced concepts, fundamentals, best practices and new developments in modern HPLC. Topics covered included advanced concepts of reversed-phase LC and instrumentation, best practices in mobile phase and column selection, recent developments in column technologies (sub-2  $\mu\text{m}$  particles, polar-embedded bonded phases, hybrids, monoliths, fused-core packing, HILIC, Chip LC), Ultra-high-pressure LC (UHPLC) and parallel analysis are also discussed. Case studies of difficult separations for polar metabolites, impurities in complex molecules and diastereomers of drug molecules with multiple chiral centers are presented.

### WHO SHOULD ATTEND

This course is intended for analysts, managers, regulators and researchers using HPLC in the pharmaceutical laboratory (or other industries). The focus is on conducting bioanalytical, DMPK and stability-indicating ICH impurity analysis of small-molecule pharmaceuticals. It is highly recommended that you have at least two years of hands-on HPLC experience.

### TOPICS

- ▶ Course Introduction/Overview
  - ▶ Concepts in Reversed-phase LC and Column Selection
    - Common-sense corollaries, column void volume ( $V_M$ ), peak volume, Plate height (H), Resolution (Rs), mobile phase factors (organic modifiers, pH, buffers), operating parameters (Flow, Gradient time ( $t_G$ ), peak capacity (n), method orthogonality, system dwell volumes and instrumental bandwidths (IBW, dispersion).
    - Modern trends of using shorter and narrower columns packed with small particles, column and bonding chemistries fundamentals, high-purity silica, hybrid particles, novel bonding chemistries and column selections guide.
  - ▶ Best Practice in HPLC Method Development
    - Essence in HPLC method development, traditional approach, 3-prong approach to efficient method development of early phase methods for IND filing, case study on method development for New Chemical Entities
  - ▶ Bioanalytical Perspectives
    - Fundamentals of chiral separations and method development for chiral molecules
    - Fundamentals of HPLC method development for bioanalytical assays, mobile phase selection, ion suppression, and method validation
  - ▶ Recent Advances and Novel Approaches
    - Hydrophilic Interaction Chromatography (HILIC), Monoliths, Sub-3  $\mu\text{m}$  and Sub-2  $\mu\text{m}$  packing, Fused-Core particle technology, Ultra-High-Pressure Liquid Chromatography (UHPLC), parallel analysis, and LC Chips and Turbulent Flow Chromatography (TFC).
- (NCEs). Automated column and mobile phase screening systems. Method development of complex molecules and formulations (molecules with multiple chiral centers and drug products with multiple APIs, separation of polar analytes)

### RECOMMENDED TEXT

M. W. Dong, *Modern HPLC for practicing scientists*, Wiley, Hoboken, June 2006.

### ABOUT THE INSTRUCTOR

**Dr. Michael W. Dong** (Lead instructor) is a Senior Scientist at Genentech, Small Molecule Drug Discovery, South San Francisco, CA. His research interests are in Fast LC, ultra-high-pressure LC, rapid HPLC method development and chiral separations. He was formerly Research Director at Synomics Pharmaceutical Services, Research Fellow/Group Leader at Purdue Pharma, Senior Staff Scientist at Applied BioSystems / Perkin-Elmer, and section-head in Hoechst Celanese. He holds a B.Sc. in Chemistry from Brooklyn College and a Ph.D. in Analytical Chemistry from City University of New York Graduate Center. He has conducted numerous HPLC training courses at national meetings (ACS, Pittcon, EAS, AAPS) on advanced HPLC, Fast LC / HTS, stability testing and HPLC method development. He pioneered Fast LC and has over 80 publications in chromatography, pharm analysis and analytical chemistry. He authored a best-seller in chromatography – “Modern HPLC for Practicing Scientists”, Wiley, 2006 and co-edited Handbook of Pharmaceutical Analysis by HPLC, Elsevier/Academic Press, 2005.

**Dr. Anne-Françoise Aubry** is Director of Bioanalytical Sciences at Bristol-Myers Squibb in Princeton NJ. She holds a doctorate in Pharmacy from the University of Dijon, France and a Ph.D. from University Pierre and Marie Curie in Paris. Following a postdoctoral fellowship at St Jude Research Hospital in Memphis, TN and McGill University in Montreal, Canada, she was appointed assistant professor at McGill University in 1992. In 1995, she left McGill to pursue a career in industry, first at ClinTrial Bio Research, in Montreal, then at DuPont Pharmaceuticals in Wilmington DE and more recently at Bristol-Myers Squibb in NJ. Throughout her career, she has been involved in many aspects of analytical development for new drug candidates including bioanalysis in support of toxicology and clinical studies and pharmaceutical analysis for API, clinical supplies and stability testing.

## Laboratory Data Analysis Using EXCEL®: New Uses for a Familiar Tool

**One-Day Course E10-15, Monday, November 15, 2010, 8:30am – 5:30pm**

Dr. Zenaida Otero Gephardt, Rowan University, Glassboro, NJ

### COURSE DESCRIPTION

This course focuses on the features of EXCEL® that can be used by experimenters and researchers to analyze their data in a simple and straightforward manner. EXCEL® can be a powerful tool in the analytical chemist's data analysis tool box. EXCEL® is widely available and can serve to enhance the quality and effectiveness of data analysis and laboratory operations. A wide range of laboratory data analysis applications will be discussed. Participants will be able to immediately use the material covered in the course to enhance their effectiveness in the laboratory.

### WHO SHOULD ATTEND

Analytical chemists at all levels will benefit from this course. Laboratory supervisors and technical personnel involved in data analysis and reporting will also benefit.

### TOPICS

Interactive exercises and practical examples will be used throughout the course.

- ▶ Introduction and the Basics of EXCEL®
- ▶ Spreadsheet Development and Manipulation
- ▶ Data Analysis Techniques
  - Assessment of data quality
  - Graphical and numerical analysis methods
    - Linear regression
    - Non-linear regression using the solver
- ▶ Custom Applications

### ABOUT THE INSTRUCTOR

**Dr. Zenaida Otero Gephardt** is Associate Professor of Chemical Engineering at Rowan University (Glassboro, NJ) and consultant through Otero Keil Associates. Her research focuses on optimization, development and mathematical modeling of chemical processes and laboratory techniques. She has developed statistical models and experimental designs for a wide range of chemical processes including high pressure, supercritical systems and multi-phase systems. Dr. Gephardt has worked with a wide range of system scales ranging from bench scale laboratory systems to large-scale industrial applications.

Dr. Gephardt has over 12 years experience with analysis and optimization applications in the chemical process industry. She teaches on-site courses for industry and provides analysis and experimental design support. Dr. Gephardt holds a Ph.D. in chemical engineering from the University of Delaware and is a registered Professional Engineer in Delaware.

## Detection and Characterization of Drug Metabolism in Drug Discovery and Development

**One-Day Course E10-16, 2010, Monday, November 15, 2010, 8:30am – 5:30pm**

Dr. Donglu Zhang, Bristol-Myers Squibb, Princeton, NJ

Dr. Mingshe Zhu, Bristol-Myers Squibb, Princeton, NJ

### COURSE DESCRIPTION

This one-day short course is designed for analytical chemists and 'new' drug metabolism scientists who would like to gain additional skills in metabolite detection and identification using advanced LC/MS and other analytical tools. The course provides an overview of current drug metabolism/disposition studies in the pharmaceutical industry, cutting-edge analytical technologies for metabolite detection, identification and quantification, and their applications to drug discovery and development with case studies.

### WHO SHOULD ATTEND

Analytical chemists and drug-metabolism scientists and others interested in analytical chemistry in drug discovery and development.

### TOPICS

- ▶ Basics of Drug Disposition and Metabolism
  - Drug disposition: ADME
  - Biotransformation reactions: Phase I and II reactions/bioactivation pathways
  - Metabolizing enzymes
- ▶ LC/MS Technologies for Metabolite Detection and Identification
  - Common analytical techniques
  - Triple quadrupole MS
  - Ion trap MS

- Triple quadrupole-linear ion trap MS (Q-trap)
- High resolution MS (Orbitrap)
- MS data mining technologies
- ▶ Metabolite Identification in Drug Discovery
  - In vitro metabolism models
  - Metabolic soft spot determination
- Reactive metabolite screening
- ▶ Metabolic Profiling and Identification in Drug Development
  - Role of drug metabolism in drug development
  - Plasma metabolite profiling in the first in human studies
  - Radiolabeled ADME study

### **ABOUT THE INSTRUCTORS**

**Dr. Donglu Zhang** received his Ph.D. in Bioorganic Chemistry (Dr. C. Dale Poulter) from the University of Utah. He had three years of postdoctoral training in enzyme mechanism/kinetics before working in the National Center for Toxicological Research of FDA to develop metabolite-generating microbial bioreactors (Dr. Carl E Cerniglia). He has been working at Bristol-Myers Squibb since 1997. His current research interests include investigative metabolism, metabolite detection, identification, and quantification, drug metabolism enzymology, LC/MS methodologies, and their applications to drug discovery and development. He has published >65 peer-reviewed articles and book chapters, and co-authored the book of "Drug Metabolism in Drug Design and Development: Basic Concepts and Practice" in 2007. Dr. Zhang is a recipient of the Ondetti & Cushman Award on co-invention of the mass-defect filtering technology, the highest scientific recognition at Bristol-Myers Squibb. He has been teaching drug metabolism short courses at ACS meetings and EAS Symposia. Contact information: Phone, 732-322-4200; email, donglu.zhang@bms.com.

**Dr. Mingshe Zhu** is a Principal Scientist in the Department of Biotransformation, Pharmaceutical Candidate Optimization, Bristol-Myers Squibb, Princeton, NJ, USA. He has over 12 years of experience in drug discovery, development and registration. His research interests include lead optimization via DMPK approaches, regulatory drug metabolism, CYP-mediated bioactivation and applications of new LC/MS and radiodetection techniques to ADME studies. Recently, his group has focused on DMPK supports to discovery and development programs and the development of new analytical technology, such as high resolution mass spectrometry/mass defect filtering and linear ion trap mass spectrometry for drug metabolite identification. Dr. Zhu received BS in Biochemistry and MS in Chemistry. He completed his Ph.D. training in analytical toxicology at SUNY at Albany, and post-doctoral fellowship in drug metabolism at University of Washington. Dr. Zhu is frequently invited to speak at conferences, society meetings and symposiums on drug metabolism and LC/MS technology. He often teaches drug metabolism short courses at American Chemistry Society meetings and Eastern Analytical Symposiums. Dr. Zhu is a recipient of the Ondetti & Cushman Award, one of the highest scientific awards at Bristol-Myers Squibb. He has published over 50 research articles including several book chapters and co-authored the book of "Drug Metabolism in Drug Design and Development: Basic Concepts and Practice" in 2007.

## **The Chemistry of Drug Degradation**

### **One-Day Course E10-17, Monday, November 15, 2010, 8:30am – 5:30pm**

Dr. Karen Alsante, Pfizer Global Research & Development, Groton, CT  
Dr. Dinos Santafianos, Pfizer Global Research & Development, Groton, CT

### **COURSE DESCRIPTION**

This workshop is designed to provide participants with an in depth of knowledge of the chemical reactions involved in the most common degradation pathways of drugs.

The Chemistry of Drug Degradation: This topic will be covered by carefully examining the major mechanisms of chemical decomposition of pharmaceuticals in the context of common functional groups. The major mechanisms of chemical decomposition of pharmaceuticals include hydrolysis/dehydration, oxidation, isomerization/ epimerization, decarboxylation, dimerization/ polymerization, cyclization, rearrangements, photolysis, and transformation products involving reaction with excipients or counterions (salt forms). Real world examples will be given to illustrate many of the degradation mechanisms.

- Identifying critical molecular structures
- Which structures are likely to react?
- Predicting the likely degradation products
- Interactive problem solving session
- Developing degradation mechanisms
- Relating the chemistry to ICH guidelines

### **WHO SHOULD ATTEND**

This one-day course will benefit analysts and formulators who develop methods and formulations, perform forced degradation and structure elucidation of impurities and degradants of pharmaceutical products. To get the most out of the course, we highly recommended that you have at least two years of pharmaceutical analysis or drug development experience.

### TOPICS

- ▶ Introductions
- ▶ General considerations
- ▶ Main degradation pathways
- ▶ Functional Groups, Drug-Excipient Reactions, and Examples
- ▶ Carbonyl chemistry:
  - Esters, Lactones
  - Carboxylic acids
  - Ketones, Aldehydes
  - Amides, Lactams
  - Carbamates
  - Imides
- ▶ Nitrogen functional groups:
  - Nitriles
  - Amines
  - Imines
  - Enamines
  - Nitro groups
- ▶ Ethers, thioethers, and sulfonyl chemistry:
  - Ethers, thioethers
  - Sulfonamides, sulfonyleureas
  - Epoxides
- ▶ Alkyl halides/hydroxyls:
  - Alkyl halides
  - Hydroxyls, thiols, phenols
- ▶ Conjugated Double Bond Systems:
  - Benzyl groups
  - Olefins, allylic groups
- ▶ Additional Reactions:
  - Epimerization, dimerization
  - Ring transformations
  - Cis/trans isomerization
- ▶ Prediction

### ABOUT THE INSTRUCTORS

**Dr. Karen Alsante** is an Associate Director in Research Analytical at Pfizer Global Research and Development: Groton, CT. Dr. Alsante received a BA with honors in chemistry from Holy Cross College in 1989 and her PhD in organic chemistry from Duke University in 1994. Dr. Alsante started at Pfizer in 1994 as a development scientist in Groton Quality Operations. In 1997, Dr. Alsante developed a Degradation Group in Analytical R&D responsible for gaining a better understanding of drug substance and drug product chemical and physical stability. In July 2004, Dr. Alsante shifted to group leader of a new Solid State Characterization group within Analytical R&D focused on crystalline/amorphous/polymorph content, particle size/morphology and particulate analysis. In January 2006, Dr. Alsante began her current position as a Research Fellow for Research Analytical focused on early analytical research activities starting in partnership with Discovery and progressing through development to Phase 2 clinical trials.

**Dr. Dinos Santafianos** is a Principal Scientist in the Research Analytical Department's degradation group at Pfizer Inc. He has more than 20 years of experience in the pharmaceutical industry, ranging from medicinal/discovery and scale up/process related chemistry to his current position in the Analytical Department. Currently he is responsible for the purposeful degradation experiments for use in understanding drug stability issues as well as assisting stability indicating HPLC method development. He has an active interest in drug-excipient interactions. The group is also actively pursuing computer technologies for use in understanding drug degradation, this includes a degradation database and predicting degradants.

## **Analytical Laboratory Techniques for Pharmaceutical Analysts**

**New One-Day Course E10-18, Monday, November 15, 2010, 8:30am – 5:30pm**

Dr. Merlin Bicking, ACCTA, Inc., St. Paul, MN

### COURSE DESCRIPTION

Good technique is essential in every successful analytical laboratory. However, laboratory analysts in the pharmaceutical and other regulated industries have particularly challenging job requirements, due to both regulatory (e.g., GMP and GLP) and economic demands. This seminar can help your entire laboratory realize better efficiency and data quality, by ensuring that every staff member has the same basic level of training. Based on discussions with analytical scientists in the pharmaceutical industry, this seminar provides a broad range of topics that are directly related to the laboratory activities of the typical analyst. Rather than simply demonstrating a particular procedure, the course provides some background information about common laboratory techniques, along with the "do's and don'ts", so that the analysts have a better perspective about why they must perform these tasks in a certain way.

