



Sandra M. Sims, Ph.D

SUMMARY

- Accomplished in product development from discovery through commercial launch
- Successful leader of multidisciplinary product development teams
- Solid record for meeting business goals and scientific milestones
- Led, managed, and developed groups of 16-24 professionals
- PhD in Pharmaceutical Sciences with 16 years in the Pharmaceutical industry

PROFESSIONAL EXPERIENCE

Pharmaceutical Development Consulting, L.L.C.

2006-Present

Provide formulation development consulting services to small pharmaceutical start-up companies. Services include devising formulation strategies and tactics for development, identifying partner companies capable of implementing the chosen strategy in a cost effective manner, providing due diligence evaluation of potential partners and assisting in devising selection criteria, project management oversight in the planning and coordination of drug product supply chain, and coordination of Chemistry, Manufacturing, and Control (CMC) regulatory document preparation.

Pfizer Inc., Kalamazoo, MI

1990-2006

Associate Director, Pharmaceutical Sciences Solids Development (2003 – 2006)

Led and mentored the Solids Development group, which included PhD/MS/BS scientists and technicians, to meet project and technical milestones for developing solid oral dosage forms. Directed animal health cephalosporin projects within the Michigan Pharmaceutical Sciences organization. Partnered with Manufacturing and the Animal Health business to achieve late stage technology transfer and launch of Excede 200, Excede 100, Spectramast LC and DC, Lutalyse 100 ml vial, and Simplicef tablets.

Associate Director, Pharmaceutical Sciences Vetmed Development (2002 – 2003)

Directed both formulation and analytical groups in the development of animal health products. Served as the Pharmaceutical Sciences representative to the Animal Health business; developed and maintained budget and project plans based on agreements with the business. Achieved timely delivery of pharmaceutical sciences support for new candidate drugs, as well as continued support of product enhancements.

Pharmaceutical Sciences Team Leader (1999 – 2001)

Led Pharmaceutical Sciences Teams for more than 12 compounds, including sterile, oral, ophthalmic, and topical dosage forms and involving therapeutic areas of infectious disease,



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urology, central nervous system diseases, and cancer. Led and coordinated all Pharmaceutical Sciences activities and resources to achieve project milestones and collaborated with full development team members to achieve overall project goals.

Principle Scientist (1992 – 1999)

Principal formulation scientist for Zyvox IV (Linezolid) from discovery through preclinical and clinical development, including formulation, package, and process development, technology transfer, scale-up, ICH stability, registration, pre-approval inspection, and launch. Supported preclinical development of Infectious Disease candidate drugs through physical-chemical testing, preclinical formulation development, and provision of dosage forms for early animal testing.

Post-doctoral Fellow, Drug Delivery Systems Research (1990 – 1992)

WESTERN MICHIGAN UNIVERSITY, Kalamazoo, MI

Visiting Professor, Pharmacology (BIOS 561)

Spring 2006

EDUCATION

Ph.D. Pharmaceutics, University of Utah, 1990
Dissertation Title: Iontophoretic Transport Mechanisms Across Skin
Major Professor: Dr. William I. Higuchi

B.S. Pharmacy, West Virginia University, 1985 (*Magna cum laude*).

PROFESSIONAL AFFILIATIONS

American Association of Pharmaceutical Scientists
American Chemical Society
American Pharmacists Association

PATENTS

1. US Patent issued August 2005 for US Patent Application 09/933,366 entitled “Oxazolidinone Solution with Enhanced Drug Loading”. Inventor: SMSims
2. US 6,796,975 entitled “Container for Linezolid Intravenous Solution”. Inventors: SMSims, PBBowman, DCWade, SCValvani, granted September 28, 2004.
3. US 6,696,426 entitled “Preservative Free Ophthalmic Oxazolidinone Antibiotic Drug Delivery Systems”. Inventors: SKSingh, PBandyopadhyay, SHasan, LCHawley, SMSims, granted on February 24, 2004



