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PROFESSIONAL EXPERIENCE

Takeda Pharmaceuticals Inc. **2016 – Present**
Vice President, Global Head
Quantitative Translational Science

Biogen Corporation **2007 – 2016**
Senior Director, Global Head
Early Development Sciences

ZymoGenetics Inc. **2002 – 2007**
Vice President
Early Development

Immunex Corporation **1999 – 2002**
Vice President
Pharmacometrics and Preclinical Development

Biogen, Inc. **1994 – 1999**
Associate Director
Preclinical Development

Johnson & Johnson **1991-1994**
Group Leader
Drug Metabolism

EDUCATION

Post-graduate: **Massachusetts Institute of Technology, Cambridge, Massachusetts**
Executive Education Center, R&D Leadership Academy Graduate, 2018

Graduate: **University of Michigan; Ann Arbor, Michigan**
Ph.D., Pharmaceutics, 1987 (Advisor: John Wagner, Ph.D.)
M.S., Pharmaceutics, 1986

University of Wisconsin; Madison, Wisconsin
M.S., Pharmacy, 1984 (Advisor: Peter Welling, Ph.D.)

Undergraduate: **University of Wisconsin; Madison, Wisconsin**
B.S., Pharmacy, 1982

AWARDS

- Citation of Merit, University of Wisconsin. 2015

PROFESSIONAL ACTIVITIES & AFFILIATIONS

Current Activities & Affiliations

- *Industry Advisory Board*, University of Florida, Center for Pharmacometrics & Systems Pharmacology
- *Fellow*, American College of Clinical Pharmacology (ACCP)
- *Member*, International Consortium on Innovation and Quality in Pharmaceutical Development
- *Member*, American Society of Clinical Pharmacology and Therapeutics (ASCPT)
- *Editorial Advisory Board*, Journal of Pharmaceutical Sciences, 2001 – present

Past Activities & Affiliations

- *Member*, NC3R/MHRA Expert Working Group on Refinement of Animal Testing for Human Pharmaceuticals
- *Scientific Advisory Board*, University of Washington School of Bioengineering, 2001-2004
- BioSafe (BIO Expert Preclinical Safety & PK/PD Scientific Advisory Committee)
- *Member*, USP Expert Panel on Complex Molecules, 2003
- *Lecturer*, University of Wisconsin Short Course on Drug Development, 2000-2003
- *Leadership Committee*, University of Wisconsin Annual Symposium on Applied Pharmacokinetics & Drug Metabolism, 1997-2006

PUBLICATIONS

1. Patel RB, Patel UR, Rogge MC, Shah VP, Prasad VK, Selen A and Welling PG. Bioavailability of Hydrochlorothiazide from 25, 50, 100 and 200 mg Tablets and Suspension Doses. J. Pharm. Sci. 1984; 73(3)
2. Johnson CA, Zimmerman SW and Rogge MC. The Pharmacokinetics of Antibiotics Used to Treat Peritoneal Dialysis Associated Peritonitis. Am. J. Kid. Dis. 1984; 4(1)
3. Patel RB, Rogge MC, Selen A, Goehl TJ, Shah VP, Prasad VK and Welling PG. Bioavailability of Hydrocortisone from Commercial 20 mg Tablets. J. Pharm. Sci. 1984; 73(7)
4. Rogge MC, Welling PG, Johnson CA and Zimmerman SW. Multiple Dose Intraperitoneal Vancomycin Kinetics During CAPD. Proceedings of the Third International Symposium on Peritoneal Dialysis, Washington, D.C. 1984
5. Selen A, Johnson CA, Rogge MC, Craig WA and Welling PG. Absorption of Theophylline from Two Sustained Release Formulations. Biopharm. Drug Disp. 1985; 6
6. Welling PG, Selen A, Pearson JG, Kwok F, Rogge MC, Ifan A, Marrero D, Craig WA and Johnson CA. A Pharmacokinetic Comparison of Cephalexin and Cefadroxil Using HPLC Assay Procedures. Biopharm. Drug Disp. 1985; 6
7. Rogge MC, Johnson CA, Zimmerman SW and Welling PG. Vancomycin Disposition During Continuous Ambulatory Peritoneal Dialysis: A Pharmacokinetic Analysis of Peritoneal Drug Transport. Antimicrob. Agents Chemother. 1985; 27(4)
8. Wagner JG, Rogge MC, Natale RB, Albert KS and Szpunar GJ. Single Dose and Steady State Pharmacokinetics of Adinazolam After Oral Administration. Biopharm. Drug Disp. 1987; 8: 405-425

9. Rogge MC, Solomon WR, Sedman AJ, Welling PG, Toothaker RD and Wagner JG. The Theophylline Enoxacin Interaction: I. Effect of Enoxacin Dose Size on Theophylline Disposition. Clin. Pharmcol. Ther. 1988; 44(5)

