MICHAEL W. DONG, Ph.D. (PUBLICATIONS)

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ADDENDUM TO RESUME, LIST OF PUBLICATIONS, INVITED SEMINARS, AND TRAINING

BOOKS AND EDITOR

1. **M. W. Dong, HPLC and UHPLC for Practicing Scientists, 2nd Ed.,** Wiley, Hoboken, NJ, 2019.
2. **M. W. Dong, Modern HPLC for Practicing Scientists**, Wiley, Hoboken, New Jersey, 2006 (A best-seller in HPLC with 8000 copies sold)
3. **Handbook of Pharmaceutical Analysis by HPLC**, S. Ahuja and **M. W. Dong** (Eds), Elsevier/Academic Press, Amsterdam, the Netherlands, 2005.
4. J.L. DiCesare, **M. W. Dong,** and L. S. Ettre. **Introduction to High-Speed Liquid Chromatography,** Perkin-Elmer, Norwalk, CT, 1981.
5. D. Guillarme and **M. W. Dong (Eds).** UHPLC: Where we are ten years after its commercial introduction, **Trends in Anal. Chem., 63**, 1-188, 2014 (Special issue).

REGULATORY FILING

Authored CMC sections of IND or IMPD of new chemical entities for oncology (AKT-0068 (Phase 0 to 2B), IAP-0152, and IAP-0917) and contributed CMC filing to NDA/BLA (OxyContin NDA amendments and BLA for Kadcyla T-DM1 antibody-drug conjugate).

SHORT COURSES AND INVITED SEMINARS PRESENTED

Short Courses Conducted

1. **HPLC/UHPLC for practicing scientists I and II:** EAS 2011-20 and Pittcon 2012-20, ACS 2014-20, United States Pharmacopeial Convention (USP) 2/2017, Chrom Forum Delaware Valley, 4/2017. Recro Pharma 12/18, City of Hope 9/2018, Gilead Sci. 10/2019.
2. **Drug Discovery and Development Processes**: EAS 2010, 14-17, Pittcon 2013, 15, 16. 19.
3. **Drug Quality Fundamentals, Quality Control of Small Molecule Drugs and Recombinant Biologics,** U. C. Santa Cruz Extension, 1.5 cr., 2012-17, HPLC 2014, New Orleans, HPLC 2019, Milan, Pittcon 2015, EAS 2014-15.
4. **HPLC method development and validation**: EAS (2005-2010, 2015), HPLC 2016, PBSS 6/16, EAS 2016, HPLC 2018 Wash. DC, Gilead Science 10/2019, Pittsburgh MSDG 3/2020, East Carolina U 3/2020, HPLC 2022 San Diego.
5. **UHPLC and UHPLC in biopharmaceutical analysis** (HPLC 2012 Anaheim, PBSS Bay Area, 6/2016, NYS biotech symposium, 5/2017.
6. **HPLC Operation and Troubleshooting,** HPLC 2018 Wash. DC, LC/MS tutorial, HPLC 2017 Jeju, Korea, HPLC 2022 San Diego.

Invited Seminars and podium presentations (2009 onward)

7. A roadmap for rapid method development webcasts (LCGC webcasts 2012), HPLC Calibration (IVT 2014), Residual Solvents by HSGC (PharmSep 2009), analysis of counterions (EAS 2013), CACO QC workshop 2014), analysis of multi-chiral molecules (HPLC 2014, Pittcon 2015), a low-cost, compact SQMS (Pittcon 2015).

8. UHPLC: Perspective, Performance and Potential Issues (SCDG 2/2010), UHPLC vs. HTLC: a debate (CaSSS, 2010), High-resolution separations for complex pharmaceuticals (Pittcon 2012), Myths in UHPLC (CASSS 2012), Seven faux pas in HPLC (EAS 2014), generic method(s) for universal pharm assays (Roche Harmonization Meeting, Ireland, 10/14, CSSC 10/2016, HPLC 2019 Milan), UHPLC in pharm analysis (keynote presentation at HPLC 2015 Beijing, 9/2015, NYS Biotech Symposium, 5/17), method development strategy for NCEs with multiple chiral centers (Pittcon 2017, CSSC 10/2018), UHPLC Instruments (Chrom Forum Delaware Valley Symposium 4/2017), HPLC method development made easy (CSSC, 4/17, MASSEP 10/2018, Pittcon Webinar 11/2019), Development of Stability-indicating methods: case studies (SOS meeting, 10/2018).
9. Chair of invited symposia – Chiral separations (Pittcon 2009), Stability-indicating Method development (Pittcon 2010), UHPLC: implementation in QC (Pittcon 2011), UHPLC for high-resolution separations (Pittcon 2012), Platform technologies in pharm. development (Pittcon 2013), QC of monoclonal antibodies and biopharmaceuticals (Pittcon 2014), UHPLC Method Development in Pharm. Analysis (Pittcon 3/17, 3/19, 3/20).

