Mark Charles Rogge, PhD, FCP

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PROFESSIONAL EXPERIENCE

Consultant **2021 – Present**
Cambridge, MA

- Serving as consultant to emerging companies on matters related to the translational science of small and large molecule development.
- Providing advice and guidance on matters related to organizational growth, scientific needs, regulatory expectations, and requirements.

Oak Hill Bio **2021 - Present**
Cheshire, United Kingdom

Scientific Advisory Board

- Serving as chair of the inflammation scientific advisory board.
- Providing advice and guidance on matters related to product development.

University of Florida **2021 – Present**
Center for Pharmacometrics and Systems Pharmacology
Orlando, FL

Research Professor

- Core research activities: 1. Conducting focused research on elucidation of product and patient covariates associated with development of anti-drug antibody development; 2. Conducting focused research on association of pathway and disease biomarker profiles with clinical benefit.
- Providing scientific oversight to post-doctoral staff on activities related to quantitative characterization of pharmacological activity and disease progression.
- Supporting the certificate and degree pathways for the Model-Informed Drug Development course through lectures and student mentoring.

Takeda Pharmaceuticals Inc. **2016 – 2021**
Cambridge, MA

Vice President, Global Head
Quantitative Translational Science

- Responsible for global Quantitative Translational Science activities and the larger R&D transformation to a Model-Informed Drug Discovery & Development environment. Functional area responsibility encompassed preclinical & clinical pharmacology, imaging, advanced modeling & simulation, and biomarker activities across the Research and Development realms.
- Led a highly diverse team of scientists who deeply interfaced with Discovery Research, Preclinical DMPK, Safety, Early and Late Clinical Sciences.

- Led a transformational change in operating structure that was focused on creation and use of significant external scientific networks to supplement in-house program team activities and advanced quantitative platform systems.
- Member of the Research Senior Leadership Team, Safety Board, Therapeutic Area Leadership Teams, and certain Joint Strategy Committees for external collaborations.

Biogen Corporation **2007 – 2016**
Cambridge, MA

Senior Director, Global Head
Early Development Sciences

- Led a translational development organization that delivered superior preclinical and clinical pharmacology support, TK/ADME, and advanced quantitative systems support for all small molecule and large molecule programs from R2D Transition through Post-Approval.
- Introduced and led all advanced modeling & simulation efforts within R&D and provided significant AM&S support to joint ventures and assessment of potential in-license products.
- Provided front-line leadership support for business development activities, core member of Joint Venture and Preferred Provider Leadership Committees. Core member of Clinical Trial Review Board, Safety Monitoring Committee, Development Sciences Review Forum, and Biomarker & Safety Advisory Committee.

Key Company Accomplishments:

- Established a role as a strong, respected, and credible leader within R&D during a time of significant company change.
- Reorganized and built staff to meet program and corporate needs. Employees were given clarity in their roles and mission. Program teams developed high respect for the value our staff brought to teams.
- Built an advanced quantitative pharmacology organization that brought objective, insightful presence to programs in the preclinical and clinical development realms.
- Developed strong interdisciplinary relationships across R&D to take advantage of the collective knowledge of our resources and bring that value to program decisions.
- Created an infrastructure of essential processes and operating procedures to ensure quality and security of data, analyses and reports.
- Served as a team member on the Aducanumab (beta amyloid), CNV802 (Nav1.7) and various antisense oligonucleotide program teams.
- Department provided significant pivotal support to all development programs and to Alprolix™, Eloctate™, Tysabri™, Avonex™, and Tecfidera™ life cycle management activities.
- Played central role in creating and maintaining the Samsung biosimilar joint venture that evolved from creating a portfolio of lead molecules in 2012 to now possessing multiple approvals in Asia, Australia, Europe and North America.

ZymoGenetics Inc. **2002 - 2007**
Seattle, WA

Vice President (Senior Director, 2002-2003)
Early Development

- Led a department that was responsible for all toxicology, preclinical and clinical PK/PD, bioassay and pharmacology assessments that supported our inflammation, immuno-oncology, hepatitis, and hemophilia programs.
- Served on Research Management, Development Operations and Portfolio Management Committees.
- Supported business development through external portfolio presentations and interactions with corporate development partners.
- Represented ZymoGenetics at regulatory agencies, scientific meetings and investor conferences.