### WHO SHOULD ATTEND

This one-day course will benefit

- New laboratory staff - either recent graduates or transfers from other groups
- Specialists who want to add new skills or need cross-training instruction
- Experienced analysts and technicians who want or need a brief refresher course
- Anyone needing the "education, training, and experience, or any combination thereof ..." to work in a GMP environment.

**TOPICS**

- ▶ Mathematical Skills: A Review of Basic Calculation Principles
  - Perspectives
  - Units, units conversions, and calculations
  - Chemical factors
  - Significant figures and rounding
  - Method-related calculations
- ▶ Using Laboratory Equipment: Avoiding the Most Common Problems
  - Analytical balances
  - pH meters
  - Filtration
- ▶ Volumetric Containers: Why We Do What We Do
  - General issues with volumetric glassware
  - Specifications and calibration
  - Volumetric flasks and pipets
  - Pipetting instruments (Pipetters)
- ▶ Solution Preparation Issues: Putting it All Together
  - Propagation of errors
  - Preparation of solutions and standards
  - Documentation and observation

**ABOUT THE INSTRUCTOR**

**Dr. Merlin K. L. Bicking**, President, ACCTA, Inc. He has extensive analytical chemistry experience in academia, contract research, independent testing laboratories, consulting, and technical training. His professional history includes development of two EPA methods, as well as numerous methods in other regulated and non-regulated industries. His publications and presentations cover a wide range of topics, including liquid chromatography theory, derivatization, method optimization, and the use of experimental design strategies in analytical chemistry. He also develops and presents technical training seminars for analytical laboratory staff.

**Infrared Spectral Interpretation I**

**One-Day Course E10-19, Monday, November 15, 2010, 8:30am – 5:30pm**

Dr. Brian C. Smith, Spectros Associates, Shrewsbury, MA

**COURSE DESCRIPTION**

This is a one-day introduction to infrared spectral interpretation. You will learn how to integrate the peak position, height, and width information in a spectrum to successfully determine unknown molecular structures and to perform identities properly. The five ways of attacking mixture spectra are discussed, then a 12-step program to interpret spectra is presented. The diagnostic infrared bands of many economically important molecules including hydrocarbons, alcohols, ketones, esters, and polymers are presented. Attendees practice interpreting many unknown spectra in class with the instructor's guidance.

**WHO SHOULD ATTEND**

This course will benefit anyone who analyzes samples to determine chemical structures, and everyone for whom measuring infrared spectra is part of their job. Beginners will benefit from the introductory nature of this course. Experienced interpreters will benefit by learning systematic approaches to interpreting spectra and the review of spectra of important functional groups.

**TOPICS**

- ▶ The Fundamentals of Infrared Interpretation
  - The properties of light
  - Molecular vibrations
  - The meaning of peak positions, heights, and widths
  - A strategic approach to spectral interpretation
    - Dealing with mixtures
    - Performing identities properly
    - A systematic 12-Step approach to infrared interpretation
- ▶ Functional Group Analysis of Hydrocarbons
  - Alkanes: C-H stretching and bending vibrations
    - Straight chain alkanes
    - Estimating hydrocarbon chain length from IR spectra
  - Aromatic hydrocarbons
    - Mono-substituted benzene rings
    - Distinguishing ortho, meta, and para isomers
- ▶ Alcohols and Phenols
  - Differentiating primary, secondary, and tertiary alcohols
  - Phenols
  - Distinguishing alcohols from water
- ▶ The Carbonyl (C=O) Functional Group
  - Introduction to carbonyl spectra
  - Ketones
  - Esters: the rule of 3
  - Summary
- ▶ Introduction to the Infrared Spectra of Polymers
  - Low- and high-density polyethylene
  - Polypropylene
  - Polystyrene
  - Polyethylene Terephthalate (PET)

**ABOUT THE INSTRUCTOR**

**Dr. Brian C. Smith** is founder and principal of Spectros Associates. He has been a spectroscopist for over 30 years and was employed by Bell Labs and Digilab. He is an experienced trainer; thousands of people have benefited from his instruction as part of Spectros Associates since 1992. Dr. Smith is the author of three popular books on spectroscopy; *Fundamentals of FTIR* and *Infrared Spectral Interpretation* published by CRC Press, and *Quantitative Spectroscopy: Theory and Practice* published by Academic Press. Dr. Smith earned

his Ph.D. in Chemistry from Dartmouth College and graduated with highest honors from Rochester Institute of Technology with a B.S. in Chemistry.

## Infrared Spectral Interpretation II

**One-Day Course E10-20, Tuesday, November 16, 2010, 8:30am – 5:30pm**

Dr. Brian C. Smith, Spectros Associates, Shrewsbury, MA

### COURSE DESCRIPTION

A more detailed look at infrared interpretation for anyone who needs to identify unknown molecules using infrared spectroscopy. Learn how molecules absorb infrared light so you can fully understand all the features in a spectrum. The spectra of economically important but spectrally complex molecules are explained using many examples. Discover how spectral subtraction and library searching can make interpreting spectra easier. Attendees practice interpreting many unknown spectra in class with the instructor's guidance.

### WHO SHOULD ATTEND

This course will benefit anyone who analyzes samples to determine chemical structures, and everyone for whom measuring infrared spectra is part of their job. All FTIR users will benefit by learning systematic approaches to interpreting spectra, the review of spectra of important functional groups, and how to use interpretation aids to make their job easier. Familiarity with the material in IR Spectral Interpretation I would be useful for attendees.

### TOPICS

- ▶ How Molecules Absorb Infrared Radiation
  - How molecules absorb infrared light
  - Assigning all the features in a spectrum
- ▶ Unsaturated Hydrocarbons
  - Alkenes:
    - Substitution patterns
    - Distinguishing Cis/Trans Isomers
    - Natural and synthetic rubbers
  - Alkynes
- ▶ Ethers
  - Saturated Ethers
  - Aromatic Ethers
  - The Methoxy Group
- ▶ Complex Carbonyl Molecules
  - Aldehydes
  - Carboxylic Acids
  - Carboxylates (Soaps)
- ▶ Organic Nitrogen Compounds
  - Amides
    - Structure, nomenclature, and bonding
  - Primary Amides
  - Secondary Amides
  - Proteins
- Amines
  - Distinguishing the three types of amines
  - Methyl groups bonded to Nitrogen
  - Amine Salts
  - Nitriles
  - The Nitro Group
- ▶ Interpretation Aids
  - Spectral subtraction: simplifying mixture spectra
    - Theory
    - Optimizing subtraction results
    - Spotting artifacts
  - Library searching
    - Background and theory
    - The search process
    - Properly interpreting search results
    - Subtract and search again: deconstructing mixtures

### ABOUT THE INSTRUCTOR

**Dr. Brian C. Smith** is founder and principal of Spectros Associates. He has been a spectroscopist for over 30 years and was employed by Bell Labs and Digilab. He is an experienced trainer; thousands of people have benefited from his instruction as part of Spectros Associates since 1992. Dr. Smith is the author of three popular books on spectroscopy; *Fundamentals of FTIR* and *Infrared Spectral Interpretation* published by CRC Press, and *Quantitative Spectroscopy: Theory and Practice* published by Academic Press. Dr. Smith earned his Ph.D. in Chemistry from Dartmouth College and graduated with highest honors from Rochester Institute of Technology with a B.S. in Chemistry.

## Infrared Spectral Interpretation I & II

**Two-Day Course E10-21, Monday and Tuesday, November 15 and 16, 2010, 8:30am – 5:30pm**

Dr. Brian C. Smith, Spectros Associates, Shrewsbury, MA

### COURSE DESCRIPTION

This course is a combination of two one-day courses: Infrared Spectral Interpretation I and Infrared Spectral Interpretation II courses.

A discount will be offered for the combined course over separately registering for the two one-day courses. See course descriptions for Infrared Spectral Interpretation I and Infrared Spectral Interpretation II for details about the course.

### WHO SHOULD ATTEND

This course will benefit anyone who analyzes samples to determine chemical structures, and everyone for whom measuring infrared spectra is part of their job. Part I: Beginners will benefit from the introductory nature of this course. Experienced interpreters will benefit by learning systematic approaches to interpreting spectra and the review of spectra of important functional groups. Part II: All FTIR users will benefit by learning systematic approaches to interpreting spectra, the review of spectra of important functional groups, and how to use interpretation aids to make their job easier. Familiarity with the material in IR Spectral Interpretation I would be useful for attendees.

### TOPICS

#### **DAY ONE:**

- See Topics listed under Infrared Spectral Interpretation I

#### **DAY TWO:**

- See Topics listed under Infrared Spectral Interpretation II

### ABOUT THE INSTRUCTOR

See Instructor information under Infrared Spectral Interpretation single course above.

## **The Role of Chromatography in the Analysis and Characterization of Protein Therapeutic Drugs**

**One-Day Course E10-22, Tuesday, November 16, 2010, 8:30am – 5:30pm**

Mr. C. David Carr, Bioanalytical Technologies, Wrightwood, CA

### COURSE DESCRIPTION

Explanations of the properties of proteins that must be characterized in the course of developing a protein therapeutic drug and monitored during production and lot release begin this class. The theory and practice of a number of chromatographic separation techniques that play key roles in the analysis and characterization of protein therapeutic drugs are then described. The chromatography techniques that are discussed include reversed-phase HPLC, ion exchange, size exclusion and several less well-known techniques in chromatography. Examples of how these are used in the development and release of protein therapeutic drugs are shown.

### WHO SHOULD ATTEND

This course is designed for young scientists embarking on a career in biotechnology analysis as well as experienced scientists starting to work with the analysis of protein therapeutic drugs. Attendees may have degrees in chemistry, biology or related fields. It is suitable for those in quality control, quality assurance, research and development and production monitoring.

### TOPICS

- ▶ Protein Properties Relevant to the Therapeutic Properties of Protein Drugs
  - Deamidation
  - Oxidation
  - Glycosylation
  - Charge state variants
  - Aggregation and denaturation
  - Pegylation and other forms of conjugation
- ▶ Reversed-Phase HPLC and its Role in Protein Therapeutic Analysis
  - Typical operating conditions for protein/peptide analysis
  - Column characteristics best suited for protein and peptide analysis
  - Optimum mobile phase conditions
- The effect of gradients and temperature on peptide separation
- ▶ How Reversed-phase HPLC is used to Characterize and Analyze Protein Therapeutics for Degradation Products, Disulfide Bonds, Glycosylation, and other Modifications
- ▶ Other Types of Liquid Chromatography and their Respective Roles in Protein Therapeutic Drug Analysis
  - Ion Exchange chromatography
  - High pH Anion Exchange Chromatography
  - Normal Phase Liquid Chromatography
  - Hydrophobic Interaction Chromatography
  - Size Exclusion Liquid Chromatography

### ABOUT THE INSTRUCTOR

**Mr. C. David Carr** graduated from the University of California, Berkeley, with a degree in chemistry and did graduate work in molecular biology at the University of California, San Diego. He has been involved in High-Performance Liquid Chromatography for nearly forty years. He has worked with the biotechnology industry for many years in the characterization and analysis of protein therapeutics. He is the author of the popular booklet *"The Handbook of Analysis and Purification of Proteins and Peptides by Reversed-Phase HPLC"* and is very experienced with the uses of chromatography, electrophoresis and mass spectrometry for the analysis of proteins and peptides. For the past ten

years he has been the principal instructor for Bioanalytical Technologies ([www.bioanalyticaltech.com](http://www.bioanalyticaltech.com)), teaching classes on the Analysis and Characterization of Protein Therapeutic Drugs. He has taught this class to scientists from most of the major biotechnology firms such as Amgen, Genentech, Biogen Idec and Genzyme as well as members of the staff of a great many smaller biotech companies.

## The Analysis and Characterization of Protein Therapeutic Drugs

**Two-Day Course E10-23, Tuesday and Wednesday, November 16 and 17, 2010, 8:30am – 5:30pm**

Mr. C. David Carr, Bioanalytical Technologies, Wrightwood, CA

### COURSE DESCRIPTION

Explanations of the properties of proteins that must be characterized in the course of developing a protein therapeutic drug and monitored during production and lot release begin this class. The theory and practice of a number of chromatographic separation techniques that play key roles in the analysis and characterization of protein therapeutic drugs are then described during the first day of the class. The chromatography techniques that are discussed include reversed-phase HPLC, ion exchange, size exclusion and several less well-known techniques in chromatography. Examples of how these are used in the development and release of protein therapeutic drugs are shown. (Note: The first day is the same as the class: The Role of Chromatography in the Analysis and Characterization of Protein Therapeutic Drugs.) The second day of the class explains and discusses Capillary Electrophoresis and Mass Spectrometry and reviews their respective roles in protein drug analysis and characterization. The purposes of these two techniques in protein drug analysis are discussed and examples are shown.

### WHO SHOULD ATTEND

This course is designed for young scientists embarking on a career in biotechnology analysis as well as experienced scientists starting to work with the analysis of protein therapeutic drugs. Attendees may have degrees in chemistry, biology or related fields. It is suitable for those in quality control, quality assurance, research and development and production monitoring.

### TOPICS

- ▶ Protein Properties Relevant to the Therapeutic Properties of Protein Drugs
  - Deamidation
  - Oxidation
  - Glycosylation
  - Charge state variants
  - Aggregation and denaturation
  - Pegylation and other forms of conjugation
- ▶ Reversed-Phase HPLC and its Role in Protein Therapeutic Analysis
  - Typical operating conditions for protein/peptide analysis
  - Column characteristics best suited for protein and peptide analysis
  - Optimum mobile phase conditions
  - The effect of gradients and temperature on peptide separations
- ▶ How Reversed-phase HPLC is used to Characterize and Analyze Protein Therapeutics for Degradation Products, Disulfide Bonds, Glycosylation, and other Modifications
- ▶ Other Types of Liquid Chromatography and their Respective Roles in Protein Therapeutic Drug Analysis
  - Ion Exchange chromatography
  - High pH Anion Exchange Chromatography
  - Normal Phase Liquid Chromatography
- Hydrophobic Interaction Chromatography
- Size Exclusion Liquid Chromatography
- ▶ The Essential Theory and Practice of Capillary Electrophoresis
  - Mobility, migration, electroosmotic flow, joule heating
  - Instrument considerations: detection, injection
  - Operating conditions for Capillary Zone Electrophoresis (CZE)
  - Examples of how CZE is used in protein drug analysis
  - Capillary isoelectric focusing electrophoresis: operating conditions and uses in protein analysis and characterization
  - Capillary gel electrophoresis: operating conditions and uses in protein drug analysis
- ▶ Mass Spectrometry as used in Protein Drug Analysis
  - Description of ion sources: electrospray and Matrix-assisted Laser Desorption (MALDI)
  - Description of commonly used mass analyzers including the quadrupole, ion trap and time of flight (TOF)
  - Operating parameters and characteristics of LC-MS
  - The use of mass spectrometry to monitor molecular weights of protein drug products and how this information is useful in identifying and monitoring protein modifications.
  - Peptide fragmentation and its role in protein drug characterization.

