

Curriculum Vitae

Wendell C. Smith, PhD
Partner & Senior Statistician
Bowsher Brunelle Smith, LLC
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Job History

Employer name: Bowsher Brunelle Smith LLC
Position: Partner and Senior Statistician
Date in Job: November 2003 – present
Core Responsibilities: Scientific leadership for contracts related to the development and validation of bioanalytical methods.

Employer name: Eli Lilly and Company
Position: Senior Research Scientist
Date in Job: July 1979 – October 2003
Core Responsibilities: Statistical leadership for the design, analysis, and reporting of method development and compound evaluation studies in drug discovery, analytical development, product development, drug disposition, investigative toxicology, and morphologic pathology. Education and consultation related to the development, validation and application of bioanalytical procedures.

Employer name: University of North Carolina at Chapel Hill
Position: Assistant Professor
Date in Job: August 1974 – June 1979
Core Responsibilities: Director of data management and statistical analysis for Lipid Research Clinics Program. Development and instruction for course on data management in biostatistics.

Employer name: Iowa State University
Position: Research Assistant / Instructor & Research Associate / Supervisor, Statistical Consulting
Date in Job: September 1968 – July 1974
Core Responsibilities: Statistical programming, teaching, supervision.

Employer name: General Motors Detroit Diesel Allison
Position: Mathematician
Date in Job: June 1966 – August 1968
Core Responsibilities: Statistical analyst, programmer in the Reliability Department

Education

Institution: Iowa State University, Ames, IA
Degree: PhD Statistics
Date: August 1974

Institution: Iowa State University, Ames, IA
Degree: MS Statistics
Date: November 1969

Institution: Purdue University, West Lafayette, IN
Degree: BS Mathematics

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Date: June 1966

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Presentations & Abstracts (Since 1993)	
Description	Date
Smith WC, Bowsher RR. Conceptual and statistical issues in bioanalytical method development and validation. Amgen Global Biostatistics and Epidemiology Shortcourse.	2004
Smith WC. Statistical issues with developing and validating bioanalytical methods. Fifth Annual Land O' Lakes Bioanalytical Conference.	2004
Smith WC. Statistical approaches to evaluating stability of biological therapeutics. AAPS National Biotechnology Conference Roundtable: Stability Assessments of Biotechnology Drugs in Biological Matrices.	2004
Smith WC. Statistical analysis of ligand binding assay validation data. AAPS Annual Meeting and Exposition Shortcourse: GLP-Compliant Validation of Ligand Binding Assays: A Practical and Rational Approach.	2003
Chiang AY, Smith WC, Main BW. Evaluation for latin square designs with repeated measurements and its application to cardiovascular safety pharmacology studies. Twenty-sixth Annual Midwest Biopharmaceutical Statistics Workshop.	2003
Smith WC. Background statistics for bioanalytical method validation. AAPS Workshop: Bioanalytical Method Validation for Macromolecules in Support of Pharmacokinetic Studies.	2003
Ray CA, Dean RA, Bowsher RR, Devanarayan V, Smith WC, Brandt JT. Development and validation of a multiplex cytokine immunoassay for clinical use. AAPS Annual Meeting and Exposition.	2001
Smith WC. Statistical procedures for determination of method accuracy and precision, limits of quantification, and run acceptance. AAPS Annual Meeting and Exposition.	2001
Smith WC. 2001. Statistical applications in assay validation. Statistical Issues in Drug Development Seminar Series, Purdue University Department of Statistics.	2001
Devanarayan V, Smith WC, Sittampalam GS, Carroll RJ. Calibration accuracy and precision: Considerations in assay optimization and method validation. Institute of International Research Analytical and Bioanalytical Method Validation Conference. Seattle, WA.	2001
Cao Y, Smith WC, Bowsher RR. Sensitive Chemiluminescent ELISA for the Bioanalysis of Carboxyl-terminal B-Chain Analogs of Human Insulin. AAPS Annual Meeting and Exposition.	2000
Ray CA, Brandt JT, Dean RA, Smith WC, Devanarayan V, Aguero MLA. Development and validation of a multiplex cytokine immunoassay. Great Lakes International Imaging and Flow Cytometry Association, Inc.	2000
Smith WC. Discordance and harmony in statistics and acceptance criteria. AAPS/APQ Open Forum on Bioanalytical Methods: "What You Don't Know Will Hurt You".	2000
Smith WC. Biomarker analytical validation: statistical concerns. DIA 3 rd Annual USA Clinical Trial Laboratory and Biomarker Symposium: New Approaches for Assessing Efficacy and Safety in Drug Development.	2000
Smith WC. Conceptual and statistical issues in method validation. NIBSC Conference on The Design and Analysis of Potency Assays for Biotechnology Products. Co-sponsored by The International Association for Biologicals, The World Health Organization, and	2000