10. Rogge MC, Solomon WR, Sedman AJ, Welling PG, Koup JR and Wagner JG. The Theophylline Enoxacin Interaction: II. Changes in the Disposition of Theophylline and its Metabolites During Intermittent Dosing of Enoxacin. Clin. Pharmcol. Ther. 1989; 46(4)

11. Woods MG, Diana GD, Rogge MC, Otto MJ, Dutko FJ and McKinlay MA. In Vitro and In Vivo Activity of Win 54954: A New Broad Spectrum Antipicornavirus Drug. Antimicrob. Agents and Chemother. 1989; 33(12)

12. Charman SA, Charman WNA, Rogge MC, Wilson TD, Dutko FJ and Pouton CW. Self-Emulsifying Drug Delivery Systems: Formulation and Biopharmaceutic Evaluation of an Investigational Lipophilic Compound. Pharm. Res. 1992; 9(1)

13. Lettieri JT, Rogge MC, Kaiser L, Echols RM and Heller AH. Pharmacokinetic Profiles of Ciprofloxacin after Single Intravenous and Oral Doses. Antimicrob. Agents and Chemother. 1992; 36(5)

14. Charman WN, Rogge MC, Boddy AW and Berger BM. Effect of Food and a Monoglyceride Emulsion Formulation on Danazol Bioavailability. J. Clin. Pharmacol. 1993; 33(4)

15. Flor SC, Rogge MC and Chow AC. Bioequivalence of Oral and Intravenous Ofloxacin after Multiple Dose Administration to Healthy, Male Volunteers. Antimicrob. Agents and Chemother. 1993; 37(7)

16. Charman WN, Rogge MC, Boddy AW, Barr WH and Berger BM. Absorption of Danazol after Administration to Different Sites of the Gastrointestinal Tract and the Relationship to Single- and Double-Peak Phenomena in the Plasma Profiles. J. Clin. Pharmacol. 1993; 33(12)

17. Lettieri JT, Rogge MC, Echols RM, Kaiser L and Heller AH. Pharmacokinetics of Ciprofloxacin after Single Oral and Intravenous Doses. Drugs 1993; 46/Suppl. 3

18. Klemens SP, Sharpe CA, Rogge MC and Cynamon MH. Activity of Levofloxacin in a Murine Tuberculosis Model. Antimicrob. Agents and Chemother. 1994; 38(7)

19. Wise R, Andrews JM, O'Neill P, Jolley A, Fowler CL and Rogge MC. The Pharmacokinetics and Tissue Distribution of FK-037, a New Parenteral Cephalosporin. Antimicrob. Agents and Chemother. 1994; 38(10)

20. Meier W, Gill A, Rogge MC, Dabora R, Majeau GR, Oleson F, Jones WE, Frazier D, Miatkowski K and Hochman PS. Immunomodulation by an LFA3-IgG1 Fusion Protein: Cell Line Dependent Glycosylation Effects on Pharmacokinetics and Pharmacodynamics. Ther. Immunol. 1995; 2

21. Alam J, Goelz S, Rioux P, Scaramucci J, Jones W, McAllister A, Campion M and Rogge MC. Comparative Pharmacokinetics and Pharmacodynamics of Two Recombinant Human Interferon beta-1a (IFN -1a) Products Administered Intramuscularly in Healthy Male and Female Volunteers. Pharm. Res. 1997; 14(4)

22. Alam J, McAllister A, Scaramucci J, Jones W and Rogge MC. Pharmacokinetics and Pharmacodynamics of Interferon Beta-1a (IFN -1a) in Healthy Volunteers after Intravenous, Subcutaneous or Intramuscular Administration. Clin. Drug Invest. 1997; 14(1)

23. Chien SC, Chow AT, Natarajan J, Williams RR, Wong FA, Rogge MC and Nayak RK. Absence of Age and Gender Effect on the Pharmacokinetics of a Single 500 mg Oral Dose of Levofloxacin in Healthy Subjects. Antimicrob Agents and Chemother. 1997; 41(7)