### ABOUT THE INSTRUCTOR

**Mr. C. David Carr** graduated from the University of California, Berkeley, with a degree in chemistry and did graduate work in molecular biology at the University of California, San Diego. He has been involved in High-Performance Liquid Chromatography for nearly forty years. He has worked with the biotechnology industry for many years in the characterization and analysis of protein therapeutics. He is the author of the popular booklet *"The Handbook of Analysis and Purification of Proteins and Peptides by Reversed-Phase HPLC"* and is very experienced with the uses of chromatography, electrophoresis and mass spectrometry for the analysis of proteins and peptides. For the past ten years he has been the principal instructor for Bioanalytical Technologies ([www.bioanalyticaltech.com](http://www.bioanalyticaltech.com)), teaching classes on the Analysis and Characterization of Protein Therapeutic Drugs. He has taught this class to scientists from most of the major biotech-

nology firms such as Amgen, Genentech, Biogen Idec and Genzyme as well as members of the staff of a great many smaller biotech companies.

## Interpretation of Mass Spectra with Practical Solutions to Problems

**One-Day Course E10-24, Tuesday, November 16, 2010, 8:30am – 5:30pm**

Dr. Birendra Pramanik, Merck Research Laboratories, Kenilworth, NJ

Dr. Mike S. Lee, Milestone Development, Newtown, PA

### **COURSE DESCRIPTION**

This introductory course covers the theory and practical interpretation of mass spectra of organic compounds and proteins/peptides through the use of practical examples. The principles of interpretation are to be illustrated by various mass spectral data from EI, CI, DCI, FAB, ESI, APCI, MALDI-MS. This course emphasizes problem-solving skills with examples encountered in industrial and academic research, including structural characterization of trace level impurities and degradation products, analysis of natural products, identification of drug metabolites and structural determination of proteins/peptides. This course provides information on methods and technologies, enabling you to address the challenges that come across routinely.

### **WHO SHOULD ATTEND**

This course is designed for practicing mass spectrometry scientists (new users, experienced professionals, chromatographers, analytical chemists, protein chemists and laboratory managers).

### **TOPICS**

- ▶ Principles of Interpretation of Mass Spectra
- ▶ Electron Impact
- ▶ Chemical Ionization
- ▶ Desorption Chemical Ionization
- ▶ Fast-atom Bombardment
- ▶ Atmospheric Pressure Ionization (ESI/APCI)
- ▶ Matrix-assisted Laser Desorption Ionization
- ▶ Applications in Problem-solving
- ▶ Examples

### **ABOUT THE INSTRUCTORS**

**Dr. Birendra N. Pramanik** has been working (for Schering-Plough Research Institute, now Merck Research Laboratories, MRL) in the area of mass spectrometry since 1980. He is currently a Distinguished Fellow at MRL. Dr. Pramanik directs mass spectrometry and NMR efforts in support of the R&D programs. The responsibility of this group is to utilize modern instrumentation (NMR, LC/NMR, HR/MS, EI, GC/MS, LC/MS, LC/MS/MS, FT-MS, UV, IR) to provide structural identification of new chemical entities (small molecules) and therapeutic proteins for the discovery and development of novel pharmaceuticals. He has published over 145 research papers mostly in the area of mass spectrometry, including chapters in books. Dr. Pramanik is a co-editor of a book on "Applied Electrospray Mass Spectrometry" (Marcel Dekker, Inc., New York, 2002). He has been an invited speaker at national and international meetings. He has served as a chairperson for the North Jersey ACS Mass Spectrometry group and as chairman for major sessions of the American Society for Mass Spectrometry meetings. He has received a number of awards, including the American Chemical Society New Jersey Regional Award for Achievements in Mass Spectrometry. He received his Ph.D. in Organic Chemistry under Professor Ajay K. Bose from Stevens Institute of Technology in 1977.

**Dr. Mike S. Lee** is President of Milestone Development Services. He actively participates in the growth of new technologies and their integration into drug development. Dr. Lee has extensive experience with pharmaceutical analysis and drug development. He has pioneered the application of LC/MS in different phases of drug development for research in biomolecules, natural products, drug metabolites, impurities, and degradants. Prior to founding Milestone Development Services, Dr. Lee was with Bristol-Myers Squibb from 1987-1998. As Director of Analytical Research and Development, Dr. Lee was responsible for departments in several research facilities providing MS, NMR, IR, HPLC, CE, and physical chemistry support. He led interdisciplinary teams responsible for rapid analysis of discovery leads and preclinical drug candidates that contributed to the Food and Drug Administration approval of Buspar<sup>®</sup>, and Serzone<sup>®</sup>, and the accelerated development and approval of TAXOL<sup>®</sup>. Dr. Lee has published over 40 research papers and book chapters about the analysis of drugs and related compounds. Dr. Lee's book entitled "LC/MS Applications in Drug Development" was recently published by J. Wiley & Sons. Dr. Lee received his B.S. in Chemistry from the University of Maryland and his M.S. and Ph.D. in Analytical Chemistry from the University of Florida under the direction of Professor Richard A. Yost.

## Data Analysis for Improved Productivity in the Analytical Laboratory

**One-Day Course E10-25, Tuesday, November 16, 2010, 8:30am – 5:30pm**

Dr. Zenaida Otero Gephardt, Rowan University, Glassboro, NJ

### **COURSE DESCRIPTION**

Statistical techniques are powerful tools that can significantly enhance productivity in the analytical laboratory. Simple statistical analyses can serve to guide experimentation, to identify sources of experimental errors, and to minimize the number of experiments required. The mathematics involved will be presented in a concise manner easily understood by those with a background in science. Basic principles will be discussed in the context of analytical laboratory applications, and a wide range of applications will be discussed. Participants will be able to immediately use the material presented to enhance their effectiveness and productivity in the laboratory.

### **WHO SHOULD ATTEND**

Analytical chemists at all levels will benefit from this course. Laboratory supervisors and technical personnel involved in data analysis and reporting will also benefit.

### **TOPICS**

- ▶ Background and Introduction to Data Analysis
- ▶ Precision and Accuracy Calculations and Applications
- ▶ Comparison of Precisions and Applications
- ▶ Comparison of Results and Applications
- ▶ Relationships Between Variables and Applications
- ▶ Analysis of Variances (ANOVA) and Applications
- ▶ Calibration Curves
- ▶ Techniques for Data Comparisons

### **ABOUT THE INSTRUCTOR**

**Dr. Zenaida Otero Gephardt** is Associate Professor of Chemical Engineering at Rowan University (Glassboro, NJ) and consultant through Otero Keil Associates. Her research focuses on optimization, development and mathematical modeling of chemical processes and laboratory techniques. She has developed statistical models and experimental designs for a wide range of chemical processes including high pressure, supercritical systems and multi-phase systems. Dr. Gephardt has worked with a wide range of system scales ranging from bench scale laboratory systems to large-scale industrial applications. Dr. Gephardt has over 12 years experience with analysis and optimization applications in the chemical process industry. She teaches on-site courses for industry and provides analysis and experimental design support. Dr. Gephardt holds a Ph.D. in chemical engineering from the University of Delaware and is a registered Professional Engineer in Delaware.

## Drug Development Process for Chemists

**New One-Day Course E10-26, Tuesday, November 16, 2010, 8:30am – 5:30pm**

Dr. Michael W. Dong, Genentech, Small Molecule Analytical Chemistry, S. San Francisco, CA,

### **COURSE DESCRIPTION**

This introductory course provides a high-level overview of the entire drug development process for new therapeutics that target human diseases, with a focus on the pivotal role of the chemist in this highly complex, costly and multidisciplinary process. It introduces the pharmaceutical (biopharm) industry (historical perspectives, trends, challenges, and issues), and discusses the many impacts to the industry from the human genome project and generic drugs. Course attendees will learn the current drug discovery process, from basic research on disease pathophysiology, identification of drug targets, high-throughput screening, and turning of hits to leads, to the nomination of the drug development candidate.

An introduction of both non-clinical drug development, leading to the filing of an Investigational New Drug (IND), and clinical drug development, from Phase I, II, III to the filing of a New Drug Application (NDA), will be presented together with an abbreviated description of the associated regulations - GLP, GMP, GCP and GTP. The role of the chemist, particularly the analytical chemist, in supporting discovery, process scale-up, formulations, stability, DMPK, QC/QA, and regulatory affair functions, will be discussed.

### **WHO SHOULD ATTEND**

This course will benefit scientists currently working in the biopharmaceutical industry who want to improve their understanding of the drug development process (including pharma trends and perspectives, drug discovery, pre-clinical and clinical development, and regulations). This course is also useful for non-pharma scientists, including instrumentation specialists, who are seeking a better technical understanding of the challenges and opportunities present in the industry. It is highly recommended that you have some fundamental understanding of biology, chemistry or biochemistry.

**TOPICS**

- ▶ Pharmaceutical Industry: Historical Perspectives, Modern Trends and Challenges
- ▶ Drug Discovery Process: from Target to Lead
  - Overall approaches: phenotypic, molecular and genomic medicine
  - Target: identification, validation, characterization
  - Leads: screening, optimization, SAR
  - ADME, DMPK and toxicology
- ▶ Non-clinical Drug Development: from Development Candidate to IND
  - Characterization of lead molecules, process scale-up, pre-formulation, analytical chemistry, stability, development of clinical trial material (CTM)
    - GLP tox studies and IND filing
- ▶ Clinical Development, NDA and Regulations
  - Clinical trials: phase I, II, III and IV
  - Pre-approval inspection and NDA
  - Regulations: GLP, GMP, GCP, and GTP and ICH guidelines
  - The role of the chemist (medicinal, organic, physical and particularly analytical chemists) in drug development process

**ABOUT THE INSTRUCTOR**

**Dr. Michael W. Dong** is a Senior Scientist at Genentech, Small Molecule Drug Discovery, South San Francisco, CA. He is responsible for multiple early development projects as well as supervising analytical support for process chemistry and pharmaceuticals in Pharmaceutical Sciences Department. He was formerly Research Director at Synomics Pharmaceutical Services, and Research Fellow/Group Leader at Purdue Pharma. He holds a Ph.D. in Analytical Chemistry from City University of New York Graduate Center, and is completing his certification in Biotechnology at U. California Santa Cruz in 2010. He has over ten years of experience in pharmaceutical development for early and late stage projects. He has conducted many training courses on HPLC, UHPLC, stability testing and method development and has over 80 publications in analytical chemistry including a best-seller in chromatography-Modern HPLC for Practicing Scientists, Wiley, 2006.

## Introduction to Near-Infrared Spectroscopy: Applications in the Pharmaceutical Industry

**One-Day Course E10-27, Tuesday, November 16, 2010, 8:30am – 5:30pm**

Dr. Emil Ciurczak, Independent Consultant, Goldens Bridge, NY

**COURSE DESCRIPTION**

Near-Infrared Spectroscopy (NIRS) is a non-destructive, rapid method for determining both chemical and physical properties of pure materials (API and excipients), packaging materials, mixtures, solutions, and solid dosage forms. This course will review the theory and equipment used in NIR, the most common software packages, and some qualitative and quantitative applications.

**WHO SHOULD ATTEND**

This course is a good introduction to analysts, lab managers, QA/QC personnel, and any person involved with process analysis (PAT/QbD). The course will benefit anyone considering NIR as a tool as well as analysts already performing NIR analyses. Attendees need not be a spectroscopist to benefit from the course.

**TOPICS**

- ▶ Basic Theory and History
  - A brief history and theory
  - Why NIR is different from “classic” spectrometric methods
  - What can be seen and where NIR may not be best applied
- ▶ Hardware Available
  - Interference and linear variable filters
  - Gratings
  - Interferometers
  - Acousto-Optic tunable filters
  - MEMS
  - Strengths and weaknesses of each, and where each would be best applied
- ▶ Software and Chemometrics
  - Multiple linear regression (MLR)
  - Principal components analysis (PCA)
  - Partial least squares (PLS)
- Mahalanobis Distances, Conformity Index, Spectral Matching
- Some 3<sup>rd</sup> party software available
- ▶ Qualitative Applications
  - Raw material ID/qualification (RMID)
  - Clinical trials/counterfeiting
  - Polymorphic changes
  - Blend uniformity
- ▶ Quantitative Applications
  - Moisture (RM, drying, Lyophilization)
  - % polymorph
  - % crystallinity
  - Assay (tablets, capsules, powders)
  - Content Uniformity
  - Process applications
- ▶ Validation of Equations (FDA, ICH, EMEA)

### RECOMMENDED TEXT

Recommended Text: /Handbook of Near-Infrared Analysis/, 3rd Edition, Burns and Ciurczak, eds., CRC Press, 2007

### ABOUT THE INSTRUCTOR

**Dr. Emil Ciurczak** has degrees in chemistry from Rutgers and Seton Hall Universities and worked in the Pharma industry since 1970 at Ciba-Geigy, Cooper Labs (Berlex), Sandoz, Merck, and Purdue Pharma. He has also worked with or consulted for Technicon (Bran+Leubbe), FOSS NIRSystems, Brimrose, Infrared Fiber Systems, and Control Development. Emil introduced NIR at Sandoz in 1983 and was checking all raw materials (100% container-wise testing) by 1985.

He is now an independent consultant, performing NIR, PAT and QbD applications and teaching courses in PAT and NIR in the US and Europe; he was the 2004 recipient of the EAS NIR Award. Emil holds nine patents for NIR equipment and software.

Emil is co-author of "The Handbook of NIR Analysis" (3 editions) and "Medical and Pharmaceutical Applications of NIR." He was a contributing editor to *Spectroscopy* from 1988 to 2005, and is presently Contributing Editor for *Pharmaceutical Manufacturing* magazine. He has published over 75 papers and has over 150 presented papers.

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## Critical cGMP and ICH Guidances for Analytical Laboratories

**New One-Day Course E10-28, Tuesday, November 16, 2010, 8:30am – 5:00pm**

Ms. Kim Huynh-Ba, Pharmalytik C.S, Newark, DE

Dr. Linda L. Ng, US Food and Drug Administration, Silver Spring, MD

### COURSE DESCRIPTION

Analytical laboratories hold major functions in the pharmaceutical industry. Throughout this course, critical cGMPs regulations, FDA guidances and ICH Quality guidelines will be introduced specifically emphasizing procedures to help individuals to comprehend the management aspects of the laboratory in order to maintain a high level of compliance that surrounds the laboratory environment. It also reviews several quality systems that support the analytical laboratory such as:

- cGMP regulations
- Analyst Training Program
- Controls of Standards and Samples
- Laboratory Records and Reports
- Analytical Method Validation
- Equipment Calibration and Qualification
- Stability Program
- Laboratory Investigation
- Audit and Inspection

### WHO SHOULD ATTEND

This one-day course will benefit analysts, QA and QC managers, regulators, and researchers, who perform analytical testing or manage an analytical laboratory for pharmaceutical analyses. It will introduce individuals to cGMP and ICH and FDA regulations that cover the quality systems, controls and operations of the laboratory functions. It is intended for manufacturers of OTC, generics and new drug products as well as contract research organizations (CROs), government labs since the pharmaceutical products have similar regulatory requirements.