Key Company Accomplishments:

- Created a department with significant technical and operational expertise to support all late research and development programs.
- Created an R&D biomarker program that spanned all therapeutic areas and an advanced modeling & simulation core staff that could bring stochastic insight to our analyses and forecasts.
- Principal leader in managing cultural change from a strict Research to a balanced R&D environment.
- Principal driver in development and approval of Recothrom™ and development strategies for rFXIII, rIL-21, IL-31 mAb antagonists, PEG-Interferon lambda and Atacicept programs (TACI-Ig).
- Key member of business development team that established multiple external collaborations.

Immunex Corporation 1999 – 2002
Seattle, WA
Vice President (Director, 1999-2001)

Pharmacometrics and Preclinical Development

- Created a department that was responsible for all preclinical ADME, Toxicology assessments and Clinical Pharmacology evaluations.
- Led efforts to create biomarker, mechanistic pharmacology, and advanced modeling & simulation strategies to support progress of drug candidates through development decision portals.
- Provided strong oversight in improving inter-departmental relationships.
- Represented company at regulatory agencies and professional trade association meetings.

Key Company Accomplishments:

- Provided primary leadership on all Enbrel™ clinical pharmacology activities associated with post-approval adult rheumatoid arthritis commitments, juvenile rheumatoid arthritis, psoriasis and ankylosing spondylitis indications.
- Championed Enbrel™ dose regimen conversion to 50 mg once-weekly and successfully led efforts to provide scientific rationale for regulatory approval.

- Provided core leadership on rIL1ra, rIL4R and rhTRAIL development teams.
- During company acquisition period created employment opportunities for all subordinates in the Amgen organization.

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

- Created the preclinical and clinical pharmacology capability that supported all R&D activities.
- Hired key senior staff to support PK/PD efforts; established membership on all project teams.
- Involved in numerous business development efforts and provided scientific expertise on external program collaborations.

Key Company Accomplishments:

- Avonex™ (rIFNβ_{1a}) team member with responsibility for all PK/PD activities; efforts resulted in approval of 1st drug to reduce the progression of disability in Multiple Sclerosis.
- Conducted toxicology, pharmacology and PK/PD activities supporting the Amevive™ (LFA3TIP-Fc) and Antova™ (CD40L mAb) IND submissions and the Amevive™ clinical pharmacology program that subsequently resulted in product approval.

Johnson & Johnson **1994**
Claremont, CA
Group Leader, Biopharmaceutics / IOLAB Facility

- Created the PK/PD and laboratory data management facility to support R&D activities.
- Responsible for all regulatory compliance related to bioanalytical laboratory activities.
- Provided scientific and administrative support during facility closure.

Johnson & Johnson **1991 – 1993**
Raritan, NJ
Group Leader, Drug Metabolism / R.W. Johnson Pharmaceutical Research Institute

- Responsible for all small molecule clinical pharmacokinetic activities.
- Member of Clinical Protocol Review Committee, Floxin™ (IV), and Levaquin™ program teams.

EDUCATION

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

Graduate: **University of Michigan; Ann Arbor, Michigan**
Ph.D., Pharmaceutical Chemistry, 1987
M.S., Pharmaceutical Chemistry, 1986

University of Wisconsin; Madison, Wisconsin
M.S., Pharmaceutical Sciences, 1984

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

AWARDS

- Citation of Merit, University of Wisconsin. 2015

PROFESSIONAL ACTIVITIES & AFFILIATIONS

Current Activities & Affiliations

- National Academy of Science, *Forum on Drug Discovery, Development and Translation*
- FDA Advisory Committee, *Pharmaceutical Science and Clinical Pharmacology*
- University of Wisconsin, School of Pharmacy, *Board of Visitors*
- American College of Clinical Pharmacology (ACCP), *Fellow*
  - *Public Policy Committee, 2018 – Present*
- *Member*, American Society of Clinical Pharmacology and Therapeutics (ASCPT)
- *Member,* International Society of Pharmacometrics (ISoP)
  - *Finance Committee, 2019 – Present*
  - *QSP/FDA Leadership Committee, 2019 - Present*
- *Editorial Advisory Board*, Journal of Pharmaceutical Sciences, 2001 – present

