

MICHAEL W. DONG, PhD

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SUMMARY

Pharmaceutical Development and Quality Control Scientist, Manager and Consultant. Subject Matter Expert in Liquid Chromatography (HPLC) and Pharmaceutical Analysis.

Scientist with extensive hands-on experience in HPLC, UHPLC, LC/MS, GC, and chiral separations for drug substances and drug products. Experience as CMC analytical team lead for multiple development projects. Pioneered Fast LC and rapid method development approaches. Authored methods, SOP's, CMC sections of INDs and NDAs, 100+ publications, and a best-seller book in chromatography. Recognized for having strong supervisory, mentoring and training skills.

Areas of specialization:

- Method development/validation
- Sample characterization
- HPLC/UHPLC, GC, MS
- Drug development leads (CMC)
- Writing, training, regulatory filings
- Empower, ChemStation

EXPERIENCE

MWD CONSULTING, NORWALK, CT

2015-present

Principal, Training and Consulting service in HPLC, pharm analysis and drug quality

GENENTECH, INC, S. SAN FRANCISCO, CA

2007-2015

Senior Scientist, Small Molecule Analytical Chemistry and Quality Control

- Developed chiral/achiral HPLC, LC/MS, GC, and IC methods for drug substances and products to support multiple projects in small molecule drug discovery.
- Supervised two to six analysts; served as analytical lead for five early development oncology projects including CMO oversight. IND/IMPd filing.
- Supported phase 0 to phase 2 drug product development (IV, capsules and tablets).
- Managed capital budgets, recruiting, process chem. lab support, automation and new technologies.

SYNOMICS PHARMA (CRO), WAREHAM, MA

2005-2007

Research Director

- Study director for 10+ clients' GLP and GMP projects.
- Conducted HPLC and GC method development/validation for drugs and consumer products.

PURDUE PHARMA TECHNICAL CENTER, ARDSLEY, NY

1999-2005

Senior Principal Scientist, Research Fellow/Group Leader, Analytical Development

Managed group of 4-6 analysts conducting method development and validation of assay and impurities methods as well as dissolution/stability testing to support solid and liquid formulation development and clinical supplies testing.

- Developed stability-indicating HPLC method for complex drug products from natural materials.
- Pioneered high-pH MS-compatible ICH methods for drug products with two APIs.

PERKIN-ELMER CORPORATION/APPLIED BIOSYSTEMS, NORWALK, CT 1993-1999
Senior Staff Scientist, Liquid Chromatography Business Unit

Developed applications, systems and columns for pharmaceutical and bioscience applications. Directed programs in microbore LC and system qualification. Designed Fast LC columns/applications, LC systems for automated method development, dissolution analysis, laboratory robotics, amino acids analysis, PCR purification and peptide mapping.

- Developed HPLC systems for analysis of PAHs, carbamates, vitamins, sugars and organic acids.
- Pioneered Fast LC (short 3- μ m 3x3 columns) that increased speed by 3-5 fold.

Additional relevant experience: applications chemist, chemical research and post-doctoral fellowship in cancer research.

PUBLICATIONS

100+ publications (>70 as first author), 3 books, and regulatory filings (Addendum list available).

AWARDS AND LANGUAGES

- NIH Research Grant - "Occurrence, tumorigenicity and metabolism of quinolines".
- U.S. Patent - Apparatus for periodically monitoring of plurality of samples (disso testing).
- Genentech outstanding employee awards (2010).
- Fluent in Chinese (written and spoken), knowledge of German and Japanese.

EDUCATION AND CERTIFICATION

Certificate in Biotechnology, U. C. Santa Cruz (2010)
PhD, Analytical Chemistry, City University of New York
Bachelor of Science, Chemistry, Brooklyn College

AFFILIATIONS AND OTHER

- American Chemical Society, Toastmasters International (Club President 2005), California Anal. Chem. Org., Chinese Amer. Chromatogr. Assoc. (board member), Eagle Scout.
- Editorial advisory board member of LCGC North Am. and Amer. Pharma. Review.
- U.C. Santa Cruz Extension instructor (Drug Quality 2012-14). Norwalk Community College, Windows software instructor, 1997-2006.
- Software: MS Office, HTML, Empower, ChemStation, MassHunter, Excalibur, LIMS (Labware), DryLab, S-Matrix Fusion AE, TrackWise, DocLink, IDBS (electronic lab notebook).