Courses Taken (2007 onwards)

10. ChemStation Operation (2007), **Agilent TOF** operation (2008), MS interpretation (Pittcon 2008), Organic chemistry for analytical chemists (EAS 2009), Thermo Orbitrap (2009), MS interpretation (CACO 2013), Malvern particle size analysis (2008), Dionex IC (2009).
11. **Tablet Processing Technologies**, U. Tenn. Hands-on (5-d, 2004), Dissolution Testing (EAS 2005), **IND filing (CACO 2011),** Physical characterization of pharmaceutical solids (2-d, EAS 2011), CRO collaboration (CACO 2012), Clinical diagnostics (CACO 2013), ADC workshop (CABS 2013), Personalized Medicine (CABS 2014), Immuno-oncology (CACO 2014), Biomarkers (CACO 2014), Antibody Therapeutics (CACO 2014)
12. **Management training: Looking Glass Experience** (5-d, 2008), Crucial Conversation (5-d, 6/09), Management Fundamentals (10/09), High Performance Communication (2011), Building and leading teams (2011), Leading with emotion (2013), personal mastery (2013), **AMA mini-MBA** (5-d Amer. Mgmt. Assoc. 2014)
13. **U. California Santa Cruz Extension** (**Biotechnology Certificate** 2010, 26 credits): Molecular Biology, Drug Development Process, GMP, Drug Discovery Process, Experimental Techniques in Mol. Biol., Human Physiology, Drug Formulations, Cellular Biology, Molecular Diagnostics, and Toxicology Fundamentals.

TECHNICAL PAPERS

130+ publications (>90 first-authored), Selected titles are shown here under classifications of Pharmaceutical, Bioscience, Fast LC and UHPLC, Food, Environmental, Toxicology, Plastics, GC, LC Columns, and Instruments.

Pharmaceutical Analysis

1. K. Huynh-Ba and M. W. Dong, Stability Studies and Testing of Pharmaceuticals: An Overview, **LCGC North Am. 38(6),** 325-336, 2020.
2. M. W. Dong, K. Huynh-Ba, and J. T. Ayers, *Development of Stability-Indicating Analytical Procedures by HPLC: An Overview and Best Practices*, **LCGC North Am. 38(8),** xxx-xxx, 2020.
3. K. Huynh-Ba and M. W. Dong, *Validation of Stability-Indicating HPLC Methods for Pharmaceuticals: Overview, Methodologies and Case Studies*, **LCGC North Am. 38(10),** xxx-xxx, 2020.
4. M. W. Dong and B. E. Boyes, Modern Trends and Best Practices in Mobile-Phase Selection in Reversed-Phase Chromatography, **LCGC North Am**. **36(10),** 752-767, 2018.

