HPLC Method Development Made Easy

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Course Description

This half-day HPLC method development course will be conducted at an intermediate level. The course reviews best practices, short cuts and tricks-of-the-trade to help the attendees to become more successful in developing HPLC methods (for potency, purity and ICH-compliant stability-indicating assays). The focus is on pharmaceutical analysis using UV detection for small molecule drugs though the approach is useful to other applications or sample types.

Target audience

This course is intended for analysts, managers, and researchers using HPLC in the pharmaceutical or other laboratories. A fundamental understanding of HPLC is assumed and some practical hands-on HPLC experience is highly recommended.

Course Agenda

1. The Traditional Method Development Approach for stability-indicating assays

- 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)
- Demonstrating method specificity and stability-indicating capability (how to conduct rapid forced degradation studies); Development of orthogonal methods
- Use of software and automated systems to facilitate screening and method optimization
- Case studies for new chemical entities, complex formulations and drug products with multiple APIs

2. The 3-Pronged Template Approach for Rapid Method Development and case studies

- Fast LC isocratic methods for potency or performance assessment
- Generic broad-gradient methods for high-throughput screening, in-process testing and purity assays
- Multi-segment gradient methods for ICH compliant stability-indicating assays of complex molecules

Biography

Dr. Michael W. Dong is a principal in MWD Consulting focusing on consulting and training services on HPLC/UHPLC, pharmaceutical analysis and drug quality. He was formerly Senior Scientist in Analytical Chemistry and Quality Control of Small Molecule Pharm. Sci. at Genentech, Research Director at Synomics Pharma, Research Fellow at Purdue Pharma, and Senior Staff Scientist at Applied Biosystems / Perkin-Elmer. He holds a Ph.D. in Analytical Chemistry from the City University of New York, and a certificate in Biotechnology from U. C. Santa Cruz. He has 100+ publications including a bestselling book on chromatography (Modern HPLC for Practicing Scientists). He is an editorial advisory board member of LCGC magazine and American Pharmaceutical Review.

Recommended text

1. M. W. Dong, ***Modern HPLC for practicing scientists,*** Wiley, Hoboken, June 2006, (ISBN-10: 047172789X).