24. Chien SC, Chow AT, Rogge MC, Williams R, and Hendrix CW. Pharmacokinetics and Safety of Oral Levofloxacin in Human Immunodeficiency-Infected Individuals Receiving Concomitant Zidovudine. Antimicrob Agents and Chemother. 1997; 41(8)
25. Chien SC, Rogge MC, Gisclon LG, Curtin C, Wong F, Natarajan J, Williams R, Fowler C and Chow AT. The Pharmacokinetic Profile of Levofloxacin Following Once Daily 500 mg Oral or Intravenous Doses. Antimicrob. Agents and Chemother. 1997; 41(10)
26. Gobburu JVS, TenHoor C, Rogge MC, Frazier DE, Thomas D and Jusko WJ. Pharmacokinetics/Dynamics of 5c8, a Monoclonal Antibody to CD154 (CD40 Ligand): Suppression of an Immune Response in Monkeys. J. Pharmacol. Exp. Ther. 1998; 286(2)
27. Rogge MC, McAllister A, Charenkavanich S, DiBiase M, Jones W, Knox SJ and Alam JJ. Impaired Bioavailability of Interferon Beta-1a (Avonex) When Administered Intramuscularly by Needle-Free Injection. Drug Delivery. 1998; 5
28. Galluppi G, Rogge MC, Green MD, Feigel D, Lesko L, Roskos L and Peck C. Integration of Pharmacokinetics and Pharmacodynamics Studies in the Discovery, Development and Review of Protein Therapeutic Agents: A Conference Report. Clin. Pharmcol. Ther. 2001; 69:387-99
29. Martin P, Vaidyanathan S, Lane J, Rogge MC, Gillette N, Niggemann B and Green J. Safety and Systemic Absorption of Pulmonary Delivered Human Interferon -1a in the Non-Human Primate. J Interferon Cytokine Res. 2002; 22:709-17
30. Foerder C, Rogge MC. Enbrel® (Etanercept). In "Biologics 2000 - Comparability of Biotechnology Products". Brown F, Lubiniecki, Murano G (eds). Dev. Biol. Basel, Karger, 2002
31. Chow A, Williams R, Chien S, N atarajan J, Rogge MC, Wong F. Absence of a Pharmacokinetic Interaction Between Digoxin and Levofloxacin. J Clin Pharm Ther. 2002; 27(1): 7-12
32. Lee H, Kimko H, Rogge MC, Wang D, Nestorov I and Peck C. Population Pharmacokinetic and Pharmacodynamic Modeling of Etanercept Using Logistic Regression Analysis. Clin. Pharmcol. Ther. 2003; 73:348-65
33. Ponce RA, Armstrong, K, Andrews K, Hensler J, Palmer TE, Heffernan J, Reynolds T, and Rogge MC. Safety of recombinant human Factor XIII in a cynomolgus monkey model of extracorporeal blood circulation. Toxicologic Pathology 2005; 33:702-710
34. Ponce RA, Visich JE, Heffernan JK, Lewis KB, Pederson S, Lebel E, Andrews-Jones L, Elliott, Palmer TE, and Rogge MC. Preclinical Safety and pharmacokinetics of recombinant human Factor XIII. Toxicologic Pathology 2005; 33:495-506
35. Visich JE, Byrnes-Blake KA, Lewis KB, Meengs B, and Rogge MC. Bioavailability and Relative Tissue Distribution of [^{125}I]-Recombinant Human Thrombin Following Intravenous or Subcutaneous Administration to Nonhuman Primates. Journal of Thrombosis and Hemostasis 2006; 4(9): 1962-1968
36. Roque R, Ponce RA, Burleson F, Cabrit M, Broly H, and Rogge MC. Influenza Virus Host Response of C57Bl/6 Mice Treated with TACI-Ig. Immunopharmacology and Immunotoxicology 2006; 28: 13-32
37. Krejsa C, Rogge MC and Sadee W. Protein Therapeutics – New Applications for Pharmacogenetics. Nature Reviews Drug Discovery, 2006; 5(6):507-521
38. Heffernan JK, Ponce RA, Zuckerman LA, Volpone JP, Visich JE, Giste E, Jenkins N, Alexander K, Appesland L, Boster D, Pederson S, Knitter G, Palmer T, Wills M, Early R, and Rogge MC. Preclinical

Safety of Recombinant Human Thrombin. Journal of Regulatory Toxicology and Pharmacology, 2007; 47:48-58