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PUBLICATIONS

1. Hilgers, AR, Smith, DP, Biermacher, JJ, Day, JS, Jensen, JL, Sims, SM, Adams, WJ, Friis, JM, Palandra, J, Hosley, JD, Shobe, EM, and Burton, PS. Predicting Oral Absorption of Drugs: A Case Study with a Novel Class of Antimicrobial Agents, *Pharm. Res.*, 20, 1149 (2003).
2. Martin GE, Robins RH, Bowman PB, Duholke WK, Farley KA, Kaluzny BD, Guido JE, Sims SM, Thamann TJ, Thompson BE, Nishimura T, Noro Y, Tahara T. Susceptibility of morpholine substituents to photo-oxidative decomposition-identification of photo-oxidative degradants of linezolid (PNU-100766). *J. Heterocyclic Chem.*, 36, 265 (1999).
3. Farley KA, Bowman PB, Brumfield JC, Crow FW, Duholke WK, Guido JE, Robins RH, Sims SM, Smith RF, Thamann TJ, Vonderwell BS, and Martin GE. Unequivocal location of sites of N-oxidation using natural abundance long-range ^1H - ^{15}N GHNMQC two-dimensional NMR. *Magn. Reson. Chem.*, 36, S11-S16 (1998).
4. Sims, SM, Ho, NFH, Geary, TG, Thomas, EM, Day, JS, Barsuhn, CL and Thompson, DP. Influence of Organic Acid Excretion on Cuticle pH and Drug Absorption by *Haemonchus contortus*", *Int. J. Parasitology*, **26**, 25 (1996).
5. Geary, TG, Blair, KL, Ho, NFH, Sims, SM and Thompson, DP. Biological Functions of Nematode Surfaces, a chapter in Molecular Approaches to Parasitology, J. Boothroyd (Ed.), pp. 57-76, Wiley-Liss, Inc., (1995).
6. Ho, NFH, Sims, SM, Vidmar, TJ, Day, JS, Barsuhn, CL, Thomas, EM, Geary, TG and Thompson, DP. Theoretical Perspectives on Anthelmintic Drug Discovery: Interplay of Transport Kinetics, Physicochemical Properties and *In vitro* Activity of Anthelmintic Drugs, *J. Pharm. Sci.*, **83**, 1052 (1994).
7. Hoogstraate, AJ, Srinivasan, V, Sims, SM and Higuchi, WI. "Iontophoretic Enhancement of Peptides: Behaviour of Leuprolide Versus Model Permeants", *J. Controlled Release*, (1994).
8. Sims, SM, Ho, NFH, Magas, LT, Geary, TG, Barsuhn, CL and Thompson, DP. Biophysical Model of the Transcuticular Excretion of Organic Acids, Cuticle pH and Buffer Capacity in Gastrointestinal Nematodes, *J. Drug Targeting*, **2**, 1 (1994).
9. Geary, TG, Sims, SM, Thomas, EM, Vanover, L, Davis, JP, Winterrowd, CA, Klein, RD, Ho, NFH and Thompson, DP. "*Haemonchus contortus*: Ivermectin-induced Paralysis of the Pharynx", *Exp. Parasit.*, **77**, 88 (1993).



