

Yaning Wang

Office of Clinical Pharmacology, Office of Translational Sciences,
Center for Drug Evaluation and Research, Food and Drug Administration

Yaning.Wang@fda.hhs.gov

(301) 796-1624

Education:

Aug. 1999 - Aug. 2003	Ph.D. in Pharmaceutics, University of Florida, GPA 4.0
Jan. 2002 - May 2003	Master of Statistics, University of Florida, GPA 4.0
Sep. 1996 - July 1999	Master of Education in Biochemistry (Instrument Analysis), Beijing University of Physical Education, China, GPA 3.7/4.0
Sep. 1992 - July 1996	Bachelor of Science in Pharmacy, Peking University Health Science Center (former Beijing Medical University), China, GPA 91/100

Positions held:

Mar. 2007 – Present	Team leader for Pharmacometrics Staff in Office of Clinical Pharmacology, Office of Translational Sciences, Center for Drug Evaluation and Research, Food and Drug Administration
Dec. 2005 – Mar. 2007	Senior Pharmacometrician and Clinical Pharmacologist in Office of Clinical Pharmacology, Office of Translational Sciences, Center for Drug Evaluation and Research, Food and Drug Administration
Sep. 2003 – Dec. 2005	Pharmacometrician and Clinical Pharmacologist in Office of Clinical Pharmacology and Biopharmaceutics, Center for Drug Evaluation and Research, Food and Drug Administration
Jan. 2002 - May 2003	Teaching Assistant in the Department of Pharmaceutics, University of Florida
Oct. 1997 - May 1999	Research Assistant at China Doping Control Center
Oct. 1996 - July 1997	Teaching Assistant for Analytical Chemistry at Beijing University of Physical Education

Honors:

Honors at Food and Drug Administration

November 2007	CDER Team Excellence Award for conduct of innovative quantitative analysis and effective communication of risk to support drug approval and labeling decisions beyond the call of duty
June 2007	CDER Group Recognition Award as a member of the QT Interdisciplinary Review Team for consultative review of protocols and full study reports of Thorough QT and similar studies for all OND review divisions
June 2007	CDER Group Recognition Award as a member of the Panitumumab Review Team for exceptional efforts in multidisciplinary CMA Pilot 1 priority review of a new

	molecular entity BLA for the treatment of metastatic colorectal cancer
November 2006	FDA Outstanding Service Award
November 2005	CDER Team Excellence for exceptional teamwork performance during the review of Tygacil I.V., a new glycycline antibiotic
May 2005	CDER Special Recognition Award for the outstanding pharmacometrics review of Riquent
May 2005	FDA Group Recognition Award for extraordinary multidisciplinary team efforts in developing and applying an exposure-response model for dose recommendation at an End of Phase 2A meeting
December 2004	Outstanding Contributions to Pharmacometrics Review Award

Honors at University of Florida

May 2003	Federico Vilallonga Memorial Award for Excellence in Graduate Studies
April 2003	Winner of oral presentation competition in Research Showcase of the College of Pharmacy at University of Florida
April 2003	Academic Achievement Award from International Center, University of Florida
April 2002	Academic Achievement Award from the College of Pharmacy and International Center, University of Florida
April 2000	Academic Achievement Award from the College of Pharmacy and International Center, University of Florida
Aug. 1999 - Aug. 2003	Alumni Fellowship (\$20,000/year), University of Florida

Honors in China

July 1999	Excellent Thesis Award (MS) from Beijing University of Physical Education
Sep. 1996	Privilege to enter the Graduate School with the General and Subject Graduate Admission Tests waived
July 1996	Excellent Thesis Award (BS) from Beijing Medical University
1992 - 1996	Medical and Pharmaceutical Scholarship from Beijing Medical University

Research experience:

Research experience in Food and Drug Administration

Sep. 2003 - Present	Evaluation of pharmaceutical drug applications (INDs and NDAs) and providing pharmacometric consultation to other reviewers
---------------------	---