To get the most out of the course, we highly recommended that you have at least two years of pharmaceutical analysis or drug development experience.

### TOPICS

- ▶ Laboratory Control and the Drug Development Process.
- ▶ Method Validation.
- ▶ Stability Program and Related Topics.
- ▶ CMC Documentation: Records and Reports.
- ▶ Preparing for Quality Audits and Inspections

### ABOUT THE INSTRUCTOR

**Ms. Kim Huynh-Ba** is the Technical Director of Pharmalytik ([www.pharmalytik.com](http://www.pharmalytik.com)). She has twenty two years of experience in various analytical areas of pharmaceutical development and a primary focus in stability sciences. Prior to Pharmalytik, she held positions in drug development at Astra Zeneca (formerly ICI Americas), DuPont Merck, DuPont Pharmaceuticals, Bristol Myers Squibb and Wyeth Vaccines. She has been advising pharmaceutical companies including companies operating under Consent Decree on harmonization and optimization of analytical best practices since 2003.

In addition to her consulting activities, Kim is a short course instructor of American Chemical Society (ACS), American Association of Pharmaceutical Scientists (AAPS), Pittsburgh Conference, many other international training groups. She is also a Visiting Professor at Rowan University, an Adjunct Professor at Illinois Institute of Technology and Temple University. She currently serves as the Secretary of the Executive Committee of the Eastern Analytical Symposium (EAS) Governing Board. She is a member of United States Pharmacopeia (USP)'s Prescription/Non-Prescription Stakeholder Forum, USP Reference Standard Project Team and Consume Health Product Association (CHPA) Impurities Working Group. Kim is a recipient of the 2008 AAPS APQ Service Award and 2008 Recognition Award of AAPS Regulatory Section. She also received the 2001 DPCAA Leadership Award.

Kim Huynh-Ba has authored numerous technical publications and book chapters. She is invited frequently to present at national and international conferences. She is the editor of the *"Handbook of Stability Testing in Pharmaceutical Development: Regulations, Methodologies and Best Practices"* (ISBN: 978-0387856261), and also *"Pharmaceutical Stability Testing to Support Global Markets"* (ISBN: 978-1-4419-0888-9).

**Dr. Linda L. Ng** is currently the Chemistry Manufacturing and Controls (CMC) Lead for Ophthalmology in the Division of New Drug Chemistry II, Office of New Drug Quality Assessment (previously the Chemistry Team Leader co-located with the Division of Anti-Inflammatory, Analgesics and Ophthalmology Products), Center for Drug Evaluation and Research, Food and Drug Administration in Silver Spring, Maryland. She served as the CDER Chair of the Analytical Methods Technical Committee, drafted the CDER Reviewer Guidance: Validation of Chromatographic Methods, and was the FDA Topic Leader for the ICH Q2 Guidance. She has been invited to present and publish nationally and internationally in the area of method validation.

Dr. Ng is serving as the President of the Sigma Xi FDA Chapter, and is on the USP Expert Committee on Pharmaceutical Analysis 6, 2005-2010. She was the Vice Chair of the USP Expert Committee on Pharmaceutical Analysis 2 (2000-2005) and Chair of the USP working group on Column Classification. For the AOAC International, she served as the Chair of the Peer-Verified Methods Advisory Committee, member of the Task Force on Integration of the Methods Validation Programs, member, General and Associate Referees of the Committee for Drugs and Related Topics, and Associate Chapter Editor of the Official Methods of Analysis. She obtained her undergraduate degree from Western College, her Ph.D. from the University of Illinois, Champaign-Urbana, and had post-doctoral training at the Massachusetts Institute of Technology. She spent ten years in the pharmaceutical industry before joining FDA as a Review Chemist and later as an Expert Review Chemist.

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## Sample Preparation: The Chemistry Behind the Techniques

**One-Day Course E10-29, Tuesday, November 16, 2010, 8:30am – 5:30pm**

Dr. Merlin K. L. Bicking, ACCTA, Inc., Woodbury, MN  
Dr. Douglas E. Raynie, South Dakota State University, SD

### **COURSE DESCRIPTION**

Come prepared to learn that sample preparation is more than just a few "low tech" procedures. Learn about the chemical principles behind the techniques, and how an understanding of these principles will produce better results in your laboratory. This course will include a survey of many traditional procedures, including information on recent advances in these techniques. Several new sample preparation technologies will also be introduced.

This is not a "recipe" course limited to a particular sample type or application. This course offers a comprehensive treatment of sample preparation as an important part of every analytical method. You will learn more than just a few manipulations; you will come away with a complete understanding of what sample preparation is and how you can use it!

This has been a popular course at EAS for many years, and has been updated to provide you with a good understanding of modern sample preparation.

### **WHO SHOULD ATTEND**

Analytical chemists from all areas, especially those who want to learn more about sample preparation techniques, including preparation laboratory staff, analysts, and supervisors, will benefit from this course.

### **TOPICS**

- ▶ Perspectives on the Importance of Sample Preparation
- ▶ General Principles Used in Sample Preparation Procedures
  - Physical changes, LeChatelier's Principle
  - Effects of temperature, time, ionic strength, and pH
  - Like-dissolves-like
  - Two-phase partitioning equilibria
- ▶ Traditional Laboratory Procedures
  - Filtration
  - Solvent evaporation
  - Solvent exchange
- ▶ Traditional Laboratory Techniques
  - Derivatization
  - Liquid-liquid extraction (techniques, variations, and recent advances)
  - Liquid-solid extraction (traditional technologies and recent advances)

- Solid Phase Extraction (SPE)
- Membrane disk extractions
- ▶ “New” Sample Preparation Technologies
  - GC sample preparation (headspace, thermal desorption)
- Supercritical fluid extraction (SFE)
- Solid phase micro extraction (SPME)
- Accelerated solvent extraction (ASE)
- Other new ideas (SBSE and others)

### ABOUT THE INSTRUCTORS

**Dr. Douglas Raynie** (Course Director) is a Research Assistant Professor in the Department of Chemistry and Biochemistry at South Dakota State University. Prior to joining SDSU, he was employed for eleven years as a Senior Scientist at Procter and Gamble’s Corporate Research Division. He earned his Ph.D. at Brigham Young University under the direction of Dr. Milton L. Lee. His undergraduate degree is from Augustana (South Dakota) College, with majors in chemistry and biology. Analytical separations research in Dr. Raynie’s laboratory includes high-resolution chromatography (high-temperature LC and SFC), chromatographic sample preparation (ASE, SFE, SPME, and SPE), chromatography theory, green analytical chemistry, and problem-based learning in analytical chemistry.

**Dr. Merlin K. L. Bicking** is President, *ACCTA, Inc.* He has extensive analytical chemistry experience in academia, contract research, independent testing laboratories, consulting, and technical training. His professional history includes development of two EPA methods, as well as numerous methods in other regulated and non-regulated industries. His publications and presentations cover a wide range of topics, including liquid chromatography theory, derivatization, method optimization, and the use of experimental design strategies in analytical chemistry. He also develops and presents technical training seminars for analytical laboratory staff.

## How to Create a More Effective Lab Safety Program

**New One-Day Course E10-30, Tuesday, November 16, 2010, 8:30am – 5:30pm**

Dr. James A. Kaufman, Laboratory Safety Institute, Natick, MA

### COURSE DESCRIPTION

Safety in The Laboratory is an intensive one-day program designed to review the fundamentals of lab safety and assist scientists and science educators in the development and improvement of their lab safety program.

Participants discuss important lab safety problems and find solutions for many of them. The course emphasizes the need to make health, safety, and the environment an integral and important part of education, work and life. You’ll learn dozens of ways to convince others that lab safety is important (and that you’re serious about it).

This course is based on “Prudent Practices, the OSHA Lab Standard, ANSI Standards, NFPA Standards, and recognized professional standards from the American Chemical Society, the American Association of Physics Teachers, NIC, ASM, and the CDC.

Learn new presentation techniques and methods for conveying the importance of lab safety to your colleagues. Learn how to comply with many OSHA, EPA, and DOT requirements that impact Laboratories.

### WHO SHOULD ATTEND

Lab Managers, lab workers, lab technicians, analytical chemists, lab supervisors, group leaders, principal investigators, researchers, science and engineering faculty and staff, clinical and forensic scientists, and anyone who would like to have and improved lab safety program, reduce the likelihood of injury, illness, regulatory violation fines, and negligence lawsuits.

### TOPICS

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|--|---|
| <ul style="list-style-type: none"> <li>▶ Introduction</li> <li>▶ Three C’s of Safety</li> <li>▶ Scope of the Problem</li> <li>▶ Accidents</li> <li>▶ Legal Aspects</li> <li>▶ Emergency Planning</li> <li>▶ Handling and Storing Chemicals</li> <li>▶ Biological and Animal Hazards</li> </ul> | <ul style="list-style-type: none"> <li>▶ Eye and Fact Protection</li> <li>▶ Disposal of Chemicals</li> <li>▶ Electrical Safety</li> <li>▶ Most Serious Problem</li> <li>▶ Safety Program Planning</li> <li>▶ Safety Information Resources</li> <li>▶ Critique and Closing Comments</li> <li>▶ Additional Questions and Answers</li> </ul> |
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### ABOUT THE INSTRUCTOR

**Dr. James Kaufman** is President/CEO of The Laboratory Safety Institute (LSI) and former Professor of Chemistry and EHS Director at Curry College. He received his bachelors degree in chemistry from Tufts University and his doctorate in organic chemistry from Worcester Polytechnic Institute (WPI). He is widely regarded as the nation’s leading expert on laboratory safety.

After two years as a post-doctoral fellow in the WPI Chemical Engineering Department converting garbage into fuel oil, Dr. Kaufman joined the Dow Chemical Company's New England Research Laboratory as a Process Research Chemist. During his four years with Dow, he became increasingly involved in laboratory safety related activities. He authored "Laboratory Safety Guidelines". Originally distributed by Dow, now over two million copies of the widely requested and reprinted brochure are in circulation.

Dr. Kaufman is the founder and President/CEO of The Laboratory Safety Institute – an international, non-profit center for safety in science and science education. LSI's lectures and training programs, AV-lending library, Mini-Grants, Internet discussion list, and publications help both academic and non-academic institutions throughout the world. Over 60,000 scientists and science educators have attended these courses and presentations. LSI is supported, in part, by grants from individuals, foundations, companies and professional societies.

LSI conducts seminars, short courses, audits and inspections for schools, colleges, and companies. They also provide advice on regulatory compliance, safety program development, facilities design, editorial commentary on laboratory texts, and expert witness testimony.

Dr. Kaufman is a former, ten-year member of the American Chemical Society's (ACS) Council Committee on Chemical Safety and is past-chairman of the 2,500-member ACS Division of Chemical Health and Safety. He is the author-narrator of the ACS Audio Course on Laboratory Safety and editor of "Waste Disposal at Academic Institutions" from Lewis Publishers. He recorded and edited the "One-Day Laboratory Safety Audio Seminar" and "Two-Day Lab Safety Video Course." Most recently, he co-authored "Safety Is Elementary: the new standard for safety in the elementary science classroom."

## Quantitative Analysis for Chromatographers

**Two-Day Course E10-31, Wednesday and Thursday, November 17 and 18, 2010, 8:30am – 5:30pm**

Dr. Harold McNair, Virginia Tech, VA  
Dr. Gregory Slack, Clarkson University, NY  
Dr. Nicholas Snow, Seton Hall University, NJ

### COURSE DESCRIPTION

This course focuses on the many challenges facing chromatographers who are performing quantitative analysis. It is geared toward analysts, supervisors and auditors who are using GC and HPLC to obtain or review quantitative chromatographic data and results. The course will focus on the whole method, including sampling and sample preparation techniques such as liquid-liquid extraction, solid phase extraction, solid phase micro-extraction and proper wet laboratory practice and glassware handling. Instrumental considerations to be discussed include optimizing injection techniques, detection and data collection in GC and HPLC and troubleshooting. Further, method validation and optimization including case studies involving analysis of potential errors in quantitative chromatographic methods will be discussed. A fundamental knowledge of chromatography, such as a previous short course or experience in GC and/or HPLC is expected.

### WHO SHOULD ATTEND

1. Analysts performing chromatography based analyses who wish to improve their quantitative results by reviewing and better understanding sample preparation, instrumental considerations, data analysis, troubleshooting, validation and method transfer.
2. Managers, supervisors and auditors who wish to review the many considerations regarding good quantitation including sample preparation, instrumentation, data analysis, troubleshooting, validation and method transfer.

A fundamental knowledge of chromatography (a basic short course or experience operating chromatographic instruments) is expected.

### TOPICS

- ▶ Sample Preparation and Fundamentals
  - Handling and using glassware
  - Chemical equilibrium: the driver of separation and analysis
  - Extraction: LLE, SPE, SPME, head-space
- ▶ Instrumentation
  - Injection techniques: GC and HPLC
  - Detectors: GC and HPLC
- Data systems and collection
- Setting up and troubleshooting Instruments
- ▶ Data Analysis
  - Method validation and transfer
  - Method optimization
  - Method troubleshooting and investigation case studies

### ABOUT THE INSTRUCTORS

**Dr. Harold McNair** is professor emeritus of Analytical Chemistry at Virginia Tech, Blacksburg, Virginia. His research interests are the isolation, concentration and characterization of trace organic molecules by GC, LC and GC/MS. Analytes of interest include pesticides in water, soil and food; biogenic amines in fish; PNA's and PCB's in water and soil; and bomb residues in all types of matrices. He has published over 156 technical papers, 8 books and 14 chapters on chromatography. He has directed the thesis work of 63 graduate students, supervised over 50 post-doctoral fellows and 80 undergraduates.

Prof. McNair has taught a variety of graduate and undergraduate classes at Virginia Tech for 34 years. He also introduced the ACS short courses in GC, LC and GC/MS at Virginia Tech and has taught over 80 of them in the past 35 years. He has actively consulted for many industries as well as EPA, FDA, FBI and TSA.

He has received a variety of national and international awards for both teaching and research, among them: Tswett Medal from the Russian Academy of Science, Keene Dimick Award and Dal Nogare Awards (Pittsburgh Conference), EAS Awards in both Chromatography and Analytical Chemistry, the Colacro Medal from South America and the ACS J.C. Giddings award in Teaching. Most recently, 2009, he received the Lifetime Achievement Award for Chromatography from LC/GC magazine.

**Dr. Gregory Slack** is the Director of Research and Technology Transfer at Clarkson University. As director of the Division of Research and Technology Transfer, he oversees the conduct and promotion of all research activities at the University. Dr. Slack received his Ph.D. in Analytical Chemistry from Virginia Polytechnic Institute and State University, Blacksburg, Virginia. He earned a Bachelor of Arts degree from the State University of New York at Potsdam. He has over 13 years of experience in the pharmaceutical industry serving increasingly responsible research and manufacturing roles at Dupont, Bristol-Myers Squibb and most recently at Wyeth Pharmaceuticals. Slack has also had academic experience, serving as adjunct research assistant professor of Chemistry at Clarkson, adjunct professor at SUNY Plattsburgh and instructor of Analytical Chemistry at the University of Massachusetts, Lowell, Continuing Education. He has authored or co-authored numerous publications and presented at professional conferences.