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10. Thompson, DP, Ho, NFH, Sims, SM and Geary, TG. Mechanistic Approaches to Quantitate Anthelmintic Absorption by Gastrointestinal Nematodes, *Parasitology Today*, **9**, 31 (1993).
11. Sims, SM, Higuchi, WI, Srinivasan, V and Peck, K. Ionic Partition Coefficients and Electro-osmotic Flow in Cylindrical Pores: Comparison of the Predictions of the Poisson-Boltzmann Equation with Experiment, *J. Colloid Interface Sci.*, **155**, 210 (1993).
12. Sims, SM, Magas, LT, Barsuhn, CL, Ho, NFH, Geary, TG and Thompson, DP. Mechanisms of Microenvironmental pH Regulation in the Cuticle of *Ascaris suum*, *Mol. Biochem. Parasitol.*, **53**, 135 (1992).
13. Ho, NFH, Geary, TG, Barsuhn, CL, Sims, SM and Thompson, DP. Mechanistic Studies in the Transcuticular Delivery of Antiparasitic Drugs II: *ex vivo/in vitro* Correlation of Solute Transport by *Ascaris suum*, *Mol. Biochem. Parasitol.*, **52**, 1 (1992).
14. Sims, SM, Higuchi, WI and Srinivasan, V. Skin Alteration and Convective Solvent Flow Effects During Iontophoresis: II. Monovalent Anion and Cation Transport Across Human Skin, *Pharm. Research*, **9**, 1402 (1992).
15. Sims, SM, Higuchi, WI and Srinivasan, V. Interaction of Electric Field and Electro-osmotic Effects in Determining Iontophoretic Enhancement of Anions and Cations, *Int. J. Pharm.*, **77**, 107 (1991).
16. Sims, SM, Higuchi, WI and Srinivasan, V. Skin Alteration and Convective Solvent Flow Effects During Iontophoresis: I. Neutral Solute Transport Across Human Skin, *Int. J. Pharm.*, **69**, 109 (1991).
17. Sims, SM and Higuchi, WI. Baseline Studies on Iontophoretic Transport in Hairless Mouse Skin: The Effect of Applied Voltage Drop and pH on the Iontophoresis of a Model Weak Electrolyte, *J. Memb. Sci.*, **49**, 305 (1990).
18. Srinivasan, V, Sims, SM, Higuchi, WI, Behl, CR and Pons, S. Iontophoretic Transport of Drugs: A Constant Voltage Approach, in J. Kost (Ed.), Pulsed and Self Regulated Drug Delivery, CRC Press, Inc., Boca Raton, FL (1990).
19. Srinivasan, V, Higuchi, WI, Sims, SM, Ghanem, AH and Behl, CR. Transdermal Iontophoretic Drug Delivery: Mechanistic Analysis and Application to Polypeptide Delivery, *J. Pharm. Sci.*, **78**, 370 (1989).
20. Skultety, PF and Sims, SM. Evaluation of the Loss of Propylene Glycol During Aqueous Film Coating, *Drug Dev. Indust. Pharm.*, **13**, 2209 (1987).



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PRESENTATIONS

1. Sims, SM and Alley, JL. Zyvox™ (Linezolid Injection): Photostability and Overwrap Selection. Poster presentation at AAPS Annual Meeting, Denver, CO, 20-25 October, 2001.
2. Poel, T, Thomas RC, Barbachyn MR, Ford CW, Zurenko GE, Adams WJ, Sims SM, Watt W and Dolak LA. Synthesis and biological evaluation of tetrahydro-4(2H)-thiopyranyl phenyloxazolidinone sulfoxides and sulfones as novel antibacterial agents. Poster presentation at 39th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), 26-29 September 1999.
3. Friis JM, Palandra J, Shobe EM, Rousch KE, Ouding RJ, Smith DP, Sims SM, Poel T, Adams WJ. Pharmacokinetics of a tetrahydro-4(2H)-thiopyranyl phenyloxazolidinone sulfoxide antibacterial agent in the rat and dog. Poster presentation at AAPS Annual Meeting, New Orleans, LA, 14-18 November 1999.
4. Friis JM, Shobe EM, Palandra J, Rousch KE, Ouding RJ, Jones BW, Weber GL, Walker GS, Loux SJ, Fagerness PE, Smith DP, Sims SM, Barbachyn MR, Poel T, Thomas RC, Adams WJ. Biotransformations and pharmacokinetics of a tetrahydro-4(2H)-thiopyranyl phenyloxazolidinone sulfoxide antibacterial agent and its metabolites in the rat. Poster presentation at 1999 Gordon Research Conference on Drug Metabolism, Plymouth, NH, 4-9 July 1999.
5. Shobe EM, Friis JM, Palandra J, Ouding RJ, Jones BW, Norris LR, VandeGiessen TL, Smith DP, Sims SM and Adams WJ. Lead finding pharmacokinetic studies of oxazolidinone antibiotics in the rat: Simultaneous screening of multiple compounds using LC-MS/MS. Presentation at 1998 Gordon Research Conference on Drug Metabolism, Plymouth, NH, 5-10 July 1998.
6. Hilgers, AR, Smith, DP, Sims, SM, Conradi, RA and Burton, PS. "Bi-directional transport properties of the Oxazolidinone antibacterials across Caco-2 monolayers", AAPS Annual Meeting (1997).
7. Barbachyn, MR, Hutchinson, DK, Brickner, SJ, Garmon, SA, Grega, KC, Little, HS, Manninen, PR, Toops, DS, Ulanowicz, DA, Demyan, WF, Daley-Yates, PT, Ford, CW, Martin, IJ, Sedlock, ML, Sims, SM and Zurenko, GE. "Potent Water Soluble Prodrugs of the Oxazolidinone Antibacterial Agent Eperezolid", 37th ICAAC Annual Meeting (199