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The International Union of Immunological Societies.	
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Cummins DJ, Devanarayan V, Smith WC, Carroll RJ. Calibration precision profiles in assay optimization. DIA International Workshop on Statistical Methods in Non-Clinical R&D.	2000
Smith WC. Validity of analytical procedures for which the calibration curve is nonlinear. AOAC International Forum on Methods for Antibiotics and Drugs in Feeds.	2000
Devanarayan V, Smith WC, Carroll RJ. Calibration precision profiles in assay optimization. Joint Statistical Meetings, American Statistical Association.	2000
Smith WC. Statistical analysis of immunoassay validation data. AAPS Workshop on Bioanalytical Methods Validation for Macromolecules.	2000
Smith WC. Statistical applications in assay validation. Statistical Issues in Drug Development Seminar Series, IUPUI Department of Mathematical Sciences.	1999
Smith WC. Statistical applications in assay validation. Statistical Issues in Drug Development Seminar Series, Purdue University Department of Statistics.	1999
Smith WC. Statistical issues in the validation of analytic dilution assays. First International Workshop on Statistical Methodology in Non-Clinical R&D.	1998
Jordan WH, Monn JW, Schoepp DD, Smith WC, Joseph P, Griffey KI, Johnson JA, Wightman KA, Tizzano JP. Kainate neurotoxicity in Fischer 344 rats inhibited by the mGluR2 agonist LY379268. Twenty-eighth Annual Meeting of the Society for Neuroscience.	1998
Smith WC, Sittampalam GS. Technical and statistical challenges in developing assays for proteins. Twentieth Annual Midwest Biopharmaceutical Statistics Workshop.	1997
Bowsher R, Woodworth J, Wilke A, Smith W, Yordy R, Lynch R. Response differences for recombinant glucagon in dogs. International Diabetes Federation Meeting.	1997
White SL, Gatlin CL, Horn JW, Shannon HE, Smith WC, Jordan WH. Morphometry of synapse and granule cell changes in the hippocampus of aging Fischer rats. Microscopy and Microanalysis 1997 Meeting.	1997
Smith WC. Similarity versus linearity in validation of analytical procedures. Tenth Annual Meeting of the Central Section AOAC.	1997
Jordan WH, Gatlin CL, Helton DR, Horn JW, Kallman MJ, Sawyer BD, Shannon HE, Smith WC, Tizzano JP, Wightman KA, White SL. Behavior, biochemistry and hippocampal morphometry in 10, 21, and 27 month old male Fischer 344 rats. Society for Neuroscience Meeting.	1997
Smith WC. Statistical methods in the development of assays for pharmaceutical applications. Fourth Annual Biopharmaceutical Applied Statistics Symposium.	1997
Smith WC. Fundamental validity of analytical dilution assays. FDA Center for Veterinary Medicine.	1995
Sittampalam, GS, Smith WC, McMorris C, Riggin A, Sportsman JR. Curve-fitting models for fluorescence measurements at trace levels. First International Conference on Fluorescence Imaging and Fluorescence Probes.	1995
Jordan WH, Fisher, LF, Gatlin CL, Hanasono GK, Smith WC, White SL. Gastric glandular morphometry in rats given LY307640 sodium, a novel proton pump inhibitor, for three months. American College of Veterinary Pathology Meeting.	1995