Dr. Nicholas Snow is Professor and Chair of the Department of Chemistry and Biochemistry and Director of the Center for Academic Industry Partnership at Seton Hall University, South Orange, NJ. His entire education from first grade through PhD was in the Commonwealth of Virginia. He holds a BS in Chemistry from the University of Virginia and a PhD from Virginia Tech where he worked under the Direction of Prof. Harold McNair on computer simulations of gas chromatographic retention. He performed postdoctoral work in forensic toxicology at the University of Virginia prior to his arrival at Seton Hall in 1994. Over the past 15 years he has published 45 research articles and book chapters on many aspects of separation science, most notably gas chromatography and sample preparation. His research group has active projects in fundamental gas chromatography, LCxGC, GCxGC, SPME, GC-MS and ion mobility spectrometry with application areas including drugs, solvents, flavors and fragrances. He is especially interested in broadening the classes of compounds amenable to GC and GC-MS analysis. He is a member of the Governing Board of the Eastern Analytical Symposium and was its President in 2001. He chaired Seton Hall's university-wide Middle States re-accreditation in 2004 and he has been recognized twice by Seton Hall's Board of Regents for outstanding teaching and service to students.

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## Troubleshooting Chromatographic Systems

**Two-Day Course E10-32, Wednesday and Thursday, November 17 and 18, 2010, 8:30am – 5:30pm**

Dr. Merlin Bicking, ACCTA, Inc., Woodbury, MN  
Dr. Douglas E. Raynie, South Dakota State University, SD

### **COURSE DESCRIPTION**

Chromatographic instruments are an integral part of almost every analytical laboratory. While modern instruments are very reliable, chromatographers must still deal with many day-to-day problems (peak shape changes, baseline shifts, retention time problems, etc.) that can arise from the instrument, the sample, or the laboratory. This seminar will provide guidance on identifying the causes of such problems, finding solutions, and preventing future problems. Basic LC and GC components will be discussed, and helpful hints will be provided on how to avoid certain problems and maximize the overall analytical efficiency in the laboratory. Students will learn about general troubleshooting strategies, common symptoms, and common solutions to common symptoms. This seminar provides practical technical information that is not available from any other source.

Students are encouraged to bring examples of problems from their own laboratories for open discussion. This has been one of the most popular courses at EAS over for many years, and regularly receives excellent reviews from participants. Come find out why!

### **WHO SHOULD ATTEND**

Anyone involved with conducting or managing GC or HPLC analyses.

### **TOPICS**

- ▶ A General Approach to Troubleshooting
- ▶ Minimizing Errors in Peak Integration
  - How do chromatographic integrators work
  - What integration baseline options are available
  - Understanding the errors and minimizing them
- ▶ GC Troubleshooting
  - Current trends in instrument design
  - Comprehensive troubleshooting strategies for GC
  - Matching symptoms with solutions
- ▶ LC Troubleshooting
  - Current operating issues in HPLC
  - Design-related problems
  - Linking symptoms and solutions with the LC Troubleshooting Matrix
- ▶ Open Discussion
  - Bring your own examples and questions

### ABOUT THE INSTRUCTORS

**Dr. Merlin K. L. Bicking** (Course Director) is President, *ACCTA, Inc.* He has extensive analytical chemistry experience in academia, contract research, independent testing laboratories, consulting, and technical training. His professional history includes development of two EPA methods, as well as numerous methods in other regulated and non-regulated industries. His publications and presentations cover a wide range of topics, including liquid chromatography theory, derivatization, method optimization, and the use of experimental design strategies in analytical chemistry. He also develops and presents technical training seminars for analytical laboratory staff.

**Dr. Douglas Raynie** is a Research Assistant Professor in the Department of Chemistry and Biochemistry at South Dakota State University. Prior to joining SDSU, he was employed for eleven years as a Senior Scientist at Procter and Gamble's Corporate Research Division. He earned his Ph.D. at Brigham Young University under the direction of Dr. Milton L. Lee. His undergraduate degree is from Augustana (South Dakota) College, with majors in chemistry and biology. Analytical separations research in Dr. Raynie's laboratory includes high-resolution chromatography (high-temperature LC and SFC), chromatographic sample preparation (ASE, SFE, SPME, and SPE), chromatography theory, green analytical chemistry, and problem-based learning in analytical chemistry.

## **PLastics-State of the Art Techniques Important in Cleaning their Surfaces** *Organized in cooperation with New York Conservation Foundation*

**NEW Two-Day Course E10-33, Wednesday and Thursday, November 17 and 18, 2010, 8:30am – 5:30pm**

Dr. Yvonne Shashoua, Department of Conservation, National Museum of Denmark, Denmark  
Ms. Kathrine Segel, Department of Conservation, National Museum of Denmark, Denmark

### COURSE DESCRIPTION

Condition surveys of plastics in art, design, modern history, industrial and toy collections conclude that 75% require cleaning. Soiling comes from air pollution, handling, use and degradation products and reduces both chemical stability and significance of plastics. Despite high demand, few conservation cleaning treatments for plastics have been established because of the fear of damaging them by abrading, leaving residues, crazing or discolouring. The cleaning techniques discussed in this short course are based on recent research into cleaning of industrial and heritage plastics. The effect of cleaning on long term stability of plastics and their effectiveness at removing soiling will be presented. The course will discuss those properties of plastics which affect the attachment of common soils and those which make the cleaning of particular plastics a high risk activity. The effect of applying mechanical cleaning techniques such as microfiber cloths, commercial sponges, brushes and dry ice both alone and in combination with aqueous and non-aqueous cleaning agents to the plastics most commonly found in heritage collections will be presented. Both theoretical and practical sessions, where participants will clean and evaluate their trials, will equip participants to minimize risk when designing cleaning treatments for plastics. Notes are provided.

### WHO SHOULD ATTEND

Heritage professionals and others who have interest in and responsibility for caring for plastics collections including art, design, modern history, industrial, medical and toy collections. Experience with plastics is not essential because a background to the relevant theories is included in the course, although a general understanding of plastics would be helpful.

### TOPICS

- ▶ Introduction to Plastics in Collections
- ▶ Physical and Chemical Properties of Plastics with Emphasis on those which have Relevance to Cleaning
- ▶ Techniques used to Evaluate Damage to Plastics Induced by Soiling and Cleaning
- ▶ Definition of Soil and its Origins
  - Descriptions of various soil types including particulate, oily and water-based
  - Degradation products as soil such as plasticizer and antiozonants
- ▶ Mechanisms by which Soils can Attach to Plastics; Effect of Soils on Plastics, both Physical and Chemical
- ▶ Mechanisms by which Soils can be Removed, both Physical and Chemical
- ▶ Mechanical Cleaning Techniques
  - Types (microfibers, sponges, brushes, abrasives, sticky agents)
  - Mechanism by which mechanical cleaning works
  - Effectiveness of mechanical cleaning on soil
- ▶ Potential Damage/Degradation Caused to Plastics by Mechanical Cleaning
- ▶ Aqueous Cleaning Agents
  - Types (water, detergents-anionic, non-ionic)
  - Mechanism by which aqueous agents work
  - Effectiveness of aqueous cleaning on soil
- ▶ Potential Damage/Degradation Caused to Plastics by Aqueous Cleaning
- ▶ Selection of Suitable Aqueous Cleaning Types for Plastics
- ▶ Solvent-Based Cleaning Agents
  - Types (polar, non-polar, commercial mixtures, alternatives such as supercritical CO<sub>2</sub> and silicones)
  - Mechanism by which solvent-based agents work
  - Effectiveness of solvent-based on soil
- ▶ Potential Damage/Degradation Caused to Plastics by Solvent Cleaning
- ▶ Selection of Suitable Types for Plastics using Solubility Parameters and Trial and Error
- ▶ Combination of Mechanical, Aqueous and Solvent-Based Techniques
- ▶ Practical Cleaning of Plastics Based on Research Findings and Case Histories

### ABOUT THE INSTRUCTOR

**Dr. Yvonne Shashoua** is Senior Researcher at the National Museum of Denmark investigating the degradation, inhibitive and interventive and conservation of plastics. After graduating in industrial chemistry she worked as a paint technologist for Berger Paints in England. She joined the British Museum as a conservation scientist in 1988, specialising in the deterioration reactions and conservation of cellulose nitrate, cellulose acetate, PVC and rubber. A scholarship from the National Museum of Denmark resulted in a PhD concerning the degradation and conservation of plasticized PVC from Danish Polymer Center, Danish Denmark's Technical University. Yvonne has 70 publications including a monograph 'Conservation of Plastics-materials science, degradation and conservation' published by Elsevier in 2008. She was coordinator of ICOM-CC's working group Modern Materials and Contemporary Art until 2005.

**Ms. Kathrine Segel** is a Conservator at the National Museum in Denmark currently engaged with POPART – an EU funded project focusing on the cleaning of plastics. Though trained as a paintings conservator, Kathrine has throughout her career focused on modern and contemporary art. In 2008 she graduated from the Royal Danish School of Conservation in Copenhagen. The subject of her master thesis was the preservation of artworks by the American artist Donald Judd. Kathrine has worked as a conservator at several different institutions inland and abroad including the Chinati Foundation in Marfa, Texas, Hamburger Bahnhof in Berlin and The National Gallery of Denmark. Kathrine is a member of INCCA – an international network of conservators working with contemporary art.

## How to Develop Validated HPLC Methods: Rational Design with Practical Statistics and Troubleshooting

**Two-Day Course E10-34, Wednesday and Thursday, November 17 and 18, 2010, 8:30am – 5:30pm**

Dr. Brian A. Bidlingmeyer, Agilent Technologies, Wilmington, DE

Dr. Stanley N. Deming, Statistical Designs, Houston, TX

### COURSE DESCRIPTION

This course offers practical training for the practicing scientist. This course takes the participant step-by-step through the concepts, techniques and tools necessary to develop validated HPLC methods. Learn a rapid, systematic approach to PLC methods development that provides sustainable validation by using statistical process control (SPC) tools. Rather than developing the HPLC method and then validating it, this course proposes following a streamlined, iterative process to integrate the method development and validation activities. The approach is effective, efficient and productive. The emphasis is on practical issues associated with developing validated HPLC methods. Case studies illustrate specific problems and how to approach them, how to carry out routine maintenance to prevent loss of validation, and how to set diagnostics to recognize behavior that requires troubleshooting. Discuss your specific method development/validation problems with instructors who have more than 60 years of combined experience in industry and academe. You will leave with a firm strategy for developing your own continually validated HPLC methods.

### WHO SHOULD ATTEND

This course is intended for individuals who will be or are developing and/or doing quantitative PLC analyses. Laboratory managers, supervisors, analysts, chemists, biologists, engineers and technicians who are responsible for the continual use of validated high-performance liquid chromatographic methods of chemical analysis should attend this course. Those working in R&D, manufacturing, QA/QC, methods development, process development, product testing, pharmaceuticals, biotechnology, organic chemicals, petroleum, environmental, foods, flavors, fragrances, pesticides, testing services laboratories, and occupational health and safety testing will all benefit from this course.

### TOPICS

- ▶ Method Evolution
  - Thinking ahead makes the tasks easier
  - The top four items to be successful
- ▶ Basic Statistical Concepts
  - Calculations with statistical significance
  - Parameters of merit
- ▶ Detection Options
  - Choices and trade-offs
  - Typical uses and sensitivities
- ▶ Determining Accuracy, Precision and Linearity
  - Making measurements
  - Proper calculation of validation parameters
- ▶ Achieving Separations
  - The chemistry of resolution
  - Follow the flow chart: a rational strategy for achieving resolution
- ▶ Sample Preparation
  - Review of techniques
  - How to improve the analysis
- ▶ Determining LOD, LOQ, MDL
  - Understanding your limits
  - A simple, fundamental statistical approach
- ▶ Achieving Method Stability and Robustness
  - System suitability
  - System component contributions
- ▶ Optimizing Using Window Diagrams
  - Finding the tallest trees in the forest
  - Choosing the best of several optima
- ▶ Using Statistical Quality Control of Separations
  - An easy graphical method
  - Achieving sustainable validation

- ▶ Troubleshooting Out-of-control Systems
  - Things you often forget to look for
  - Group discussion of typical issues
- ▶ Putting It All Together
  - Approaching the steps to validating a method
  - When steps are necessary and when they're not
- ▶ Case Studies

### ABOUT THE INSTRUCTORS

**Dr. Brian A. Bidlingmeyer** is employed by Agilent Technologies in Wilmington, DE. He is an accomplished separation scientist who has work experience in the chemical, pharmaceutical and instrumentation industries. He has published 2 books and more than 80 papers. Brian is the Chairman-elect of the Separations Science Subdivision of the American Chemical Society's Analytical Division and is active in the ASTM committee concerning chromatographic practices. He has made significant contributions to the practice and understanding of modern HPLC and has received numerous awards including the Heinrich Emmanuel Merck Prize for contributions to analytical chemistry, the International Ion Chromatography Award for contributions to that area, and an IR 100 Award for a new method for amino acid analysis (Pico Tag Method). He is presently an associate editor of the *Journal of Chromatographic Science*.

**Dr. Stanley N. Deming** is Professor Emeritus at the University of Houston in Houston, TX. He is also the President of Statistical Designs, a firm that offers short courses and consulting in the areas of methods development, process optimization, statistical experimental design and the statistical analysis of laboratory data. He has taught (with Dr. Stephen L. Morgan) more than 500 highly acclaimed short courses for the ACS and other organizations. He has co-authored 3 books and approximately 100 papers. He has been a member of the editorial boards of *Critical Reviews in Analytical Chemistry*, the *Journal of Chemometrics*, and *Chemometrics and Intelligent Laboratory Systems*.

## Practical Headspace Gas Chromatography

**One-Day Course E10-35, Wednesday, November 17, 2010, 8:30am – 5:30pm**

Dr. Mary Ellen P. McNally, DuPont, Wilmington, DE  
Dr. Thomas A. Brettell, Cedar Cress College, Allentown, PA

### COURSE DESCRIPTION

Headspace sampling is an established technique for volatile sample introduction in chromatography. When complicated sample matrices make sample preparation difficult, the gas headspace above the sample is a valuable source of information. Accurately measuring this gas phase can be challenging. Specifically, the challenges are establishing a representative sample, devising an accurate calibration for the matrix of interest and replicate analyses from a static system. These topics as well as discussions on theory, appropriate apparatus and instrumentation, and applications from the pharmaceutical industry (specifically addressing the new USP467 Guidelines), forensic science, manufacturing, environmental, and food and flavor industry will be presented in this course.

### WHO SHOULD ATTEND

This one-day course will benefit method development scientists, R&D analysts, R&D formulators, QC analysts, regulatory affairs associates, R&D, RA and QA/QC managers for both bulk drug and finished dosage form developers and manufacturers.

