ADVANCED HPLC IN PHARMACEUTICAL ANALYSIS

One-Day Course E07-XX: 8:30 a.m. – 5:00 p.m.
Michael Dong, Synomics Pharma Services, Wareham, MA
Kim Huynh-Ba, Pharmalytik C.S, Newark, DE

COURSE DESCRIPTION
This is a one-day HPLC training course at an intermediate/advanced level. The course will help the attendees to become more successful in pharmaceutical assays and ICH impurity testing. It presents an overview of modern trends in HPLC columns/instruments, “best practices”, and regulatory aspects in pharmaceutical analysis. The focus is on reversed-phase analysis of drug substances and drug products (small-molecule).

WHO SHOULD ATTEND
This intermediate/advanced level course focuses on reversed-phase analysis of drug substances and drug products (small molecule) and is designed for analysts, managers and researchers who currently use HPLC in a pharmaceutical laboratory. To get the most out of the course, it is highly recommended that you have at least two years of hands-on HPLC experience in the pharmaceutical area.

TOPICS
1. Advanced Concepts in HPLC Equipment and Trends—Developments in HPLC pumps: dual piston in series, micro-pistons, high-pressure vs. low-pressure mixing; how to increase autosampler precision; how to increase method sensitivity using UV/PDA detection; specialized detectors for non-chromophoric analytes (ELSD, CAD, CLND); understanding system dwell volumes and instrumental bandwidths (dispersion).
2. Modern Developments in HPLC Columns and Column Selection—Modern trends of using shorter and narrower columns packed with small particles; high-purity silica, hybrid particles, and novel bonding chemistries; how to choose bonded phases to enhance selectivity (C18, CN, phenyl, polar-embedded); how to select HPLC columns for different assays (assay, impurity testing, LC/MS).
3. Best Practice in HPLC Method Development—Review strategies and modern method development trends; method optimization to meet ICH reporting guidelines; phase-appropriate method development and validation; case studies: combinational products, complex formulations and genotoxic impurities.
4. How to Get Started in Fast LC (and Ultra-high-pressure LC)—Fundamentals of Fast LC and Ultra-high-pressure LC; benefits: fast analysis, rapid method development and validation, lower solvent consumption and increased mass sensitivity; how to get started: instrumental requirements, instrument and method modifications; case study: method migration from HPLC, Fast LC to UPLC.
5. Regulatory Aspects in Pharmaceutical Testing—Impact of analytical testing in the drug development process; cGMP requirements for analytical test methods; review ICH Q2 A&B guidelines for method development/validation; method specificity through forced degradation activities.
6. Managing Validation Data for Quality and Compliance—Recent FDA 483 observations related to analytical method validation; overview of Q3 for impurities monitoring; system suitability of HPLC test methods; method adjustments vs. method modifications; change control on method validation.


ABOUT THE INSTRUCTORS
Dr. Michael W. Dong (Lead instructor) is Research Director at Synomics Pharma at Wareham, MA, where he is responsible for method development of complex formulations and trace genotoxic impurities. Formerly, he was a Research Fellow/Group Leader at Purdue Pharma, a Senior Staff Scientist at Perkin-Elmer, and a 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 advanced HPLC short courses at EAS, Pittcon, HPLC, ACS and AAPS. He pioneered Fast LC and has over 80 publications in chromatography and analytical chemistry. He authored “Modern HPLC for practicing scientists,” Wiley, 2006 and co-edited “Handbook of Pharmaceutical Analysis by HPLC”, Elsevier/Academic Press, 2005. Some of the lecture materials are based on these two references.
Kim Huynh-Ba is the Technical Director of Pharmalytik C.S. (www.pharmalytik.com). She is specializing in Analytical Development, Stability, Outsourcing and Technology Transfer management. She has almost 20 years of experiences in various analytical areas of pharmaceutical development, especially in the Stability Sciences. She has involved with several projects harmonizing or optimizing analytical best practices in several companies, including those are under Consent Decree. She has authored numerous technical publications and is a frequent invited speaker at national and international conferences conducting training on cGMPs, lab compliance, stability testing and quality issues in pharmaceutical industry. She is the founder and co-chair of the AAPS Stability Focus Group and serves on the Governing Board of Eastern Analytical Symposium (EAS).