Research experience in the Department of Pharmaceutics, University of Florida

Aug. 2000 - Aug. 2003	Preclinical and clinical evaluation of beclomethasone dipropionate using pharmacokinetic and pharmacodynamic modeling and simulation
Aug. 2002 - Dec. 2002	Application of Bayesian method (PKBugs) in population

Feb. 2002 - Mar. 2002	pharmacokinetic analysis in comparison with NONMEM Pharmacokinetic and pharmacodynamic analysis of beclomethasone dipropionate and beclomethasone 17-monopropionate in human subjects with WinNonlin
Jan. 2002 - Mar. 2002	HPLC/MS/MS method development for the measurement of beclomethasone dipropionate and beclomethasone 17-monopropionate in rat tissues and plasma
May 2001 - Aug. 2001	HPLC/MS/MS method development for the measurement of budesonide and its two metabolites in human plasma
July 2000 - Aug. 2000	HPLC/MS/MS method to detect ATI-2000 and ATI-2042 in Beagle dog urine after solid phase extraction
June 2000 - July 2000	The mechanism for the formation of sodium adducts of some glucocorticoids under APCI-MS
May 2000 - July 2000	Spare sampling for the assessment of cortisol suppression
May 2000 - June 2000	Optimization of an HPLC/MS/MS method for the detection of Loteprednol etabonate in human plasma

Research experience in China

Sep. 1997 - May 1999	Comparison of HPLC/MS and HPCE/MS in analyzing Erythropoietin (EPO)
Oct. 1997	9th and 10th International Olympic Committee Reaccreditation
Oct. 1998	Tests of the China Doping Control Center: Qualification and quantification of 9 doping agents in human urine including steroids, stimulants, narcotics and diuretics by GC/MS, HPLC/MS and GC/MS/MS
Sep. 1997 - Oct. 1998	Immune affiliation pretreatment and GC/MS/MS detection of low concentration steroids in human urine
Sep. 1995 - May 1996	Detection of residual organic solvent in pharmaceutical bulk by GC
Sep. 1994 - Sep. 1995	Development of a novel anti-cancer drug: 8-chloro Adenosine

Industry experience

May 2002- Aug. 2002	Summer internship in DMPK department at Aventis Pharmaceuticals, Bridgewater, NJ. Tasks: Data management with SAS and Splus, modeling with WinNonlin and NONMEM and simulation with Pharsight Trial Simulator
---------------------	--

Software proficiency	Pharsight Trial Simulator, NONMEM, WinNonlin, SAS, Splus, WinBUGS, Kinetica and SCIENTIST.
-----------------------------	--

Publications:

The Value Meal: The Effect of Food on Lapatinib Bioavailability, Atiqur Rahman, Richard Pazdur, **Yanling Wang**, Shiew-Mei Huang, and Lawrence L Lesko, Journal of Clinical Oncology (accepted) 2007

Leveraging Prior Quantitative Knowledge to Guide Drug Development Decisions and Regulatory Science Recommendations: Impact of FDA Pharmacometrics During 2004-2006, **Yaning Wang**, Venkatesh A. Bhattaram, Pravin Jadhav, Lawrence L Lesko, Rajanikanth Madabushi, Robert Powell, Wei Qiu, He Sun, Dong S Yim, Jenny J Zheng, Jogarao V.S. Gobburu, Journal of Clinical Pharmacology (accepted) 2007

Concentration-QT Relationships Play a Key Role in the Evaluation of Proarrhythmic Risk During Regulatory Review, Christine E. Garnett, Nhi Beasley, V. Atul Bhattaram, Pravin R. Jadhav, Rajanikanth Madabushi, Norman Stockbridge, Christoffer W. Tornøe, **Yaning Wang**, Hao Zhu, and Jogarao V. Gobburu, Journal of Clinical Pharmacology (accepted) 2007

Derivation of Various NONMEM Estimation Methods, **Yaning Wang**, Journal of Pharmacokinetics and Pharmacodynamics, 34: 575-93, 2007