### TOPICS

- ▶ Introduction
  - Introduction and background of speakers
  - Logistics
  - Course outline/scope of course
  - Course materials
- ▶ Theory: Basic Principles of Headspace GC
  - Partition ratio
  - Phase ratio
  - Physical chemical aspects
  - Multiple headspace extraction
  - Static headspace
  - Passive headspace
    - SPME
  - Dynamic headspace (Purge and Trap)
  - Headspace single drop microextraction Techniques
- ▶ Instrumentation
  - Gas tight injection
  - Balanced-pressure system
  - Pressure-loop system
  - Sample preparation
  - Sample vials
- ▶ Quantitation
- ▶ System Optimization/Troubleshooting
  - Transfer line
  - Interfaces
- ▶ Applications
  - Pharmaceutical applications
    - <USP467>
    - European pharmacopoeia tests
  - Forensic applications
    - Blood alcohol determination
  - Environmental applications
  - Manufacturing/industrial applications
  - Food and flavor applications
- ▶ Wrap Up/Reflections/Discussion

### ABOUT THE INSTRUCTORS

**Dr. Mary Ellen P. McNally** (Course Director) is a Senior Research Associate at the Stine Haskell Research Center for the Crop Protection Products business unit of E.I. du Pont de Nemours & Co., Inc. in Newark, DE. Her main research areas are in the fields of separations, sample preparation and sensors. Most of her work has been focused in the environmental area, both in environmental fate of agricultural products, ultra-trace level analysis and detection as well as analysis associated with manufacturing and process development. Her Ph.D. thesis was in the area of Headspace analysis of priority pollutants. Dr. McNally received the American Microchemical Society Steyermark Award for her work conducted in the field of microanalysis, the Chromatography Forum of Delaware Valley Award for contributions to theory, instrumentation and applications to the field of chromatography and service to the organization. Mary Ellen has been recognized for her contributions to the field of supercritical fluids by the Midwest Supercritical Fluid Chromatography Discussion and the Tri-State Analytical Supercritical Fluid Discussion Groups. Dr. McNally is a member the editorial advisory board for LCGC magazine and a former member of the Instrumentation Panel and the Advisory Board for the journal of Analytical Chemistry and the editorial board of Talanta. Within DuPont, Dr. McNally has received DuPont's highest award for contributions to trace level analysis as well as the DuPont Scientific Leadership Award. This award afforded her the opportunity to work at the Imperial College in London in capillary electrochromatography as well as LC and CE on a microchip and at the Molecular Engineering Cooperative Research Center of CSIRO in Sydney Australia working in the area of biosensors.

**Dr. Thomas A. Brettell** retired in 2007 as the Director of the New Jersey State Police Office of Forensic Sciences and is presently an Assistant Professor in the Chemical and Physical Sciences Department at Cedar Crest College. Dr. Brettell's main research areas are in chromatography and medico-legal aspects of alcohol. His Ph.D. thesis was in the area of Headspace Gas Chromatographic analysis of fire debris accelerants. He has taught advanced separation courses and has taught in the gas chromatography course sponsored by the Chromatography Forum of the Delaware Valley. In 1993, he received a commendation from the NJSP Superintendent for his work on a narcotics investigation. Dr. Brettell is the past Chair of the Criminalistics Section of the American Academy of Forensic Sciences and the past President of the Chromatography Forum of the Delaware Valley. Tom was presented the Chromatography Forum of the Delaware Valley Award in 1997 for service to the Forum and accomplishments in the field of separation science, and also served on the Advisory Board of the Journal of Analytical Chemistry from 1996 to 1998. In 2004, Dr. Brettell was appointed to the Governor's Advisory Council Against Sexual Violence and served until 2006. He presently serves on the National Safety Council's Committee on Alcohol and Other Drugs. Dr. Brettell is a certified Diplomat of the American Board of Criminalistics and a Fellow in the American Academy of Forensic Sciences.

## **Impurity and Degradant Identification: Strategies for Structure Elucidation via Chromatography, MS and NMR**

**One-Day Course E10-36, Wednesday, November 17, 2010, 8:30am – 5:30pm**

Dr. Thomas R. Sharp, Pfizer Global Research and Development, Groton, CT

Dr. Brian L. Marquez, Pfizer Global Research and Development, Groton, CT

Mr. Todd Zelesky, Pfizer Global Research and Development, Groton, CT

### COURSE DESCRIPTION

This course is designed to take participants through the process of impurity/degradant identification from start to finish. This course will be taught based on application driven materials and will only deal with very limited theory. This course will provide methods and approaches to solve a wide array of the impurity/degradation problems faced by structure elucidation scientists. The substrate provided will help guide individuals to solving more complex problems.

### WHO SHOULD ATTEND

This one-day course will benefit anyone interested in the practice of organic molecular structure determination. Focus and discussed examples will be on impurities and degradants found in pharmaceutical drug substances and products, but the principles are easily generalized.

### TOPICS

- ▶ Impurity/Degradant Isolation Techniques
  - Mass directed fraction collection
  - Supercritical fluid chromatography (SFC)
  - Trends in normal phase and reverse phase isolations
- ▶ MS and LC-MS
  - Historical perspective
  - Ionization methods and instrumentation
  - Accurate mass measurements
  - Clusters
  - Isotopes, isotopes, isotopes
  - Polymer patterns and multiply charged ions
- Electrospray versus APCI
- LC-MS-compatible buffers
- MS-silent compounds
- ▶ NMR and LC-NMR
  - Basics of NMR and why it is an important tool for small molecule structure elucidation
  - Types of experiments used to solve particular problems
  - Utilization of hyphenation techniques: LC-NMR, LC-MS/NMR, other variations
  - Reaction NMR—monitoring real-time chemical reactions by NMR

**▶ Example Problems**

- Case studies involving isolation, MS and NMR
- Case studies involving more advanced NMR and MS
- techniques
- Participants will discuss several case studies during this course

**ABOUT THE INSTRUCTORS**

**Dr. Thomas R. Sharp** (Course Director) is an associate research fellow emeritus from Pfizer. He retired as a member of the research analytical co-discovery group in 2009. He previously headed a resource laboratory responsible to the division and the corporation focusing on the application of mass spectrometry to the structure elucidation of drug substance, impurity, and degradant molecules of interest to the company. He is now a member of the research analytical co-discovery group, providing early analytical chemical support to early development stage candidate molecules, which still includes impurity/degradant identification, as well as investigations into the computational chemistry aspects of molecule stability evaluation and expert systems development. He received his undergraduate degree in Zoology from Western Illinois University (1972), his Ph.D. from Indiana University (1977) in Biological Chemistry, has held postdoctoral appointments at Penn State University and Case Western Reserve University School of Medicine, fellowships from the American Cancer Society and the Muscular Dystrophy Association of America, and faculty/staff appointments at the University of Utah and Texas A&M University before joining Pfizer in 1991. Dr. Sharp received a Master's degree in Computer Science (1999) from Rensselaer Polytechnic Institute.

**Dr. Brian L. Marquez** is an associate research fellow at Pfizer Global Research and Development, Groton, CT. He currently leads the Structure Elucidation Group within the development organization. His team is responsible for the isolation and identification of unknown impurities and degradants from all stages of the drug development process. In addition, his group has the opportunity to explore and implement new advances in the fields of structure elucidation including NMR, MS, and isolation techniques. He received his undergraduate degree in Biochemistry and Biophysics from Oregon State University (1997) and his Ph.D. from Oregon State University (2001) in Medicinal Chemistry (Marine Natural Products Chemistry). Dr. Marquez has also held positions at Wyeth and Amgen doing structure elucidation by NMR spectroscopy.

**Mr. Todd C. Zelesky** is a scientist at Pfizer Global Research and Development, Groton CT. He currently works in the Structure Elucidation Group within the development organization. He is responsible for the isolation of impurities and degradants from all stages of the drug development process. He has explored and taken part in the implementation of technologies such as supercritical fluid chromatography that have impacted the isolation workflow and processes within the Structure Elucidation Group. He received his undergraduate degree in Chemistry at the University of Connecticut in 2000. Mr. Zelesky has also worked in The Forced Degradation Group as well as The Polymer Analysis and Characterization Group in Analytical Research and Development at Pfizer in Groton CT.

## **Laser Desorption Mass Spectrometry and Other MS Techniques for Identifying Trace Impurities in Biocompatibility Testing**

**New One-Day Course E10-37, Wednesday, November 17, 2010, 8:30am – 5:30pm**

Dr. Kevin Owens, Drexel University, Philadelphia, PA  
Dr. William Erb, Ethicon Inc., Somerville, NJ

### **COURSE DESCRIPTION**

This is a short course that will provide a basic understanding of Laser Desorption Mass Spectrometry. It will also cover topics in sample preparation and results interpretation. Topics that will also be covered include troubleshooting and instrument variables necessary to enhance the results. Finally, the significance of the results with respect to biocompatibility will be covered.

### **WHO SHOULD ATTEND**

Anyone interested in the determination of trace components in biomaterials. The presentation will be for someone at the BS level.

### **TOPICS**

- ▶ Introduction to Chemical Biocompatibility
- ▶ Fundamentals and Theory of Laser Desorption and MALDI Mass Spectrometry
- ▶ Other Mass Spectrometry Techniques Utilized for Chemical Biocompatibility
- ▶ Sample Preparation for Chemical Biocompatibility
- ▶ Applications of MS on Chemical Biocompatibility
- ▶ Troubleshooting and Pitfalls

### **ABOUT THE INSTRUCTOR**

**Dr. Kevin Owens** received a B.S. in Chemistry from the University of New Hampshire in 1982. He went on to receive a Ph.D. in Analytical Chemistry from Indiana University in 1989, working under the direction of Dr. James P. Reilly using molecular beam techniques to study

the gas phase spectroscopy of small aromatic molecules. Detection of these species involved both laser induced fluorescence and multiphoton ionization followed by time-of-flight mass spectrometry (TOFMS) detection. He then joined the faculty of the Chemistry Department of Drexel University where he is currently an Associate Professor. The research interests of his group include studying the mechanism of the matrix-assisted laser desorption/ionization (MALDI) process, investigating the application of MALDI to the analysis of synthetic polymer systems, and extending the quantitative capability of MALDI by the development of electrospray sample deposition techniques. Other work in the group involves TOFMS instrument development (particularly improving the detection efficiency of high mass ions) and the development of automated data processing techniques based on the genetic algorithm and correlation analysis techniques.

**Dr. William J. Erb**, Scientist, at Ethicon Inc., is a member of the Analytical Characterization Group. His primary responsibility is to advance the mass spectrometry facility with a focus on biocompatibility and new material characterization. His research interest is the development and application of mass spectrometry techniques as a tool for improved understanding and development of polymer chemistries for medical devices. Erb graduated with a PhD degree in Analytical Chemistry in 2007 from Drexel University. He has multiple years of experience utilizing MALDI TOFMS, LC/MS, and GC/MS to characterize polymers. William has presented numerous talks and publications on proper sample handling and preparation to educate about the importance of the effect on the results obtained from mass spectrometry. He received the American Institute of Chemists Graduate Achievement Award in 2007 from Drexel University, and has received gold and silver encore awards at Ethicon.

## Leachables and Extractables in Pharmaceutical Development

***One-Day Course E10-38, Wednesday, November 17, 2010, 8:30am – 5:30pm***

Dr. Daniel L. Norwood, Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT

Mr. James O. Mullis, Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT

### COURSE DESCRIPTION

Leachables, both organic and inorganic, originating from pharmaceutical container closure systems, represent a significant impurity issue in many drug product types. The greatest regulatory concern is with Orally Inhaled and Nasal Drug Products (OINDP), parenteral and injectable drug products, and ophthalmic drug products. Other drug product types (e.g. transdermals, topicals, etc.) are also not exempt from regulatory concern. This course will present the current state of regulatory policy related to leachables and potential leachables (i.e. extractables) organized as to drug product type. The course will also cover laboratory evaluation of potential leachables (i.e. extractables), qualitative and quantitative analysis of leachables and extractables (for both stability studies and routine quality control), and safety evaluation of leachables within the context of an overall pharmaceutical development process.

### WHO SHOULD ATTEND

Anyone involved in pharmaceutical development programs in which leachables/extractables issues are significant.

### TOPICS

- ▶ Fundamental Definitions and Concepts
- ▶ Origins of Leachables/Extractables – the Pharmaceutical Container Closure System
- ▶ Regulatory Environment for Leachables/Extractables – “Risk-based” Approach
  - “High Risk” drug products
  - Inhalation drug products (OINDP)
  - Parenteral/injectable drug products
  - Ophthalmic drug products
  - “Low Risk” drug products types
  - Solid oral dosage forms
- ▶ Evaluation of Organic Extractables
  - Container closure system formulation–information from suppliers
  - Laboratory controlled extraction studies
  - Qualitative analysis of organic extractables
  - Quantitative analysis of organic extractables
  - Routine control of organic extractables
- ▶ Evaluation of Organic Leachables
  - Development and validation of leachables methods based on drug product type – case studies
  - Inhalation drug products
  - Injectable, parenteral and ophthalmic drug products
  - Solid oral dosage forms
  - Leachables stability studies
  - Routine control of organic leachables
- ▶ Safety Evaluation of Leachables – the PQRI Threshold Concept
- ▶ Possible Trends in Leachables/Extractables Regulation, Analysis and Control
  - Quality by Design (QbD)
  - Staged approach to safety thresholds

### ABOUT THE INSTRUCTORS

**Dr. Daniel L. Norwood** is Distinguished Research Fellow in the Analytical Sciences Department at Boehringer Ingelheim Pharmaceuticals, Inc. in Ridgefield, CT. He is responsible for a section which includes Trace Analysis (Mass Spectrometry, Gas Chromatography, Metals Testing), Nuclear Magnetic Resonance Spectroscopy (NMR), and Mechanistic Toxicology Research Support. Dr. Norwood received his Ph.D. in Environmental Chemistry from the University of North Carolina at Chapel Hill, School of Public Health, and has over 30 years of experience in structure elucidation and trace organic analysis in the pharmaceutical, biomedical, environmental and geochemical areas. Dr. Norwood has held senior pharmaceutical industry positions at Magellan Laboratories, Inc. and the Glaxo Research Institute. He

was also Medical Research Assistant Professor at Duke University Medical Center, Durham, North Carolina, and has held an appointment as Adjunct Assistant Professor at the University of North Carolina, School of Public Health. He chairs the PQRI (Product Quality Research Institute) Working Group on Leachables and Extractables, is a member of the PQRI PODP Leachables and Extractables Working Group, and participates in various International Pharmaceutical Aerosol Consortium (IPAC-RS) technical teams.

**Mr. James O. Mullis** is Principal Scientist in the Trace Analysis Group, Physical and Chemical Analysis Section in the Analytical Sciences Department at Boehringer Ingelheim Pharmaceuticals, Inc. in Ridgefield, CT. Mr. Mullis received his B.S. in Chemistry from the University of North Carolina at Chapel Hill and M.S. in Chemistry from Georgia Tech. He has over 20 years of experience in structure elucidation and trace organic analysis in pharmaceutical development, particularly in the area of leachables and extractables. He has participated as an instructor in PQRI training courses related to leachables and extractables, and currently is a member of the IPAC-RS OINDP Materials Technical Team.

