

# MICHAEL W. DONG, Ph.D.

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## SUMMARY

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

A scientist with extensive hands-on experience in HPLC, UHPLC, LC/MS, GC, and chiral separations for small molecule drug substances and drug products. Experienced CMC analytical team lead for multiple early- and late-stage development projects. Pioneered Fast LC, rapid method development approaches, including the use of generic gradient (u)HPLC, and high-pH methods. Authored methods, SOPs, CMC sections of INDs and NDAs, 130+ publications, and 4 books including a best-seller book in HPLC. Strong supervisory, mentoring, problem-solving, consulting, project management, and training skills.

#### **Areas of specialization:**

- Method development/validation
- Consulting (HPLC, pharm. Anal.)
- HPLC/UHPLC, GC, MS
- Drug development leads (CMC)
- Writing, training, regulatory filings
- Empower, ChemStation (OpenLab)

## EXPERIENCE

**MWD CONSULTING, NORWALK, CT** 2015-present  
**Principal Consultant.** Provides expert training and consulting services in HPLC/UHPLC, pharm analysis, HPLC method development and validation, CMC, and drug quality at [mwd-consulting.com](http://mwd-consulting.com); Clients include pharmaceutical companies, USP, CROs, and instrument companies.

**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 development, including APIs with multiple chiral centers.
- Supervised two to six analysts; served as analytical lead for five early-stage development oncology projects, including CMO oversights and IND/IMPd filings.
- Supported phase 0 -2 drug substance and product process 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' research GLP and GMP projects.
- Conducted HPLC and GC method development/validation for drugs and consumer products.

**PURDUE PHARMA TECHNICAL CENTER, ARDSLEY, NY** 1999-2005

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

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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, including herbal OTC products.

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

**PERKIN-ELMER CORPORATION/APPLIED BIOSYSTEMS, NORWALK, CT 1980-1999**  
**Senior Application Chemist - 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 acid analysis, fast protein analysis, PCR purification/quantitation, and peptide mapping.

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

**Additional relevant experience: Applications chemist, HPLC product marketing specialist for the Far East, chemical/environmental research, and a post-doctoral fellowship in cancer institute.**

## PUBLICATIONS

130+ publications (>90 as first author), four books including a best-seller in HPLC, 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 a plurality of samples (dissolution testing).
- Genentech outstanding employee awards (2010, 2011).
- Fluent in Chinese (written and spoken: Mandarin, Cantonese, and Shanghainese); Knowledge of German (3 y) and Japanese (1y).

## EDUCATION AND CERTIFICATION

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

## AFFILIATIONS AND OTHER

- Amer. Chem. Soc. (ACS career consultant), Toastmasters International (ATM Silver, President 2005), Chinese Amer. Chromatogr. Assoc. (board), Eagle Scout, Conn. Sep. Sci. Council (CSSC).
- Advisory board member of LCGC and Amer. Pharm. Review; Columnist for LCGC (2013-present).
- U.C. Santa Cruz Extension instructor (Drug Quality 2012-17).
- Software: M.S. Office, HTML, Empower, ChemStation, MassHunter, Excalibur, LIMS (Labware), DryLab, S-Matrix Fusion, TrackWise, DocLink, IDBS (electronic lab notebook).