

## **HPLC and UHPLC for Practicing Scientists 2: Best Practices in Method Development and Operation/Troubleshooting**

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### **Course description**

This intermediate 1-day workshop will provide the analytical scientist with a clearer understanding and a solid working knowledge of best practices (method development, HPLC operation, and troubleshooting) of HPLC and UHPLC (ultra-high-pressure liquid chromatography). The focus is on pharmaceutical analysis of small molecule drugs. A brief survey of biopharmaceutical, food, environmental, chemical, and bioscience applications is included.

### **Who Should Attend**

Analysts, scientists, researchers, and managers in pharmaceutical and other industries who want to get an updated overview of the fundamentals of HPLC and UHPLC in pharmaceutical analysis and other applications. A basic understanding of chemistry and HPLC with some hands-on experience is assumed.

### **Day 2: HPLC 2: Applications, UHPLC, Method Development, and Troubleshooting**

#### **4. HPLC Applications and an Overview of UHPLC**

- A. HPLC applications including pharmaceutical, biopharmaceuticals, food, environmental, chemical, and bioseparations
- B. UHPLC overview, perspectives, and benefits: UHPLC concepts, instrumentation, and benefits (fast separations, high-resolution analysis, and rapid method development)
- C. Potential issues and how to mitigate (viscous heating, operating nuances, compatibility to existing methods, injection precision, detector sensitivity vs. mixing volumes), method translation from HPLC to UHPLC, transition from HPLC to UHPLC.

#### **5. HPLC Method Development and Validation**

- A. Tradition strategy for HPLC method development and a survey of automated tools and software (DryLab, ACD AutoChrom, and Fusion QbD)
- B. 3-pronged template approach for rapid method development

C. Use of a universal generic gradient method for the assay of multiple NCEs and stability-indicating assays with simple adjustments

D. A brief overview of method validation and method transfer with case studies.

## **6. HPLC Operation and Troubleshooting**

A. Mobile phase and sample preparation and best practice in HPLC operation

B. Maintenance and troubleshooting guide with case studies

C. Diagnosing and solving problems (pressure, baseline, peak, data performance)

## **Biography**

Dr. Michael W. Dong is a principal consultant in MWD Consulting, focusing on consulting and training services on HPLC, pharmaceutical analysis, and drug quality. He was formerly Senior Scientist in Analytical Chemistry and Quality Control at Genentech, Research Director at Synomics Pharma, Research Fellow at Purdue Pharma, Senior Staff Scientist at Applied Biosystems/Perkin-Elmer, section head at Celanese Research Company, and postdoctoral research fellow at Naylor-Dana Institute for Disease Prevention.

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 Santa Cruz. He has 130+ publications and five books, including a bestselling book on chromatography (HPLC and UHPLC for Practicing Scientists, 2<sup>nd</sup> Ed., Wiley, 2019). He is an advisory board member of LCGC magazine, American Pharmaceutical Review, Chinese American Chromatography Association, and Connecticut Separation Science Council. He has been a columnist of "Perspectives of Modern HPLC" for LCGC North America since 2013. Michael was born in Shanghai and raised in Hong Kong. He is multilingual, an Eagle Scout, and a long-term Toastmaster.

### **Recommended textbook:**

M. W. Dong, **HPLC and UHPLC for Practicing Scientists**, 2<sup>nd</sup> Ed., Wiley, Hoboken, New Jersey, 2019. *List price is \$99.95 though it can be purchased at Amazon.com at a substantial discount for both the paperback and the E-book.*