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## Supercritical Fluid Chromatography for the Pharmaceutical Industry

**New One-Day Course E10-39, Wednesday, November 17, 2010, 8:30am – 5:30pm**

Dr. Larry T. Taylor, Virginia Tech, Blacksburg, VA

Mr. Larry Miller, Amgen, Cambridge, MA

### **COURSE DESCRIPTION**

This course will focus on the fundamentals and advances in supercritical fluid chromatography (SFC) employing carbon dioxide-based mobile phases and packed column stationary phases. Particular emphasis will be directed toward pharmaceutical and other industrial fields where SFC plays or will play a critical role. The day-long course will cover:

Analytical and preparative scale separations

Advantages of carbon dioxide-based mobile phases relative to conventional liquid mobile phase solvents with commercially available normal phase packed columns in terms of: (1) column efficiency per unit time, (2) sample throughput, (3) cost of analysis, (4) detector compatibility and interface design, (5) multiple stacked columns for enhanced resolution, (6) screening of columns & modifiers, and (7) hyphenation with sample preparation

- Guidelines for stationary phase selection
- Comparisons of SFC with normal phase HPLC
- Detection with emphasis on mass spectrometry
- Instrumentation for preparative scale separations in conjunction with high throughput requirements
- Fundamental physico-chemical properties of compressible fluid phases within the context of chromatographic science
- Role of both mobile phases modifiers and additives in the separation of polar analytes
- Applications that incorporate a wide variety of functional groups relevant to pharmaceutical science such as quaternary amine salts, phospholipids, polyphenols, and surfactants
- A unified chromatographic approach in which solvating power, diffusivity, and viscosity are variables

### **WHO SHOULD ATTEND**

Anyone who has an interest in packed column or open tubular column supercritical fluid chromatography coupled with both spectroscopic and flame-based detectors will find this course beneficial. Subcritical fluid and enhanced fluidity chromatography are also applicable. Actual experience in analytical or preparative scale SFC, however, is not necessary. Some knowledge of chromatographic principles is desirable.

### **TOPICS**

- |  |  |
|--|--|
| ▶ Introduction to Supercritical Fluids and SFC | ▶ Fundamentals and Applications of Preparatory SFC |
| ▶ Instrumentation for SFC                      | ▶ Applications of Achiral and Chiral SFC           |
| ▶ Methods Development in SFC                   | ▶ Validation and Sensitivity in SFC                |

### **ABOUT THE INSTRUCTOR**

**Dr. Larry T. Taylor:** Emeritus Professor of Chemistry, Virginia Tech, Blacksburg, VA USA

- Member of Editorial Board: J. Chromatogr. Sci., Chromatographia, J. Supercrit. Fluids
- Member of the Organizing Committee: 4th – 10th International Symposia on SFC and SFE
- Chair of Scientific Committee: SFC 2008 Zurich, SFC 2009 Philadelphia, SFC 2010 Stockholm

**Mr. Larry Miller:** Principal Scientist, Amgen, Cambridge, MA, USA

- Twenty five years of small molecule purification experience at mg to kg scale
- Member of Scientific Committee: Prep 2009 and SFC 2009 meeting
- Author or co-author of more than 20 peer reviewed publications and two book chapters.

## Metrology in the Analytical Laboratory

**One-Day Course E10-40, Wednesday, November 17, 2010, 8:30am – 5:30pm**

Dr. Jerry D. Messman, Stranaska Scientific LLC, Fort Collins, CO

### COURSE DESCRIPTION

Metrological practices with respect to chemical analysis are becoming more rigorous because of formalized measurement assurance programs and the evolving emphasis on international standardization and laboratory accreditation. Analytical metrology broadly encompasses many measurement operations including analytical instrument qualification, analytical methods testing (chemical metrology or metrology in chemistry), and physical properties characterization. This course provides a basic introduction to many facets of the overall analytical measurement process including calibration, reference material standardization, traceability, estimation and reporting of measurement uncertainty, and how they together can impact the quality and reliability of measurement results and the confidence in any consequential actions or decisions. Much of the course material is gleaned from authoritative international references. Instruction is provided from a broad perspective to make it relevant to a wide range of analytical laboratories including those in the biotech, chemical, clinical, environmental, food and beverage, forensic, industrial hygiene, petrochemical, and pharmaceutical industries.

### WHO SHOULD ATTEND

This course is intended for laboratory analysts, technicians, supervisors and managers who have metrological responsibilities for ISO 17025 accreditation, analytical methods testing, quality assurance and internal quality audits. It is also beneficial to metrologists, calibration specialists, and instrument service technicians who must demonstrate technical competence in analytical instrument qualification.

### TOPICS

- ▶ Metrological Definitions, Terms and Concepts
- ▶ Key Government Agencies and International Organizations
- ▶ Measurement Scales and Units
- ▶ Calibration Hierarchy
- ▶ Reference Material Standards
- ▶ Metrological Traceability
- ▶ Measurement Uncertainty
- ▶ Analytical Methods Testing (Chemical Analysis)
- ▶ Analytical Instrument Qualification: UV/VIS/NIR, IR/Raman, Fluorescence, HPLC

### ABOUT THE INSTRUCTOR

**Dr. Jerry D. Messman** holds a Ph.D. degree in analytical chemistry from the University of Maryland (College Park, MD USA). Jerry has been involved in various spectrometric aspects of analytical chemistry and metrology throughout his entire professional career beginning 30 years ago with the National Bureau of Standards (NBS). During his tenure at the National Institute of Standards and Technology (NIST) from 1988 to 1992, Jerry was responsible for rejuvenation of the high-accuracy spectrophotometric standards program in the Chemical Sciences and Technology Laboratory. During that time, he directed all NIST technical activities involving the production, certification, and recertification of UV/VIS spectrophotometric Standard Reference Material (SRM) artifacts. For the past 17 years, Jerry has served as Managing Director and Senior Scientist of Stranaska Scientific LLC, an analytical research and development company dedicated to the scientific and educational advancement of analytical metrology worldwide. Jerry is an elected member of CITAC, an acronym for the Cooperation on International Traceability in Analytical Chemistry.

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## Dissolution: A Rational Approach to Developing and Validating Methods for a Variety of Purposes

**One-Day Course E10-41, Thursday, November 18, 2010, 8:30am – 5:30pm**

Mr. Gregory Martin, Complectors Consulting, Pottstown, PA

### COURSE DESCRIPTION

Dissolution testing plays multiple roles for drug products, throughout the product lifecycle from early development to mature marketed product. This course provides an in-depth and interactive presentation on developing and troubleshooting dissolution methods for a variety of applications, including early development, biorelevant dissolution, in-vivo/in-vitro comparisons and marketed products. Real world examples of methods, issues, (sometimes unexpected) testing results and interpretation of data will be used, and there will be ample opportunity for discussion by participants both throughout the course and at the end.

### WHO SHOULD ATTEND

Scientists who develop or apply dissolution methods (e.g. stability, quality control) and those who need to understand dissolution testing and its implications for formulation selection, manufacturing and regulatory filings (both those at the bench and their managers) will benefit from this course.

**TOPICS**

- ▶ General Considerations
  - A variety of potential reasons for dissolution testing
  - Regulatory requirements and compendia guidances
  - Identifying the design requirements for your particular method
- ▶ Dissolution Method Development Fundamentals
  - Apparatus: selection and qualification
  - Dissolution medium
  - Testing parameters: speed, sampling times
  - Measurement options: UV, HPLC, others
  - Interactive exercise on method development
- ▶ Evolution of Dissolution Methods
  - Early development: formulation selection
  - Late development: establishing specifications
  - Marketed products: post approval changes
- ▶ Correlating In-Vitro and In-Vivo Data
  - Bio-relevant dissolution
  - Comparing dissolution data to animal and human data
  - Different types of correlations
- ▶ Method Troubleshooting
  - Extensive presentation of common issues observed during method development and product lifecycle, and appropriate ways to diagnose and respond to issues
  - Discussion of issues observed by participants
- ▶ Course Review
  - Questions and answers

**ABOUT THE INSTRUCTOR**

**Mr. Gregory Martin** is President of Complectors Consulting, which provides consulting services and technical training related to pharmaceutical analysis (particularly dissolution), regulatory and compendial issues and improving lab efficiency. He has 30 years experience in the pharmaceutical industry, including extensive responsibility for dissolution method development and troubleshooting, including 24 years at Merck and Co where he was Director of Pharmaceutical Analytical Chemistry. He has made numerous presentations on dissolution method development and instrument calibration, HPLC method development and validation, and related substances including residual solvents. He has served on the USP Dissolution Project Teams and PhRMA Dissolution Expert Committee. He is also Vice Chair of the USP General Chapters Expert Committee, where he has had significant impact on several General Chapters, including Residual Solvents, Validation of Analytical Procedures, Instrument Qualification and Chromatography.

## Application of Mass Spectrometry for Characterizing and Profiling Impurities/Degradation Products and Potential Genotoxic Impurities of Drug Substances and Drug Products

**One-Day Course E10-42, Thursday, November 18, 2010, 8:30am – 5:30pm**

Dr. Nagella Nukuna, AstraZeneca Pharmaceuticals LP, Wilmington, DE

**COURSE DESCRIPTION**

Characterization and control of impurities during the drug development process is crucial and is becoming increasingly important to abide by the regulatory reporting thresholds. In this course, a general overview of mass spectrometry and its efficient use in characterizing impurities of active drug substances and drug products will be covered. The use of collision induced dissociation fragmentation and high-resolution mass spectrometry for fine structural characterization will be discussed. In its highly interactive format, students will understand the current ICH guidelines for PGI analysis and regulations for impurities in the drug development process. The course will include a series of real world LC/MS and LC/MS/MS applications as well as interpretation problems applicable to pharmaceutical processes.

**WHO SHOULD ATTEND**

This one-day course is suitable for both novices in mass spectrometry and those who have had some basic mass spectrometry training. It will serve as an intense refresher and an opportunity to share best practices for pharmaceutical scientists in impurity characterization by mass spectrometry.

**TOPICS**

- ▶ The 3 Concepts of Mass Spectrometry
  - Ionization, mass analysis, detection
- ▶ Interpretation of API Mass Spectra of Impurities
  - Molecular ion
  - Isotope abundance
  - Nitrogen rule
  - Adduct ions, dimers and multiple charges
- ▶ High Resolution/Accurate Mass Spectrometry of Impurities
  - Calibration
  - Double bond equivalent
  - Hydrogen deuterium exchange for heteroatom side chain characterization
- ▶ Tandem Mass Spectrometry for Impurity Characterization
  - Product ion scans
  - Precursor ion scans
  - Neutral loss scans
  - Selected reaction monitoring
  - Short overview on generating and interpretation of CID spectra
- ▶ FDA and ICH Guidelines for Impurities and PGI's
- ▶ Strategies for Characterizing and Controlling Impurities
  - Quantitation of PGI's / best techniques
- ▶ Real Life Solving of Problems

### ABOUT THE INSTRUCTOR

**Dr. Nagella Nukuna** is an established mass spectrometrists with a Ph.D. from Case Western Reserve University, Cleveland OH in 2001 focused on utilizing mass spectrometry to characterize amino acids, peptides and proteins in biological systems. She followed up her Ph.D. with a post-doc at the Cleveland Clinic Cell Biology mass spectrometry facility where she did research on Proteomics and characterization of conformational changes in biological molecules by mass spectrometric techniques. She joined the pharmaceutical industry in AstraZeneca in 2004 as the mass spectrometry specialist in analytical development in Wilmington. Dr. Nukuna is a peer reviewed mass spectrometrists with major contributions in JACS, JCI, JBC and FRBM. She has taught courses in Mass Spectrometry and offered hands on and course training sessions at AstraZeneca and was a Chemistry instructor at Washington College, Chester Town, MD.

## **Practical Solutions to Characterization of Protein Therapeutics Using Mass Spectrometry**

**New One-Day Course E10-43. Thursday, November 18, 2010. 8:30am – 5:00pm**

Dr. Guodong Chen, Bristol-Myers Squibb, Princeton, NJ

Dr. Li Tao, Bristol-Myers Squibb, Hopewell, NJ

Dr. Ragu Ramanathan, Bristol-Myers Squibb, Princeton, NJ

### COURSE DESCRIPTION

This introductory course covers the theory and practical implementation of mass spectrometry (MS) techniques for characterization of protein therapeutics in the laboratory. It emphasizes problem-solving skills with examples encountered in biopharmaceutical industries, including characterization of chemical modifications and post-translational modifications of protein therapeutics. The interpretation of proteins/peptides mass spectra will be illustrated with practical examples. This course will focus on electrospray ionization (ESI) and matrix-assisted laser desorption / ionization (MALDI) techniques in protein analysis, and will survey the various mass analyzer options for characterization of protein therapeutics. A thorough coverage of approaches toward method development for both qualitative and quantitative analysis of protein therapeutics will provide a good starting point for understanding practical issues facing implementation of MS techniques in the laboratory.

### WHO SHOULD ATTEND

This course is designed for practicing analytical scientists (new users, chromatographers, analytical chemists, protein chemists, and laboratory managers) performing/supporting recombinant protein characterization/analysis, in-process testing, quality control, quality assurance, research and development, and manufacturing.

### TOPICS

- ▶ Introductions to Mass Spectrometry (MS)
  - Ionization
  - Electrospray ionization (ESI)
  - Matrix-assisted laser desorption / ionization (MALDI)
  - Mass spectra of proteins / peptides
  - Peptide fragmentation
- ▶ Commonly Used Mass Analyzers
  - Quadrupoles
  - Ion trap
  - Ion cyclotron resonance (ICR)
  - Time-of-Flight
  - Orbitrap
  - Tandem MS (MS/MS)
  - Activation methods for proteins/peptides
- ▶ MS Method Development
  - Issues, peptide mass fingerprinting
  - LC/MS
  - MALDI-MS
- ▶ Characterization of Protein Therapeutics
  - Oxidation
  - Deamidation
  - Glycosylation
  - Chemical modification
  - Pegylation / conjugation
- ▶ Quantitative Analysis of Protein Therapeutics
  - Quantification of post-translational modifications
  - In vivo quantitation
- ▶ Case Studies

### ABOUT THE INSTRUCTOR

**Dr. Guodong Chen** (Course Director) has extensive pharmaceutical research experience in major pharmaceutical companies, including Eli Lilly and Co., Schering-Plough (now Merck & Co.) and Bristol-Myers Squibb. He is currently heading a mass spectrometry group at Bristol-Myers Squibb's Princeton site, providing mass spectrometric/analytical support to drug discovery and development programs in small molecule pharmaceuticals and biologics. He is the author and/or co-author of over 50 research publications covering the broad area of mass spectrometry and analytical chemistry. He authored/co-authored nine book chapters. He has over 55 presentations at conferences and academic institutes. He also organized/chaired scientific sessions at various forums, including major sessions on mass spectrometry of small molecule pharmaceuticals and biologics at Eastern Analytical Symposium, Pittsburgh Conference on Analytical Chemistry and Applied Spectroscopy, American Society for Mass Spectrometry (ASMS) conference and American Chemical Society (ACS) conference. Dr. Chen was the Chairperson of the North Jersey Section of ACS Mass Spectrometry Discussion Group (2004) and

in 2006, he received Early Career Award in Mass Spectrometry. He was an invited Analytical Chemistry Program Chair for ACS MARM Conference (2005) and elected President of Chinese American Chemical Society-Tri State (2007). He serves as founding coordinator for ASMS Protein Therapeutics Interest Group (2009-2011). Dr. Chen was a recipient of Schering-Plough President's Award for Discovery, the highest scientific award at Schering-Plough. He received his Ph.D. in Analytical Chemistry/Mass Spectrometry from Purdue University under the direction of Professor R. Graham Cooks.