5. M. W. Dong, Ten Common-Sense Corollaries in Pharmaceutical Analysis by HPLC, **LCGC North Am, 36(8),** 506-509, 2018.
6. M. W. Dong and R. M. Woods, Quality Control Methodologies for Pharmaceutical Counterions, **LCGC North Am, 34(10),** 792-797, 2016.
7. M. W. Dong, A Universal Reversed-Phase HPLC Method for Pharmaceutical Analysis, **LCGC North Am, 34(6),** 408-419, 2016.
8. D. Kou, L. Wigman, P. Yehl, and **M. W. Dong,** Separation Science in Drug Development, Part 4: Quality Control, **LCGC North Am. 33(12),** 900-909, 2015.
9. M. W. Dong, Separation Science in Drug Development, Part 3: Analytical Development, **LCGC North Am, 33(10),** 764-775, 2015.
10. B. Lin, J. H. Pease, and **M. W. Dong**, Separation Science in Drug Development, Part 2: High – Throughput Characterization. **LCGC North Am. 33(8),** 534-545, 2015.
11. M. Wong, B. Murphy, J. H. Pease, and **M. W. Dong**, Separation Science in Drug Development, Part 1: High –Throughput Purification. **LCGC North Am. 33(6)**, 402-413, 2015.
12. M. W. Dong, Seven Common Faux Pas in Modern HPLC. **LCGC North Am. 32(8),** 552-557, 2014.
13. M. W. Dong, D. Guillarme, S. Fekete, R. Rangelova, J. Richards, D. Prudhomme, and N. P. Chetwyn. High-resolution separations of complex pharmaceuticals by UHPLC: Case studies and quality control implications, **LC GC North Am**. **32(11),** 868-76, 2014.
14. T. Remarchuk, F. St-Jean, D. Carrera, S. Savage, H. Yajima, B. Wong, S. Babu, A. Deese, J, Stults, M. Dong, D. Askin, J. Lane, and K Spencer, Synthesis of Akt Inhibitor GDC-0068 (Ipatasertib). Part II. Total Synthesis and First Kilogram Scale-up, **Organic Process Research and Development, 18 (12),** 1652–1666, 2014.
15. M. W. Dong, A Three-Pronged Template Approach for Rapid HPLC Method Development. **LCGC North Am. 31(8),** 612-621, 2013.
16. D. Guillarme and **M. W. Dong**. Newer developments in HPLC impacting pharmaceutical analysis: A brief review, **Amer. Pharm. Rev. 16(4),** 36-43, 2013.
17. M. W. Dong, Essence of Modern HPLC: Advantages, limitations, fundamentals, and opportunities. **LCGC North Am. 31(6),** 472-479, 2013.
18. M. W. Dong, E.X. Zhao, D.T. Yazzie, C. C. Gu, and J. D. Pellett. A Generic HPLC/UV Platform Method for Cleaning Verification. **Amer. Pharm. Rev. 15(6),** 10-17, 2012.
19. L. Dai, A. C. Quiroga, K. Zhang, H. B. Runes, D.T. Yazzie, K. Mistry, N. P. Chetwyn, and M. W. Dong, A Generic Headspace GC Method for Residual Solvents in Pharmaceuticals: Benefits, Rationale, and Adaptations for New Chemical Entities, **LC.GC, 28**(1), 54-66, 2010.
20. M. W. Dong. Ultra-high-pressure LC in pharmaceutical analysis: Performance and practical issues. **LC.GC 25(7)**, 656-666, 2007.
21. M. W. Dong, G. Miller, and R. Paul, MS-compatible ICH impurity analysis with a high-pH mobile phase: Advantages and pitfalls, **J. Chromatog. 987**, 283-290, 2003.
22. M. W. Dong. And J. L. Pace, A rapid HPLC method for multivitamin analysis, LC.GC **14(9)**, 794-803, 1995.
23. M. W. Dong, R.D. Conlon, and A. F. Poile. Developing Rugged LC Methods using an Automated Solvent Optimization System. **Amer. Lab. 20(5)**, 50-59 and **20(6)**, 50-58, 1988.
24. M. W. Dong, J. Lepore, and T. Tarumoto, Factor affecting the ion-pair chromatography of water-soluble vitamins, **J. Chromatogr. 442**,81-95, 1988.
25. M. W. Dong and D.C. Hockman, Automated Dissolution Analysis by Liquid Chromatography. **Pharm. Technol. 11**(3), 70-82, 1987.

Bioscience

26. R. E. Moore, K. Broster, K. Cook, K. D'Silva, E. Niederkofler, A.O. Bailey, J. Bones, and **M. W. Dong**. Antibody-Drug Conjugates: Perspectives and Characterization. **LCGC North Am. 36(6**), 362-274, 2018.
27. T. Zhang, C. Quan, and **M. W. Dong**, HPLC for Characterization and Quality Control of Therapeutic Monoclonal Antibodies. **LCGC North Am. 32(10),** 796-808, 2014.
28. M. W. Dong, Tryptic Mapping by Reversed-phase Liquid Chromatography. In "**Advances in Chromatography, Vol. 32,"** P. Brown (Ed), Marcel Dekker, New York, pp. 21-51, 1992.
29. E. Katz and **M. W. Dong.** Rapid Analysis and Purification of Polymerase Chain Reaction (PCR) Products. **BioTechniques 8(5)**, 546-555, 1990.
30. M. W. Dong, J.R. Gant, and B. Larsen. Advances in Fast Reversed-phase Chromatography of Proteins. **BioChromatog. 4(1)**, 19-34, 1989.
31. M. W. Dong and A. D. Tran, Factors influencing the performance of peptide mapping by RPLC, **J. Chromatogr. 499**, 125-139, 1990.
32. M. W. Dong and J. L. DiCesare, Amino acid analysis by HPLC: an overview of six methods, **LC 1**(4), 222 -228, 1983.