Past Activities & Affiliations

- International Consortium on Innovation and Quality in Pharmaceutical Development
  - *Chair, Clinical Pharmacology Leadership Group, 2015-2016*
  - *Board of Directors, 2018 - 2020*
- American Association of Pharmaceutical Scientists (AAPS)
  - *Chair, Pharmacokinetics, Pharmacodynamics and Drug Metabolism Section, 2001*
- NC3R/MHRA Expert Working Group on Refinement of Animal Testing for Human Pharmaceuticals
- BioSafe (BIO Expert Preclinical Safety & PK/PD Scientific Advisory Committee)
  - *Founding Member*
  - *Chair, 2010*
- University of Washington School of Bioengineering, 2001-2004, *Scientific Advisory Board*
- USP Expert Panel on Complex Molecules, 2003
- University of Wisconsin Short Course on Drug Development, 2000-2003, *Course Organizer and Lecturer*
- University of Wisconsin Annual Symposium on Applied Pharmacokinetics & Drug Metabolism, 1997-2006, *Leadership Committee*

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, Natarajan 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

51. Das R, Wille L, Zhang L, Chen C, Winchester W, Selimkhanov J, Wykosky J, Apgar JF, Burke JM, Rogge M, Hua F, and Vakilynejad M. A quantitative systems pharmacology model of colonic motility with applications in drug development. Journal of Pharmacokinetics and Pharmacodynamics, 2019; 46(5): 485-498

52. Leach, M.W., O. Clarke, D., Dudal, S., Han, C., Li, C., Yang, Z., Brennan, F.R., Bailey, W.J., Chen, Y., Deslandes, A., Loberg, L.I., Mayawala, K., Rogge, M.C., Todd, M. and Chemuturi, N.V., Strategies and Recommendations for Using a Data-Driven and Risk-Based Approach in the Selection of First-in-Human Starting Dose: An International Consortium for Innovation and Quality in Pharmaceutical Development (IQ) Assessment. Clin. Pharmacol. Ther. 2020. https://doi.org/10.1002/cpt.2009

53. Pai S.M., Othman A.A., Rusch L., Masters J., Greene D., Rogge M., Gries J-M, Clementi W., Kumar P., and Derendorf H., Science and Evidence-based Review & Approval of COVID-19 Treatments and Vaccines: A Statement of Support for the U.S. FDA. The Journal of Clinical Pharmacology. J Clin Pharmacol. 2021 Mar;61(3):277-279.

54. Bai JPF, Schmidt B, Gadkar K, Damian V, Earp JC, Friedrich C, Graaf P, Naik K, Madabushi R, Musante CJ, Rogge M, and Zhu H. FDA-Industry Scientific Exchange on assessing quantitative systems pharmacology models in clinical drug development: a meeting report, summary of challenges/gaps, and future perspective. *AAPS J* 23**,** 60 (2021). https://doi.org/10.1208/s12248-021-00585-x

55. Grundmann O, Parag K, Rogge M. Regulation of Dietary Supplements and Nutraceutical Products in the United States: An Argument for Greater Oversight and Uniform Standards. J Clin Pharmacol. Grundmann, O., Kumar, P., Rogge, M. and (2022), Regulation of Dietary Supplements and Nutraceutical Products in the United States: An Argument for Greater Oversight and Uniform Standards. Grundmann O, Kumar P, Rogge M; ACCP Public Policy Committee. Regulation of Dietary Supplements and Nutraceutical Products in the United States: An Argument for Greater Oversight and Uniform Standards. J Clin Pharmacol. 2022 Jan;62(1):14-16. doi: 10.1002/jcph.1982. Epub 2021 Nov 30. PMID: 34648654.

56. Rogge M, Parag K, Grundmann O. Front-Line Healthcare Professionals Lack Critical Knowledge in Dietary Supplement and Nutraceutical Products: A Call to Action for Comprehensive Educational Opportunities. J Clin Pharmacol. Rogge M, Kumar P, Grundmann O; ACCP Public Policy Committee. Front-Line Health Care Professionals Lack Critical Knowledge in Dietary Supplement and Nutraceutical Products: A Call to Action for Comprehensive Educational Opportunities. J Clin Pharmacol. 2022 Jan;62(1):17-19. doi: 10.1002/jcph.1985. Epub 2021 Dec 10. PMID: 34648667.

57. Venkatakrishnan K, Gupta N, Smith PF, Lin T, Lineberry N, Ishida T, Wang L, Rogge M. Asia-Inclusive Clinical Research and Development Enabled by Translational Science and Quantitative Clinical Pharmacology: Towards a Culture That Challenges the Status Quo. Clin Pharmacol Ther (Accepted for publication).