**Dr. Li Tao** is a group leader in the Department of Biologics Product and Process Development, at Bristol-Myers Squibb Co. His group is responsible for biophysical characterization of protein therapeutics using mass spectrometry, chromatography, and spectroscopic techniques. Dr. Tao's group works on protein therapeutics from late stage discovery, through in-process testing, comparability, and stability studies during development, to eventual post-market commitment studies. Dr. Tao received a B.S. in Chemistry in 1986, a M.S. in Physical Chemistry in 1989, both from the University of Science and Technology of China. Dr. Tao received his Ph.D. in Analytical Chemistry from the University of Florida under the direction of Dr. Robert T. Kennedy in 1998. During his graduate studies, he developed several fast immunoassay systems based on capillary electrophoresis and laser-induced fluorescence detection. He also performed on-line monitoring of insulin release from a single islet using the system he developed. Since joining BMS in 1998, Dr. Tao has been with both drug discovery and drug development organizations, working on recombinant therapeutic targets and recombinant protein therapeutics. His work has been focusing on characterization and analysis of recombinant proteins using mass spectrometry. Dr. Tao also has hands-on experience in microbial fermentation and protein purification for recombinant protein production in an industry setting. Dr. Tao is an author/co-author for 15 peer-reviewed publications or book chapters.

**Dr. Ragu Ramanathan** received a B.Sc. in Chemistry from the University of Southern Mississippi and a Ph.D. in Physical Chemistry/Mass Spectrometry from the University of Florida. His graduate research focused on coupling of electrospray ionization (ESI) to Fourier transform ion cyclotron resonance (FTICR) mass spectrometer. After spending three years as a postdoctoral research fellow with Professor Michael L. Gross at the Washington University, St. Louis, Missouri, Dr. Ramanathan managed the Center for Advanced Mass Spectrometry at the Analytical Bio-Chemistry Laboratories, Columbia, Missouri. In 1998, Dr. Ramanathan joined Schering-Plough Research Institute's (SPRI) Drug Metabolism and Pharmacokinetics (DMPK) Department and completed his tenure as a senior principal scientist in 2008. While at SPRI, Dr. Ramanathan was involved in the application of LC-MS for profiling and characterization of metabolites of drug candidates in the preclinical development and clinical stages. Dr. Ramanathan was with Pfizer Global Research and Development from 1999 to 2002 as a group leader of the Ann Arbor site biotransformation group. Dr. Ramanathan is currently an associate director at the Bristol-Myers Squibb, Co. and is responsible for elucidating biotransformation pathways of development drug candidates. Dr. Ramanathan's accomplishments include 35 peer-reviewed papers, 10 book chapters, a book entitled "Mass Spectrometry in Drug Metabolism and Pharmacokinetics" and over 60 oral/poster presentations. He also served as a chairperson for the North Jersey ACS Mass Spectrometry Discussion Group and as a chairman for DMPK sessions of the American Society for Mass Spectrometry and Eastern Analytical Symposium meetings.

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## Fundamentals of Microbiology for Chemists

**One-Day Course E10-44, Thursday, November 18, 2010, 8:30am – 5:30pm**

Dr. Anthony M. Cundell, Merck Research Laboratories, Union, NJ

### COURSE DESCRIPTION

This course will explore the pharmaceutical microbiology from the perspective of the drug product life cycle, from development through manufacturing process. It will encompass a brief introduction to microbiology, microbial testing methods, and an overview of the role of microbiology in drug substance and drug product manufacturing, and product quality attributes of drug products. Emphasis will be given to method development and validation, environmental monitoring, in-process, release and shelf-life testing of products, critical elements of QC microbiology laboratory and the relationship of the microbiology to manufacturing process and product quality. Case histories will be presented to illustrate current microbiological issues.

This course will cover microbiological requirements, practice and issues in both pharmaceutical and biotechnology products. The differences between chemistry and microbiology as scientific disciplines will be emphasized. The course will be directed towards the non-microbiologist specifically the chemist working in the pharmaceutical industry.

### WHO SHOULD ATTEND

This one-day course will benefit chemists, QA and QC managers, regulators, and researchers who are non-microbiologist and wish to become more familiar with the pharmaceutical microbiology.

### TOPICS

- ▶ Fundamentals of Microbiology
- ▶ Compendial Microbial Testing Methods
- ▶ Microbial Method Qualification
- ▶ Specification Setting
- ▶ Microbial Risk Assessment
- ▶ Environmental Monitoring
- ▶ Water Monitoring
- ▶ Auditing Microbiology Laboratories
- ▶ Regulatory Requirements and Inspections
- ▶ Product Recalls for Microbial Contamination

**ABOUT THE INSTRUCTOR**

**Dr. Tony Cundell** works in the Merck research laboratories as the Director, Pharmaceutical Sciences Microbiology in Union, New Jersey. Among his many accomplishments, Dr. Cundell was Chair of the PDA Task Force responsible for the publication of the 2000 Technical Report #33 "The Evaluation, Validation, and Implementation of New Microbiological Testing Methods." He is a member of the 2005-2010 USP Microbiology and Sterility Assurance Committee of Experts. He has published extensively in the areas of rapid microbial methods, water activity determination, sterilization processes, microbial identification, and risk assessment.

Dr. Cundell has a Ph.D. in Microbiology from the University of Canterbury, New Zealand as well as both a MS degree in Biochemistry, and a BS degree in Biochemistry and Chemistry from Victoria University of Wellington, New Zealand.

**Practical Introduction to Raman Spectroscopy****One-Day Course E10-45, Thursday, November 18, 2010, 8:30am – 5:30pm**

Dr. Frederick H. Long, President Spectroscopic Solutions, LLC., Randolph, NJ

**COURSE DESCRIPTION**

Spectroscopic methods such as Raman Spectroscopy have become important tools for at line and on line analysis in a variety of industries and will become increasing more common in the pharmaceutical industry in the near future. This class will provide an overview of Raman spectroscopy. The class will cover basic instrumentation issues and an introduction to the chemometrics and multivariate analysis required to make these instruments useful in a research, QC, or manufacturing setting. Numerous examples and case studies will be presented including raw material identification, process monitoring, and quantitative chemical imaging of coatings. Relevant FDA and USP guidance for instrument qualification and method validation will also be discussed.

**WHO SHOULD ATTEND**

Chemists, Engineers, and Quality professionals who need to learn the basics of Raman spectroscopy. This class is ideally suited for someone who may purchase a Raman spectrometer in the near future.

**TOPICS**

- ▶ Introduction
- ▶ Primer on NIR and Raman Spectroscopy
- ▶ Instrumentation Issues
- ▶ Chemometrics and Multivariate Analysis
- ▶ Example Applications and Case Studies
- ▶ Method Validation
- ▶ FDA Guidance and USP Requirements
- ▶ Demonstration of Chemometrics Software
- ▶ Summary and Wrap-up

**ABOUT THE INSTRUCTOR**

**Dr. Frederick H. Long** established Spectroscopic Solutions in the summer of 2001. Spectroscopic Solutions provides consulting and training in the areas of process analytical technology, spectroscopy, and statistics for regulated and non regulated industries. His firm has done work for numerous international pharmaceutical, consumer health-care companies, and scientific instrumentation suppliers. Recently Dr. Long has taught classes at EAS and PITTCO on Near IR spectroscopy, process analytical technology, and quality by design. He received his S.B. and S.M. in Physics from the Massachusetts Institute of Technology and a Ph.D. in Chemical Physics from Columbia University.

**Authoring High Quality Technical Reports****One-Day Course E10-46, Thursday, November 18, 2010, 8:30am – 5:30pm**

Mr. Greg Cuppan, McCulley-Cuppan, LLC, Salt Lake City, UT

**COURSE DESCRIPTION**

In this course, we explore techniques for writing high-quality technical reports across disciplines in the analytical sciences. The content is designed for professionals working at the intermediate through advanced levels, and addresses three critical topics: managing discussion logic in technical reports (because shared priorities matter); managing document organization (because structure helps shape meaning); and attending to readers needs (because people's ability to find, understand, and use the information is essential). We will address key features of high-quality documents: crafting effective abstracts, discussions, conclusions, and summaries; designing highly effective data displays; controlling content emphasis through use of subordinate and coordinate organization; and writing unambiguous technical prose. The course will introduce writing tools to expedite the authoring process, and will offer participants tips for authoring like an expert technical writer. The course is 40% presentation, 25% discussion, and 35% individual exercises. Applied practice will involve exhibit documents, case problems, and open forum question/answer sessions. Participants will receive a course manual that includes annotated examples of high-quality professional writing and rich reference material.

**WHO SHOULD ATTEND**

All analytical science professionals working at the intermediate through advanced levels involved in authoring or review of technical reports.

**TOPICS**

- ▶ Introduction and Workshop Overview
- ▶ Attending to Readers Needs: How do People Actually Read Technical Reports
- ▶ Managing Logic in Technical Reports
  - How to create and manage the logic trail in your report
  - How to present and discuss issues in your report
  - Critical components of a logical argument
  - Authoring effective abstracts, discussions, conclusions, and summaries
  - Controlling POV (point of view) in development history and summary reports
- ▶ The 10 rules for highly effective data displays
- ▶ Managing Document Organization
  - What do we mean by “flow”
  - The importance of controlling subordinate and coordinate organization in technical reports
- ▶ Writing Effectively at the Paragraph and Sentence Level
- ▶ Methods and Tools for Efficiently Drafting Your Report
  - Six tasks in the writing process: planning, organizing, drafting, revising, reviewing, and editing
  - The writer’s toolbox

**ABOUT THE INSTRUCTOR**

**Mr. Greg Cuppan** is the Managing Principal of McCulley-Cuppan LLC, a group he co-founded in 1998. Mr. Cuppan has spent 28 years working in the life sciences with 15 years providing consulting and training services related to scientific writing in the chemical, pharmaceutical, and medical device industries. Mr. Cuppan’s principal focus is with the development and refinement of authoring practices used to create complex technical reports. Mr. Cuppan has personally presented workshop sessions on technical and scientific report writing to thousands of individuals in over 60 companies and institutions in the U.S., Europe, and Japan.

**Theory and Practice of Ultra High-Pressure Liquid Chromatography (UHPLC)**

**One-Day Course E10-47, Thursday, November 18, 2010, 8:30am – 5:30pm**

Dr. Michael E. Swartz, Synomics Pharma, Wareham, MA

**COURSE DESCRIPTION**

UHPLC is a chromatographic technique that offers advantages of higher efficiency, speed and sensitivity by using sub-two  $\mu\text{m}$  particles operated at pressures exceeding that of typical HPLC separations, in the range of 6000-15,000 psi. The true advantages of UHPLC can only be recognized, however, by properly applying the theory and principals of chromatography as it relates to these smaller particles and higher pressures. This course will examine the extension of chromatographic theory from HPLC to UHPLC using sub-two  $\mu\text{m}$  particles operated at high pressures, and how to develop new methods, or to convert existing methods to take advantage of this new technology. Several key applications and case studies will also be highlighted.

**WHO SHOULD ATTEND**

This one-day course will benefit chromatographers (from analysts to group managers) responsible for method development and method optimization in research, development and QC laboratories. It is designed to provide the basic theory of operation and implementation, as well as to showcase ways in which UHPLC can be used to improve existing methods, data quality and laboratory throughput.

**TOPICS**

- ▶ Theory Extension to Sub-two  $\mu\text{m}$  Particles Operated at High Pressures
  - The vanDeemter equation
  - Chemistry of resolution
  - UHPLC instrumentation
  - UHPLC justification and applicability
- ▶ UHPLC Method Development
  - Chemometric approaches
  - Column/method scouting approaches
  - Examples
- ▶ UHPLC Method Conversion
  - HPLC to UHPLC method migration
  - Calculations and proper scaling
  - Reverse engineering UHPLC to HPLC methods
  - Justification
  - Examples
- ▶ Solving Separation Challenges with UHPLC—Case Studies
  - Pharmaceutical
  - Fine chemicals
  - Biotherapeutics
  - Beyond UV detection

**ABOUT THE INSTRUCTOR**

**Dr. Michael E. Swartz** recently joined Synomics Pharmaceutical Services in Wareham, MA as Research Director, after having been at Waters Corporation as a Principal Consulting Scientist (and other roles) since 1985. Dr. Swartz received his bachelor's degree in Chemistry from the State University of New York College at Cortland, Master's degrees in Chemistry and Forensic Chemistry from Northeastern University, and Ph.D. degree in Chemistry from the University of Rhode Island. He is the author of books on validation, combinatorial chemistry and capillary electrochromatography, several book chapters on various subjects, over 50 manuscripts, 4 patents, and has presented over 175 contributed and invited papers at various technical symposia around the world. Dr. Swartz's interests include general liquid chromatography and mass spectrometry theory, with an emphasis on development, increased sensitivity, and validation of high sample throughput and automated methods for the both the research and regulated pharmaceutical industry. He has served on the Scientific Editorial Advisory Board of LCGC magazine since 1998, where he co-authors the popular *Validation Viewpoint* column, and maintains the [www.validationscience.com](http://www.validationscience.com) web site. Professional memberships include: American Chemical Society (ACS), American Association of Pharmaceutical Scientists (AAPS), MASSEP, and Sigma Xi. Dr. Swartz has consulted, taught courses and lectured on method development and validation and other topics worldwide for over 25 years.

## Special Events in the Exposition Area

### **FREE Light Lunch for all Conferees and Exhibitors:**

Monday, Tuesday and Wednesday, 11:30 to 1:00

Have lunch or a snack and see the latest offerings from our exhibitors.

### **FREE Beverages for all:**

Monday at 10:30 and 2:30

Tuesday at 10:30 and 2:30

Wednesday at 10:30 and 2:30

\$50.00 Visa Gift Cards Ruffled off –

At each of the beverage breaks, except Monday AM. Open to all present.

### **Take a Technology Tour!**

Last year's Technology Tour brought many more conferees to the booths of participating Exhibitors. Conferees loved it because of the additional reward – and the fun of a scavenger hunt! In 2010, the Technology Tour will be even better.

The EAS Final Program will contain a special card listing the Technology Tour Exhibitors. If a conferee visits eight of these exhibitors and gets the card marked, he/she can redeem the card for an additional gift at the EAS Souvenir Booth.

Here are some of the exhibitors participating in the Technology Tour:

Advanced Chemistry Development (ACD/Labs)

Ahura Scientific

Atlantic Analytical Laboratories

Claisse, Corporation Scientifique

Distek

Hitachi

Horizon Technology

Kaiser Optical Systems

Millipore

Phenomenex

pION

Robertson Microlit Laboratories

Shimadzu

Thermo Scientific

YMC America

Additional exhibitors interested in participating in the Technology Tour should contact Sheree Gold, Exposition Director, at 610-742-4981 or by e-mail at [easinfo@aol.com](mailto:easinfo@aol.com)