

Abstract

HPLC method development is an arduous and time-consuming process generally conducted by experienced separation scientists. This seminar describes short cuts and tricks-of-the-trade to the separation scientist in rapid development of (u)HPLC methods (potency and ICH-compliant stability-indicating assays) using a 3-pronged method template approach and a universal generic gradient methodology. Method development case studies in pharmaceutical development including those for quality control of drug candidates with multiple chiral centers are used to illustrate these approaches.

1. M. W. Dong and K. Zhang, UHPLC in method development, **Trend in Anal. Chem.**, 63, 21-30, 2014.
2. M.W. Dong, A Three-Pronged Template Approach for Rapid HPLC Method Development. **LCGC North Am.** **31(8)**, 612-621, 2013.

Biography

Dr. Michael W. Dong is a principal consultant 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 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, Wiley). He is an editorial advisory board member of LCGC magazine, American Pharmaceutical Review and Chinese American Chromatography Association. He has been a columnist with LCGC North America since 2013 on "Perspectives on Modern HPLC".