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Horn DM, Jordan WH, Holloway DC, Smith WC, Richardson FC. Dose-dependent induction of GST-P+ staining foci by the rat hepatocarcinogen methapyrilene (MP) in the medium-term bioassay. American Association for Cancer Research Meeting.	1994
Chay SH, Herman JL, Smith WC, Pohland RC. Tissue distribution of 14C-daptomycin in male Fischer 344 rats following a single 10 mg/kg intravenous dose determined by phosphor imaging and image analysis assisted quantitative whole-body autoradiographic techniques. Society of Whole-body Autoradiography Meeting.	1994
Main BW, Means JR, Rinkema LE, Smith WC, Sarazan RD. Cardiovascular effects of sub-lethal intravenous doses of tilmicosin alone, and in combination with propranolol or dobutamine, in conscious unrestrained dogs. FASEB Experimental Biology Meeting.	1993
Helvering LM, Richardson KK, Horn DM, Wightman KA, Hall RL, Smith WC, Engelhardt JA, Richardson FC. Expression of TRPM-2 during involution and regeneration of the rat liver. American Association of Cancer Research Meeting.	1993
Gatlin CL, Jordan WH, Shryock TR, Smith WC. 1993. Quantitation of experimental atrophic rhinitis by image analysis. AALAS Technician Symposium.	1993
Shryock TR, Gatlin CL, Jordan WH, Smith WC. Use of digitized image analysis (DIA) to quantitate conchal atrophy for the development of a model of induced swine atrophic rhinitis. Conference of Research Workers in Animal Diseases (CRWAD).	1993
Easley SF, Scheetz II ME, Barker BJ, Mowrey DH, Smith WC, Vise MA, Wicker AL, Coleman MR. Validation of an analytical enzyme linked immunosorbent assay (ELISA) for the determination of bST in milk. AOAC International Meeting.	1992

Publications	
Description	Date
Ray CA, Bowsher RR, Smith WC, Devanarayan V, Willey MB, Brandt JT, Dean RA. Development, validation, and implementation of a multiplex immunoassay for the simultaneous determination of five cytokines in human serum. Journal of Pharmaceutical and Biomedical Analysis 36(5): 1037-1044.	2005
Chiang AY, Smith WC, Main BW, Sarazan RD. Statistical power analysis for hemodynamic cardiovascular safety pharmacology studies in beagle dogs. Journal of Pharmacological and Toxicological Methods 50: 121-130.	2004
DeSilva B, Smith W, Weiner R, Kelley M, Smolec J, Lee B, Khan M, Tacey R, Hill H, Celniker A. Recommendations for the bioanalytic method validation of ligand-binding assays to support pharmacokinetic assessments of macromolecules. Pharmaceutical Research 20(11):1885-1900.	2003
Lee JW, Smith WC, Nordblom GD, Bowsher RR. Validation of assays for the bioanalysis of novel biomarkers: practical recommendations for clinical investigation of new drug entities. Chapter 6: Biomarkers in Clinical Drug Development. Marcel Dekker Inc., 119-148. (In press)	2003
Baker TK, VanVooren HB, Smith WC, Carfagna MA. Involvement of calcium channels in the sexual dimorphism of cadmium-induced hepatotoxicity. Toxicology Letters 137: 185-192.	2003
Bowsher RR and Smith WC. A practical approach for clinical drug development: analytical validation of assays for novel biomarkers. AAPS Newsmagazine 5 (6): 18-25.	2002

