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

BOOKS AND EDITOR

1. **M.W. Dong, Modern HPLC for Practicing Scientists**, Wiley-Interscience, Hoboken, NJ, 2006 (A best seller in chromatography with 4000 copies sold).
2. **Handbook of Pharmaceutical Analysis by HPLC**, S. Ahuja and **M.W. Dong** (Eds), Elsevier/Academic Press, Amsterdam, 2005. Authored five chapters including key concepts, instrumentation, sample preparation, operation, and calibration.
3. J.L. DiCesare, **M.W. Dong** and L. S. Ettre. **Introduction to High-Speed Liquid Chromatography**, Perkin-Elmer, Norwalk, CT, 1981.
4. 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 several new small molecule new chemical entities for oncology indications (AKT-0068 (Phase 1 and 2), IAP-0152 and IAP-0917) and contributed CMC filing to NDA/BLA (OxyContin NDA amendments and BLA for Kadcyra T-DM1 antibody-drug conjugate).

SHORT COURSES AND INVITED SEMINARS PRESENTED

Short Courses Conducted

1. **Essentials of Modern HPLC/UHPLC I and II** (EAS 2011-14 and Pittcon 2012-14, ACS 4/14)
2. **Drug Discovery and Development Processes for Scientists** (EAS 2010, 14), Pittcon 2013, 15)
3. **Drug Quality Fundamentals, Quality Control of Small Molecule Drugs and Recombinant Biologics** (UC Santa Cruz Extension, 1.5 cr., 2012-14, HPLC 2014, Pittcon 2015, EAS 2014).
4. HPLC method development in pharmaceutical analysis EAS (2005 -2010).
5. Modern HPLC for bioanalytical and DMPK Scientists (Pittcon 2010)

Invited Seminars (2009 onward)

6. A roadmap for rapid method development webcasts (LCGC webcasts 2012), HPLC Calibration (IVT 2014), QbD method development (EAS 2009), Residual Solvents by HSGC (PharmSep 2009), , column standardization, 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).
7. UHPLC: Perspective, Performance and Potential Issues (SCDG 2/10), 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 rapid sample characterization (Roche Harmonization Meeting, Ireland, 10/14).
8. 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 3/14).

Courses Taken (2007 onwards)

9. 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).
10. **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), Immunooncology (CACO 2014), Biomarkers (CACO 2014), Antibody Therapeutics (CACO 2014)
11. **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. workshop on accounting, finance, strategy, marketing and management, 20 14)
12. **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

100+ publications (>70 first authored), selected titles shown here under classifications of Pharmaceutical, Bioscience, Fast LC and UHPLC, Food, Environmental, Plastics, GC, LC Columns and Instruments.

Pharmaceutical Analysis

1. 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.
2. B. Lin, J. H. Pease and **M. W. Dong**, Separation Science in Drug Development, Part 2: High – Throughput Characterization. **LCGC North Amer, 23(8)**, 534-545, 2015.
3. M. W. Dong, Separation Science in Drug Development, Part 3: Analytical Development, **LCGC North Am, 33(10)**, xxx-xxx, 2015.
4. D. Kou and **M. W. Dong**, Separation Science in Drug Development, Part 4: Quality Control, **LCGC North Am, 33(12)**, xxx-xxx, 2015, *in preparation*.
5. M.W. Dong, Seven Common Faux Pas in Modern HPLC. **LCGC North Am. 32(8)**, 552-557, 2014.
6. 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.
7. 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.
8. L. Wigman, T. Remarchuk, S. R. Gomez, A. Kumar, M. W. Dong, C. D. Medley, and N. Chetwyn, Byproducts of Commonly Used Coupling Reagents: Origin, Toxicological Evaluation and Methods for Determination, **Amer. Pharm. Rev., 17 (1)**, Feb 2014.

9. M.W. Dong, A Three-Pronged Template Approach for Rapid HPLC Method Development. **LCGC North Am.** **31(8)**, 612-621, 2013.
10. D. Guillarme and **M. W. Dong**. Newer developments in HPLC impacting pharmaceutical analysis: A brief review, **Amer. Pharm. Rev.** **16(4)**, 36-43, 2013.
11. M.W. Dong, Essence of Modern HPLC: Advantages, limitations, fundamentals and opportunities. **LCGC North Am.** **31(6)**, 472-479, 2013.
12. 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.
13. 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.
14. M.W. Dong. Ultra-high-pressure LC in pharmaceutical analysis: Performance and practical issues. **LC.GC** **25(7)**, 656-666, 2007.
15. 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.
16. 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.
17. M.W. Dong and D.C. Hockman. Automated Dissolution Analysis by Liquid Chromatography. **Pharm. Technol.** **11(3)**, 70-82, 1987.

Bioscience

18. 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.
19. S. Fekete, **M.W. Dong**, T. Zhang, and D. Guillarme. High resolution reversed phase analysis of recombinant monoclonal antibodies by ultra-high pressure liquid chromatography column coupling, **J. Pharm. Biomed. Anal.** **83**, 273-278, 2013.
20. 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.
21. E. Katz and **M.W. Dong**. Rapid Analysis and Purification of Polymerase Chain Reaction (PCR) Products. **BioTechniques** **8(5)**, 546-555, 1990.
22. M.W. Dong, J.R. Gant and B. Larsen. Advances in Fast Reversed-phase Chromatography of Proteins. **BioChromatog.** **4(1)**, 19-34, 1989.

HPLC, Fast LC and Ultra-high-pressure LC

23. S. Fekete, D. Guillarme and M.W. Dong, Superficially Porous Particles: Perspectives, Practices and Trends. **LCGC North Am.** **32(6)**, 420-433, 2014.
24. M. W. Dong and K. Zhang, UHPLC in method development, **Trend in Anal. Chem.**, **63**, 21-30, 2014,
25. M.W. Dong, Myths in UHPLC. **LCGC North Am.** **31(10)**, 868-880, 2013.
26. 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.
27. M.W. Dong and J.R. Gant. Short-Three-Micron Columns: Applications in High-Speed Liquid Chromatography. **LC.GC** **2**, 294- 302, 1984.

28. 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

29. M.W. Dong. How hot is that pepper. **Today's Chemist at Work**, 9(5), 17-20, 2000.
30. 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.
31. M.W. Dong and J.L. DiCesare. Improved Separation of Natural Oil Triglycerides Using Columns Packed with 3- μ m Particles. **J. Amer. Oil Chem. Soc.** **60**, 788-791, 1983.

Environmental Analysis

32. 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.
33. 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.

Plastics and GC Analysis

34. 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.
35. M.W. Dong. Novel Applications for Headspace GC. **Chromatographia** **8**, 447-451, 1981.
36. 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

37. M.W. Dong, New HPLC Systems and Products introduced at Pittcon 2015: A Brief Review. **LCGC North Amer.** **33(4)**, 254-261, 2015.
38. M.W. Dong, HPLC Systems and Related Products introduced at Pittcon 2014: A Brief Review. **LCGC North Amer.** **32(4)**, 270-279, 2014.
39. 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.
40. 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.
41. 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.