BOOK CHAPTERS

Applications of Quantitative System Pharmacology Modeling to Model Informed Drug Development. In Methods in Molecular Biology. Andy Z.X. Zhu and Mark Rogge (in press)

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
10. Pharmacometrics Japan 2020, Keio University, 2020

PODUM/POSTER PRESENTATIONS

More than 60 national and international presentations, which includes 35 invited oral presentations, at scientific society meetings, government agencies, and universities. Topics relate to preclinical safety testing, ADMET/DMPK, early drug development, and quantitative methods for informed decision-making.

1. APhA, Academy of Pharmaceutical Sciences, 1983
2. Wisconsin Pharmaceutical Association, 1983
3. Third International Symposium on Peritoneal Dialysis, 1984
4. Inter-science Congress on Antimicrobial Agents and Chemotherapy, 1984
5. AAPS, Annual Meeting, 1987
6. University of Michigan, Invited Presentation, 1987
7. AAPS, Annual Meeting, 1988
8. AAPS, Annual Meeting, 1989
9. University of Rhode Island, Invited Presentation, 1989
10. Northeastern Regional Pharmaceutics Association, Invited Presentation, 1990
11. Fourth European Congress of Biopharmaceutics and Pharmacokinetics, 1990
12. Third International Symposium on New Quinolones, 1990
13. University of Rhode Island, Invited Presentation, 1990
14. International Congress on Chemotherapy, 1991
15. Inter-science Congress on Antimicrobial Agents and Chemotherapy, 1992
16. Fourth International Symposium on Quinolones, 1992
17. Inter-science Congress on Antimicrobial Agents and Chemotherapy, 1992
18. International Congress on Chemotherapy, 1993
19. Inter-science Congress on Antimicrobial Agents and Chemotherapy, 1993
20. Inter-science Congress on Antimicrobial Agents and Chemotherapy, 1994
21. University of Arizona, Invited Presentation, 1995
22. AAPS Eastern Regional Meeting, 1996
23. AAPS Annual Meeting, 1996
24. AAPS Annual Meeting, 1997
25. American College of Rheumatology Annual Meeting, 1997
26. PhRMA Conference on Biologicals and Biotechnology, Invited Presentation, 1997
27. Covance Biotechnology Symposia (Boston, San Francisco), Invited Presentation, 1997
28. International Investigative Dermatology, 1998
29. Northeastern University, Invited Presentation, 1998

30. BIO ‘98, Invited Presentation, 1998
31. AAPS Annual Meeting, 1998
32. ASCPT Annual Meeting, Invited Presentation, 1999
33. Society for Investigative Dermatology, 1999
34. FDA Short Course on Pharmacokinetics, Invited Presentation, 2000
35. Biologics 2000, Invited Presentation, 2000
36. University of Washington, Invited Presentation, 2000
37. Sierra Biomedical Research Symposium, Invited Presentation, 2001
38. University of Washington, Invited Presentation, 2001
39. ASCPT Annual Meeting, 2002
40. EULAR Annual Meeting, 2002
41. AAPS-FDA Symposium, Invited Presentation, 2002
42. Loma Linda University, Invited Presentation, 2003
43. AAPS Annual Meeting, Invited Presentation, 2003
44. Long Island University, Invited Presentation, 2004
45. PAGE, 2004
46. AAPS National Biotechnology Conference, Invited Presentation, 2005
47. University of Washington, Invited Presentation, 2005
48. AAPS National Biotechnology Conference, Invited Presentation, 2006
49. University of Washington, Invited Presentation, 2006
50. BIO Preclinical Safety Annual Meeting, Invited Presentation, 2007
51. SOT Annual Meeting, Invited Presentation, 2008
52. SOT Annual Meeting, Invited Presentation, 2009
53. AAPS National Biotechnology Conference, Invited Presentation, 2009
54. SOT Annual Meeting, Invited Presentation, 2010
55. BIO Annual Meeting, Invited Presentation, 2010
56. EMA Scientific Working Group, Invited Lectures, 2011
57. ASCPT, Invited Presentations (2), 2013
58. FDA-Industry Roundtable, Invited Presentation, 2013
59. ACTRIMS/ECTRIMS, 2014
60. ACoP, 2014
61. ACCP, Invited Presentation, 2017
62. FDA, Invited Presentation, 2018

PATENTS (Issued, Pending)

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.
4. ***Orexin 2 Receptor Agonist Compositions and Uses Thereof.*** Rogge M., Faessel H., Lu H., Venkatakrishnan K., Wagner J.