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Miller KJ, Bowsher RR, Celniker A, Gibbons J, Gupta S, Lee JW, Swanson SJ, Smith WC, Weiner RS. Workshop on bioanalytical methods validation for macromolecules: Summary Report. <i>Pharmaceutical Research</i> 18 (9): 1373-1383.	2001
Cao Y, Smith WC, Bowsher RR. A sensitive chemiluminescent enzyme immunoassay for the bioanalysis of carboxyl-terminal b-chain analogues of human insulin. <i>Journal of Pharmaceutical and Biomedical Analysis</i> 26: 53-61.	2001
Findlay JWA, Smith WC, Lee JW, Nordblom GD, Das I, DeSilva BS, Khan MN, Bowsher RR. Validation of immunoassays for bioanalysis: a pharmaceutical industry perspective. <i>Journal of Pharmaceutical and Biomedical Analysis</i> 21: 1249-1273.	2000
Smith WC, Sittampalam GS. Conceptual and statistical issues in the validation of analytic dilution assays for pharmaceutical applications. <i>Journal of Biopharmaceutical Statistics</i> 8(4): 509-532.	1998
Losonsky JM, Shryock TR, Smith WC, Gatlin CL, Francisco CJ, Kuriashkin IV, Clarkson RB, Jordan WH. Morphometry of computed tomography and magnetic resonance imaging of the porcine nasal turbinates. <i>Canadian Journal of Veterinary Research</i> 62: 287-292.	1998
White SL, Smith WC, Fisher LF, Gatlin, CL, Hanasono GK, Jordan WH. Quantitation of glandular gastric changes in rats given a proton pump inhibitor for 3 months with emphasis on sampling scheme selection. <i>Toxicologic Pathology</i> 26(3):403-410.	1998
Horn DM, Jordan WH, Holloway DC, Schaberg ES, Smith WC, Richardson FC. Dose-dependent induction of GST-P+ staining foci by the rat hepatocarcinogen methapyrilene in the medium-term bioassay. <i>Fundamental and Applied Toxicology</i> 29:194-197.	1996
Gatlin CL, Jordan WH, Shryock TR, Smith WC. The quantitation of turbinate atrophy in pigs to measure the severity of induced atrophic rhinitis. <i>Canadian Journal of Veterinary Research</i> 60:121-126.	1996
Main BW, Means JR, Rinkema LE, Smith WC, Sarazan RD. Cardiovascular effects of the macrolide antibiotic tilmicosin, alone and in combination with propranolol or dobutamine, in conscious unrestrained dogs. <i>Journal of Veterinary Pharmacology and Therapeutics</i> 19:225-232.	1996
Sittampalam GS, Smith WC, Miyakawa TW, Smith DR, McMorris C. Application of experimental design techniques to optimize a competitive ELISA. <i>Journal of Immunological Methods</i> 190:151-161.	1996
Staschke KA, Richardson KK, Mabry TE, Baxter AJ, Scheuring JC, Huffman DM, Smith WC, Richardson FC, Calacino JM. Differential effects of the incorporation of 1-(2-deoxy-2-fluoro-b-D-arabinofuranosyl)-5-iodouracil (FIAU) on the binding of the transcription factors, AP-1 and TFIID, to their cognate target DNA sequences. <i>Nucleic Acids Research</i> 24:4111-4116.	1996
Helvering LM, Richardson KK, Horn DM, Wightman KA, Hall RL, Smith WC, Engelhardt JA, Richardson FC. Expression of TRPM-2 during involution and regeneration of the rat liver. <i>Cancer Letters</i> 71:133-142.	1993
Gatlin CL, Schaberg ES, Jordan WH, Kuyatt BL, Smith WC. Point counting on the MacIntosh: A semi-automatic image analysis. <i>Analytical and Quantitative Cytology and Histology</i> 15(5):345-350.	1993