HPLC, Fast LC, and UHPLC

33. M. W. Dong, UHPLC 1: Perspectives and Instrumental Features, **LCGC North Amer. 35(6)**, 374-381, 2017.
34. M. W. Dong and D. Guillarme, UHPLC 2: Benefits, **LCGC North Amer. 35(8)**, 486-495, 2017.
35. M. W. Dong, UHPLC 3: Potential Issues, **LCGC North Amer. 35(11)**, 818-823, 2017.
36. S. Fekete, D. Guillarme, and M. W. Dong, Superficially Porous Particles: Perspectives, Practices, and Trends. **LCGC North Am. 32(6),** 420-433, 2014.
37. M. W. Dong and K. Zhang, UHPLC in method development, **Trend in Anal. Chem.,** 63, 21-30, 2014.
38. M. W. Dong, Myths in UHPLC. **LCGC North Am. 31(10),** 868-880, 2013.
39. M. W. Dong. Ultra-high-pressure LC in pharmaceutical analysis: Benefits, impacts, and issues. In "**Chromatography: A science of discovery,**" R.L. Wixom and C.L. Gehrke (ed.), Wiley, Hoboken, New Jersey, 2010, pp. 328-333.
40. M. W. Dong and J.R. Gant. Short-Three-Micron Columns: Applications in High-Speed Liquid Chromatography. **LC.GC 2**, 294- 302, 1984.
41. J.L. DiCesare, M. W. Dong, and J.G. Atwood. Very-High-Speed LC II: Some Instrumental Factors Influencing Performance**. J. Chromatogr. 217,** 369-386, 1981.

Food Analysis

42. M. W. Dong. How hot is that pepper? **Today's Chemist at Work**, 9(5), 17-20, 2000.
43. M. W. Dong. HPLC Analysis of Organic Acids in Juice and Wine Using Resin and Reversed-Phase Columns. **LC.GC 16(12)**, 1092-1097, 1998.
44. M. W. Dong and J.L. DiCesare. Improved Separation of Natural Oil Triglycerides Using Columns Packed with 3-µm Particles**. J. Amer. Oil Chem. Soc. 60**, 788-791, 1983.

Environmental Analysis

45. Z.A Grosser, J. F. Ryan, and M. W. Dong, Environmental Chromatographic Methods, and Regulations in the United States of America**. J. Chromatog. 642**, 75-87, 1993.

46. M. W. Dong, J.X. Duggan, and S. Stefanou, A Quick Turnaround HPLC Method for Polynuclear Aromatic Hydrocarbons in Soil, Water, and Waste Oil. **LC.GC 11(11),** 802-810, 1993.
47. M. W. Dong, D. C. Locke, and D. Hoffmann, Characterization of Aza-arenes in basic organic portion of suspended particulate matter, **Env. Sci. & Technol., 11,** 612-618, 1977.
48. M. W. Dong, D. Hoffmann, D. C. Locke, and E. Ferrand, The occurrence of caffeine in the air of New York City, **Atmos. Environ. 11,** 651-653, 1977.
49. M. W. Dong, D. C. Locke, and E. Ferrand, HPLC method for routine analysis of major parent polycyclic aromatic hydrocarbons in suspended particulate matter, **Anal. Chem. 48**(2). 368-372, 1976.

Toxicology

50. M. W. Dong, I. Schmeltz, E. Jacobs and D. Hoffmann, Aza-Arenes in Tobacco Smoke, **J. Anal. Toxicol. 2** (5), 21-25, 1978.
51. L. Wigman, T. Remarchuk, S. R. Gomez, A. Kumar, M. W. Dong, C. D. Medley, and N. Chetwyn, Byproducts of commonly used coupling reagent, toxicological evaluation and methods for determination, **Amer. Pharm. Rev. 17** (2), Feb. 2014.
52. D. Hoffman, M. W. Dong, and S. S. Hecht, Origin in tobacco smoke N'-Nitrosonornicotine, a tobacco-specific carcinogen, **J. Natl. Cancer Inst. 58**(6)**,** 1841-44, 1977.
53. M. W. Dong, I Schmeltz, E. Jacobs, and D. Hoffmann, Aza-arenes in tobacco smoke, **J. Anal. Toxicol., 2,** 21-25, 1978.