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8. Gadwood, RC, Kamdar, BV, Sims, SM, Martin, IJ, Zurenko, GE. and Ford, CW. "Synthesis of Oxazolidinone Antibacterial Agents Incorporating Morpholine and Piperazine N-oxides: Oxazolidinone Prodrugs Having High Water Solubility", 37th ICAAC Annual Meeting (1997).
9. Sims, SM, Cooper, AM, Cook, KJ, Smith, DP and Patel, MV. "Microemulsions: Formulation Rationale, Drug Solubilization and Oral Absorption Potential of a Poorly Soluble Drug", *Pharm. Research*, 11, S-312, PDD 7551 (1994).
10. Sims, SM, Ho, NFH., Geary, TG, Thomas, EM, Day, JS and Thompson, DP "Dynamic Interplay Between Organic Acid Excretion and Cuticle pH on Drug Absorption by *Haemonchus contortus*", *Proceedings of the 20th International Symposium on Controlled Release of Bioactive Materials*, (1993).
11. Thompson, DP, Ho, NFH, Sims, SM, Barsuhn, CL, Thomas, EM and Geary, TG. "Organic Acid Excretion by *Ascaris suum* and *Haemonchus contortus*: Implications for Microenvironmental pH Regulation and Drug Absorption", 22nd Annual Keystone Symposium, *J. Cellular Biochem.*, 17C, S-120 (1993).
12. Sims, SM, Ho, NFH, Thompson, DP, Geary, TG and Barsuhn, CL. "Role of Microenvironmental Cuticle pH and Buffer Capacity in Controlling Transcuticular Uptake of Organic Electrolytes by Nematodes", *Pharm. Research*, 9, S-174, PDD 7023 (1992).
13. Sims, SM, Magas, LT, Ho, NFH, Thompson, DP, Geary, TG and Barsuhn, CL. "Biophysical Model of Transcuticular Excretion Kinetics of Organic Acids and Cuticle pH and Buffer Capacity in Gastrointestinal Nematodes", *Pharm. Research*, 9, S-174, PDD 7022 (1992).
14. Sims, SM, Thomas, EM, Davis, JP, Ho, NFH, Barsuhn, CL, Geary TG and Thompson, DP. "Transcuticular Organic Acid Excretion by *Haemonchus contortus*: Implications for Drug Absorption", American Society of Parasitologists 67th Annual Meeting, Philadelphia, PA, August (1992).
15. Thompson, DP, Ho, NFH, Sims, SM, Day, JS, Vidmar, TJ, Thomas, EM, Conder, GA and Geary, TG. "Interplay of Absorption Kinetics, Physico-chemical Properties and *In vitro* Activity Among Selected Anthelmintics", American Society of Parasitologists 67th Annual Meeting, Philadelphia, PA, August (1992).
16. Geary, TG, Sims, SM, Vanover, L, Davis, JP, Thomas, EM, Ho, NFH, Winterrowd, CA, Klein, RD and Thompson, DP. "Ivermectin Paralyzes the Pharynx of *Haemonchus*