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Sportsman JR, Smith WC, Winely CL. Practical automation and interpretation of quantitative assays for antibodies to therapeutic proteins: The example of human growth hormone. <i>Clinical Chemistry</i> 35(8):1623-1630.	1989
Davidian M, Carroll RJ, Smith WC. Variance functions and the minimum detectable concentration in assays. <i>Biometrika</i> 75(3):549-56.	1988
Carroll, RJ, Davidian M, Smith WC. Variance functions and the minimum detectable concentration in assays". Chapel Hill (NC): Institute of Statistics Mimeo Series 1701 p 32.	1986
Callaghan JT, Peterson BH, Smith WC, Epinette WW, Ransburg RC. Delayed hypersensitivity to mumps antigen in humans. <i>Clinical Immunology and Immunopathology</i> 26:102-110.	1983
Smith WC, Han CP. Probability of selecting the 'correct' model and determination of sample size in regression. University of Texas at Arlington Department of Mathematics Technical Report 182 p19.	1982
Ross JW, Baker RS, Hooker CS, Johnson IS, Schmidtke JR, Smith WC. 1982. Procedure for detection of potential e. coli peptides (ECPs) in biosynthetic human insulin (BHI), antibodies to ECPs in patients treated with BHI, and measurement of bacterial endotoxins in BHI. In: <i>Hormone Drugs, Proceedings of the FDA-USP Workshop on Drugs and Reference Standards for Insulins, Somatropins, and Thyroid-axis Hormones</i> 127-38.	1982
Baker RS, Ross JW, Schmidtke JR, Smith WC. 1981. Preliminary studies on the immunogenicity and amount of escherichia coli polypeptides in biosynthetic human insulin. <i>Lancet</i> 1139-1142.	1981
Smith WC, Han CP. 1981. Error rate for testing a contrast after a significant F test. <i>Communications in Statistics, Part B</i> , 10(6):545-56.	1981
Ernst N, Fisher M, Smith WC, Gordon T, Rifkind B, Littler AL, Mishkel MA, Williams OD. 1980. The association of plasma high-density lipoprotein cholesterol with dietary intake and alcohol consumption. <i>Circulation</i> 62:41-52.	1980
Sposito, VA, Smith WC, McCormick GG. 1978. Minimizing the sum of absolute deviations". <i>Applied Statistics and Econometrics, Monograph No. 12, Vandenhoeck and Ruprecht</i> p60.	1978
Smith WC, Helms RW. 1977. Assuring data quality at the analysis phase of a large collaborative study. <i>American Statistical Association 1977 Proceedings of the Statistical Computing Section</i> 61-68.	1977
Markley JB, Mattern WD, Smith WC, Koch GG. 1976. Methodological considerations in the design of a statistical data management system for the study of kidney dialysis patients. <i>American Statistical Association 1976 Proceedings of the Statistical Computing Section</i> 218-222.	1976
Sposito VA, Smith WC. 1976. On a sufficient condition and a necessary condition in L_1 estimation. <i>Journal of The Royal Statistical Society, Series C</i> 25(2):154-157.	1976
Smith WC, Han CP. 1975. Integration of bivariate probability density functions over nonrectangular regions. <i>Proceedings of The Computer Science and Statistics Eighth Annual Symposium on the Interface</i> 248-251.	1975

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Professional Affiliations	
Description	Date
American Association of Pharmaceutical Scientists	2000 - Present
American Statistical Association	1968 - Present
Biometrics Society	1981 - 2004
Drug Information Association	1999 - 2000
Phi Kappa Phi	1972
Mu Sigma Rho	1973

Professional Activities	
Description	Date
Lecturer, IUPUI School of Public and Environment Affairs	1981
Program co-chair, Spring Regional ENAR Meetings	1983
Referee, Clinical Chemistry	2000
Referee, Journal of Pharmaceutical and Biomedical Analysis	2000
Referee: ACM '80 Proceedings	1980
Referee, Controlled Clinical Trials: Design and Methods	1979
Referee, The American Statistician	1977 - 1993
Registrar, Midwest Biopharmaceutical Statistics Workshop	1981 - 1982
Session moderator, AAPS Workshop on Bioanalytical Methods Validation for Macromolecules	2000
Session organizer/chair, Midwest Biopharmaceutical Statistics Workshop	1986
Session organizer/chair, Spring Regional ENAR Meetings	1984
Session chair, Spring Regional ENAR Meetings	1980
Session chair, Third Annual SUGI Conference	1978
Session chair, Fourth Annual Symposium on Coordinating Clinical Trials	1977
Session chair, Second Annual SUGI Conference	1977

Awards/Honors	
Description	Date
Journal of Pharmaceutical and Biomedical Analysis outstanding paper award (third place). Cao Y, Smith WC, Bowsher RR.	2001
Joint Statistical Meetings outstanding presentation award (runner-up). Devanarayan V, Smith WC, Carroll RJ. Biopharmaceutical Section, American Statistical Association.	2000
The Meritorious Service Award, Midwest Biopharmaceutical Statistics Workshop	1997

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Task Forces / Committees / Boards	
Description	Date
AAPS Ligand Binding Assay Bioanalytical Focus Group (LBABFG)	2000 - Present
AAPS Workshop on Bioanalytical Methods Validation for Macromolecules Planning Committee	2000
AAPS/LBABFG Bioanalytical Methods Validation (BMV) Committee	2000 - 2003
Biometrics Society ENAR Advisory Board	1983 - 1985
National Heart Lung, and Blood Institute Site Visit Team	1975 - 1978
NIH Technical Merit Review Panel	1978