Plastics and GC Analysis

54. W.M. Reuter, M. W. Dong, and J. McConville. A System for High-Performance Gel Permeation Chromatography (GPC). **Amer. Lab. 23(5)**, 45-58, 1991.
55. M. W. Dong. Novel Applications for Headspace GC. **Chromatographia 8**, 447-451, 1981.
56. M. W. Dong, A.H. DiEdwardo, and F. Zitomer, Determination of Residual Acetaldehyde in PET Bottles and Resins by Automated Headspace Analysis. **J. Chromatog. Sci. 18**, 242-246, 1980.

HPLC Columns and Instrument

57. K. Shoykhet, K. Broeckhoven, and M. W. Dong, Modern HPLC Pumps: Perspectives, Principles, and Practice, **LCGC North Amer. 37(6**), 374-384, 2019.
58. C. Paul, F. Steiner, and M. W. Dong, HPLC Autosamplers: Perspectives, Principles, and Practices, **LCGC North Amer. 37(8**), 514-529, 2019.
59. M. W. Dong and J. Wysocki, Ultraviolet detectors: Perspectives, Principles, and Practices, **LCGC North Amer. 37(10**), 750-759, 2019.
60. R. Mazzarese, S. M. Bird, P. J. Zipfell, and M. W. Dong, Chromatography Data Systems: Perspective, Principles and Trends, **LCGC North Amer. 37(12**), 852-866, 2019.
61. M. W. Dong, HPLC Column Standardization in Pharmaceutical Development: A Case Study, **LCGC North Am, 34**(8), 540-545 (2016).
62. M. W. Dong, New HPLC Systems and Related Products Introduced in 2019-2020: A Brief Review, **LCGC North Am, 38(4),** 220-228, 2020.
63. M. W. Dong, New HPLC Systems and Related Products Introduced in 2018-2019: A Brief Review, **LCGC North Am, 37(4),** 252-259, 2019.
64. M. W. Dong, New HPLC Systems and Related Products Introduced in 2017-2018: A Brief Review, **LCGC North Am, 36(4),** 256-265, 2018.

65. M. W. Dong, New HPLC Systems, and Related Products: A Brief Review, **LCGC North Am, 35(4),** 246-257, 2017.
66. M. W. Dong, HPLC Column Standardization in Pharmaceutical Development: A Case Study, **LCGC North Am, 34(8),** 540-545, 2016.
67. M. W. Dong, New HPLC Systems and Related Products Introduced at Pittcon 2016: A Brief Review. **LCGC North Amer. 34(4),** 262-273, 2016.
68. M. W. Dong, New HPLC Systems, and Products introduced at Pittcon 2015: A Brief Review. **LCGC North Amer. 33(4),** 254-261, 2015.
69. M. W. Dong, HPLC Systems and Related Products introduced at Pittcon 2014: A Brief Review. **LCGC North Amer. 32(4),** 270-279, 2014.
70. M. W. Dong, HPLC Systems and Related Products introduced at Pittcon 2013: A Brief Review. **LCGC North Amer. 31(4),** 313-325, 2013.
71. M. W. Dong and K. Louie, A case of sporadic LC assay results, **LCGC North Amer. 30 (2),** 1-4, 2012.
72. M. W. Dong, L.C. Lauman, D.P. Mowry, M. Canales, and M. E. Arnold, A Windows-based HPLC System. **Amer. Lab. 25(14)**, 37-45, 1993.
73. M. W. Dong, J. R. Gant, and P. A. Perrone, Guard and Scavenger Columns, extending the lifetime of LC columns, **LC Mag., 3**(9), 786-793, 1985.
74. J. L. DiCesare, M. W. Dong, and J. R. Gant, Influence of injector bypass on lifetime of small-particle LC columns, **Chromatographia, 15** (9), 595-598, 1982.
75. J. L. DiCesare, M. W. Dong, and J. S. Ettre, Very-high-speed LC: The system and selected applications, **Chromatographia, 14** (5), 257-268, 1981.

Manuals and Cookbooks

76. M. W. Dong, Perkin-Elmer HPLC Analysis Cookbooks: HPLC System for Carbamate Analysis, LC-291; HPLC System for PAH Analysis, LC-292; HPLC System for Vitamin Analysis, LC-294; HPLC System for Carbohydrate Analysis, LC-299, Perkin-Elmer Corp., Norwalk, CT, 1993-94.
77. M. W. Dong, Operating Manuals for Amino Acid Analysis System, 1985; Peptide Mapping System, 1990; PCR Analysis System, 1991, Perkin-Elmer Corp., Norwalk, CT, 1985-91.