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- contortus*", American Association of Veterinary Parasitologists Annual Meeting, Boston, MA, August (1992).
17. Ho, NFH, Sims, SM, Day, JS, Vidmar, TJ, Thomas, EM, Conder, GA, Geary, TG and Thompson, DP. "Relationship Between Drug Transport and Bioactivity Among Selected Anthelmintics: *In vitro* and *In vivo* Correlations", American Association of Veterinary Parasitologists Annual Meeting, Boston, MA, August (1992).
 18. Sims, SM, Thomas, EM, Davis, JP, Ho, NFH, Barsuhn, CL, Geary, TG and Thompson, DP. "Organic Acid Excretion by *Haemonchus contortus*: Implications for Cuticle Microenvironmental pH Regulation and Drug Absorption", American Association of Veterinary Parasitologists Annual Meeting, Boston, MA, August (1992).
 19. Thompson, DP, Geary, TG, Ho, NFH, Sims, SM, Williams, JF, Huntington, M, Mackenzie, CD, Pax, RA and Bennett, JL. "The Cuticle as a Potential Target for Macroparasitocidal Agents" World Health Organization, Macroparasitocidal Chemotherapy Project, Geneva, Switzerland, July (1992).
 20. Sims, SM, Magas, LT, Geary, TG, Thompson, DP, Ho, NFH, Barsuhn, CL, Thomas, EM and Mohan, M. "Physiology of Organic Acid Excretion by Parasitic Nematodes", American Society of Parasitologists 66th Annual Meeting, Madison, WI, August (1991).
 21. Sims, SM, Thompson, DP, Ho, NFH, Barsuhn, CL, Thomas, EM and Geary, TG. "Mechanistic Studies on Solute Transport in *Haemonchus contortus*", American Society of Parasitologists 66th Annual Meeting, Madison, WI, August (1991).
 22. Sims, SM, Magas, LT, Ho, NFH, Thompson, DP, Geary, TG and Barsuhn, CL. "Influence of the Microclimate pH of the Cuticle on the Transport Properties of *Ascaris suum*", American Society of Parasitologists 66th Annual Meeting, Madison, WI, August (1991).
 23. Ho, NFH., Thompson, DP, Sims, SM, Barsuhn, CL and Geary, TG. "Mechanistic Studies on Transcuticular Transport in *Ascaris suum*: *ex vivo/in vitro* Correlations", American Society of Parasitologists 66th Annual Meeting, Madison, WI, August (1991).
 24. Thompson, D.P., Ho, N.F.H., Sims, S.M., Barsuhn, C.L. and Geary, T.G. "Mechanistic Studies in the Transcuticular Delivery of Antiparasitic Drugs: *Ex vivo/in vitro* Correlation of Transport by *Ascaris suum*", American Association of Veterinary Parasitologists Annual Meeting, Seattle, WA, July (1991).
 25. Sims, SM, Ho, NFH, Thompson, DP, Magas, LT, Barsuhn, CL, Geary, TG and Thomas, EM. "Effects of Microenvironmental pH on Transcuticular Drug Transport in



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- Gastrointestinal Nematodes", *Proceedings of the 18th International Symposium on Controlled Release of Bioactive Materials*, 249 (1991).
26. Sims, SM, Higuchi, WI, Srinivasan, V and Peck, K. "Ionic Partition Coefficients and Electro-osmotic Flow in Cylindrical Pores: Comparison of the Predictions of the Poisson-Boltzmann Equation with Experiment", *Proceedings of the 18th International Symposium on Controlled Release of Bioactive Materials*, 150 (1991).
 27. Hoogstraate, AJ, Srinivasan, V, Sims, SM and Higuchi, WI. "Iontophoretic Behavior of Leuprolide Versus Model Permeants", *Proceedings of the 18th International Symposium on Controlled Release of Bioactive Materials*, 299 (1991).
 28. Sims, SM, Higuchi, WI and Srinivasan, V. "Convective Solvent Flow and Skin Alteration Effects on Iontophoretic Transport of Model Cations and Anions Through Human Skin", *Pharm. Research*, **7**, S-185 (1990).
 29. Sims, SM, Higuchi, WI and Srinivasan, V. "Electro-osmotic and Skin Alteration Effects on Transport of Uncharged Solutes Through Human Skin During Iontophoresis", *Proceedings of the 17th International Symposium on Controlled Release of Bioactive Materials*, 222 (1990).
 30. Sims, SM and Higuchi, WI. "The Effect of Electro-osmosis on the Transport of an Uncharged Molecule During Iontophoresis", *Pharm. Research*, **6**, S-147 (1989).
 31. Mathot, R, Srinivasan, V, Higuchi, WI and Sims, SM. "A Model Iontophoresis System for Fundamental Studies Using Nuclepore[®] Membranes", *Proceedings of the 16th International Symposium on Controlled Release of Bioactive Materials*, 52 (1989).
 32. Sims, SM, Higuchi, WI and Srinivasan, V. "A Quantitative Assessment of the Parallel Lipid-Aqueous Pore Pathway Model for the Iontophoretic Transport of Weak Electrolytes", *Pharm. Research*, **5**, S-131 (1988).
 33. Sims, SM, Higuchi, WI and Iminidis, G. "Contribution of Mucus Secretion to the Generation of an Acidic Microclimate at the Mucosal Surface of Rat Jejunum: A Theoretical Model Approach", AAPS Midwestern Regional Meeting, Reno, NV (1987).