HPLC and UHPLC Method Development and Validation

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Course description

This intermediate 1/2-day tutorial will provide the analytical scientist with a clearer understanding of the best practices in HPLC method development and validation in pharmaceutical analysis.

Who Should Attend

Analysts, scientists, researchers, and managers who want to get an updated overview of the fundamentals of HPLC and UHPLC method development in pharmaceutical analysis. A basic understanding of chemistry and HPLC, with some at least one year of hands-on experience is assumed.

1. **HPLC Method Development: Best Practices** *(90 min)*

A. Tradition strategy for HPLC method development

Glossary, Insights, Steps in traditional method development, Scouting gradient, Method fine-tuning and optimization, Case study 1: Phase 0 method for an NCE

General strategy, Method development trends, “Orthogonal” methods, Automation screening systems and software

B. A 3-pronged template approach for rapid method development

Fast LC isocratic methods for potency assessment, Generic broad-gradient methods, Multi-segment gradient methods for stability-indicating assays of complex molecules, Case studies.

C. Use of a universal generic gradient method(s) for the assay of multiple NCEs

Rationales for selection of SPP and bonded phase, Fast LC method capable of Pc of 100-300 in 2 to 5 minutes, Method adjustments for stability-indicating assays, Case studies.

2. **HPLC Method Validation** *(60 min)*

A. An overview of method validation parameters, best practices, and regulatory guidelines

3. Q&A *(10-20 min)*

Biography

Dr. Michael W. Dong is a principal consultant of MWD Consulting, focusing on training and consulting on HPLC/UHPLC, CMC, method development, and pharmaceutical analysis. He was formerly Senior Scientist at Genentech, 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 the University of California at Santa Cruz. He has 130+ publications and four books, including a bestselling book on chromatography (HPLC and UHPLC for Practicing Scientists, Wiley). He has conducted 130+ Short courses at national meetings and private clients (ACS, Pittcon, EAS, HPLC, and USP). He is an editorial advisory board member of LCGC North America, American Pharmaceutical Review, and Chinese American Chromatography Association. He has been a columnist of "Perspectives in Modern HPLC" for LCGC North America since 2013.

Recommended textbook:

M. W. Dong, **HPLC and UHPLC for Practicing Scientists**, 2nd Ed., Wiley, Hoboken, New Jersey, July 2019.