39. Munafo A, Priestley A, Nestorov I, Visich J, and Rogge MC. Safety, Pharmacokinetics and Pharmacodynamics of Atacicept in Healthy Volunteers. European Journal of Clinical Pharmacology, 2007; 63(7): 647-656
40. Li Z, TenHoor C, Marbury T, Swan S, Ticho B, Rogge MC and Nestorov I. Clinical Pharmacokinetics of Tonapofylline: Evaluation of Dose Proportionality, Oral Bioavailability, and Gender and Food Effects in Healthy Human Subjects. The Journal of Clinical Pharmacology, 2011; 51(7): 1004-1014
41. Hu X, Miller L, Richman S, Hitchman S, Glick G, Liu S, Zhu Y, Crossman M, Nestorov I, Gronke R, Baker D, Rogge MC, Subramanyam M, Davar G. A Novel PEGylated Interferon Beta-1a for Multiple Sclerosis: Safety, Pharmacology, and Biology. The Journal of Clinical Pharmacology, 2012; 52(6): 798-808
42. Horvath C, Andrews A, Baumann A, Black L, Blanset D, Cavagnaro J, Hastings K, Hutto D, MacLachlan T, Milton M, Reynolds T, Roberts S, Rogge MC, Sims J, Treacy G, Warner G, Green D. Storm forecasting: additional lessons from the CD28 superagonist TGN1412 trial. *Letter to Editor.* Nature Reviews Immunology, 2012; 12(10): 740
43. O'Connor A and Rogge MC. Nonclinical Development of a Biosimilar: The Current landscape. Bioanalysis, 2013; 5(5): 537-544
44. Rogge MC, Yun L, Galluppi G. Interferon Beta Assessment in Non-Chinese and Chinese Subjects: Clearance and Pharmacodynamic Activity of an Endogenous Cytokine Is Not Race Dependent. The Journal of Clinical Pharmacology, 2014; 54(10): 1153-1161
45. He P, Kerr D, Marbury T, Ries D, Farwell W, Stecher S, Dong Y, Wei D, Rogge MC. Pharmacokinetics of Renally Excreted Dexpramipexole in Subjects with Renal Insufficiency. Clinical Pharmacology in Drug Development, 2014; 54(12):1383-90
46. Nestorov I, Neelakantan S, Ludden T, Li L, Jiang H, Rogge MC. Population Pharmacokinetics of Recombinant Factor VIII Fc Fusion Protein. Clinical Pharmacology in Drug Development, 2015; 4(3): 163-74
47. Rogge MC, Dresser M, Fossler M, Heald D, Stoch SA, Vanevski KM, Bello A. Clinical Pharmacology, *creating current and future success in Drug Development*. The Journal of Clinical Pharmacology, 2015; 55(11): 1193-7
48. Lui L, Bello A, Dresser MJ, Heald D, Komjathy S, O'Mara E, Rogge MC, Stoch SA, Robertson S. Best Practices for the Use of Itraconazole as a Replacement for Ketoconazole in Drug-Drug Interaction Studies. The Journal of Clinical Pharmacology, 2016; 56(2): 143–51
49. Biliouris K, Gaitonde P, Yin W, Norris D, Wang Y, Henry S, Fey R, Nestorov I, Schmidt S, Rogge M, Lesko L, and Trame M. A semi-mechanistic population pharmacokinetic model of nusinersen: an antisense oligonucleotide for the treatment of Spinal Muscular Atrophy. CPT Pharmacometrics Syst Pharmacol, 2018; 7(9): 581-92
50. Yin W and Rogge M. Targeting RNA: *a transformative therapeutic strategy.* Clinical Translational Science, Clinical Translational Science, 2019; 12, 98–112

BOOKS

Co-Editor, ***Preclinical Drug Development***, Informa Healthcare, New York, NY
1st Edition 2005
2nd Edition 2009

ON-LINE LECTURES

1. Rogge M. (2009), "Pharmacokinetics, Toxicokinetics and Safety Margins", in Bussiere, J. (ed.), Non-Clinical Testing for Toxicity of Pharmaceuticals: The Biomedical & Life Sciences Collection, Henry Stewart Talks Ltd, London (online at http://www.hstalks.com/?t=BL0772073-Rogge)
2. Rogge M. (2011), "Phase Ib and Phase II Studies and the Utility of PD Endpoints and Biomarkers": AAPS Press.
3. Rogge M., Vakilynejad M. (2018), Quantitative Systems Pharmacology: High-Value Platforms that Enable Model Informed Decision Making in the Early Development Through the Post-Approval Period. Invited FDA Staff Lecture.

PLENARY PRESENTATIONS

1. Georgetown-FDA Joint Symposium on Development of Biotechnology-Derived Drugs, 1999
2. EUFEPS Symposium on New Drug Development Technology, 2002
3. Georgetown Conference on Application of Physiologically-Based PK/PD Models to Support Drug Development, 2002
4. USP Expert Panel on Establishing Equivalence for Complex Active Ingredients, 2003
5. FDA-BIO Preclinical Regulatory Forum, 2005
6. FDA-DIA Open Forum on Follow-On Protein Products, 2005
7. FDA-DIA Open Forum on Follow-On Protein Products, 2012
8. FDA /AAPS/ASCP Workshop on Food Effect Guidance, 2015
9. FDA/Brookings Forum on Improving Productivity in Pharmaceutical R&D, 2015

PATENTS

1. Improved recombinant human interferon beta-1a formulation. Goelz S., Alam J. and Rogge M.
2. Methods of treating pain and inflammation in neuronal tissue using IL31Ra and OSMRb antagonists. Bilsborough J., Krejsa C., Zuckerman L. and Rogge M.
3. Methods of treating pain and inflammation in neuronal tissue using IL31 antagonists. Bilsborough J., Krejsa C., Zuckerman L. and Rogge M.