Impact of Pharmacometric Reviews on New Drug Approval and Labeling Decisions - A Survey of 31 New Drug Applications Submitted Between 2005-2006, Venkatesh A. Bhattaram, Charles Bonapace, Dakshina M. Chilukuri, John Z. Duan, Christine Garnett, PharmD, Jogarao V.S. Gobburu, Seong H. Jang, Leslie Kenna, Lawrence J. Lesko, Rajanikanth Madabushi, Yuxin Men, J. Robert Powell, Wei Qiu, Roshni P. Ramchandani, Christoffer W. Tornøe, **Yaning Wang**, Jenny J. Zheng, Clinical Pharmacology and Therapeutics (2007) 81: 213-221

The Role of SN-38 Exposure, UGT1A1*28 Polymorphism and Baseline Bilirubin Level in Predicting Severe Irinotecan Toxicity, Roshni P. Ramchandani, **Yaning Wang**, Brian P. Booth, Amna Ibrahim, John R. Johnson, Atiqur Rahman, Mehul Mehta, Federico Innocenti, Mark J. Ratain and Jogarao V.S. Gobburu, Journal of Clinical Pharmacology 47: 78-86, 2007

Impact of Pharmacometrics on Drug Approval and Labeling Decisions - A Survey of 42 New Drug Applications, Venkatesh A Bhattaram, Brian P. Booth, Roshni P. Ramchandani, B. Nhi Beasley, **Yaning Wang**, Veneeta Tandon, John Z. Duan, Raman K. Baweja, Patrick J. Marroum, Ramana S. Uppoor, Nam Atiqur Rahman, Chandras G. Sahajwalla, J. Robert Powell, Mehul U. Mehta and Jogarao V.S. Gobburu, The AAPS Journal, 7(3): E503-E512, 2005

Population Pharmacokinetics of the Active Metabolite of Leflunomide in Pediatric Subjects with Polyarticular Course Juvenile Rheumatoid Arthritis, Jun Shi, Steven J. Kovacs, **Yaning Wang**, Thomas M. Ludden and Vijay O. Bhargava. Journal of Pharmacokinetics and Pharmacodynamics, 32(3-4): 419-39, 2005

Brain Permeability of Inhaled Corticosteroids, Vikram Arya, Manish Issar, **Yaning Wang**, James D. Talton, Guenther Hochhaus, Journal of Pharmacy and Pharmacology, 57 (9): 1159-1168, 2005

Mass balance studies, Shashank Rohatagi, **Yaning Wang**, and Domenick Argenti. in "Pharmacokinetics in Drug Development: Clinical Study Design and Analysis (Volume 1)", ed. by P. Bonate and D Howard. AAPS press, pp 100-130 (2004)

Simultaneous quantification of beclomethasone dipropionate and its metabolite, beclomethasone 17-monopropionate in rat plasma and different tissues by liquid chromatography positive electrospray ionization tandem mass spectrometry, **Yaning Wang**, Gunther Hochhaus. Journal of Chromatography B, 2004 Jun 15;805(2):203-10

Pharmacokinetic and pharmacodynamic evaluation of beclomethasone dipropionate, **Yaning Wang**, Doctoral thesis, Department of Pharmaceutics, University of Florida, 2003

Simultaneous quantification of budesonide and its two metabolites, 6b-hydroxybudesonide and 16a-hydroxyprednisolone, in human plasma by liquid chromatography electrospray ionization tandem mass spectrometry. **Y. Wang**, H. Moellmann and G. Hochhaus. Biomedical Chromatography. 17:158-164, 2003

SPE/RIA vs LC/MS for measurement of low levels of budesonide in plasma, H. Dimova, **Y. Wang**, S. Pommery, H. Moellmann, G. Hochhaus. Biomedical Chromatography. 17; 14-20, 2003

Presentations:

QT Analysis and E14, **Yaning Wang**, 2007 AAPS Annual meeting, San Diego, CA, November 2007

Application of Disease Model in Oncology for Survival Prediction, **Yaning Wang**, Office of Clinical Pharmacology Annual Science Day Meeting, Rockville, MD, October 2007

Flexible Statistical Methods for Early Clinical Trials, **Yaning Wang**, representative speaker from FDA, FDA/Industry Statistics Workshop, Sponsored by the ASA Biopharmaceutical Section in cooperation with the FDA Statistical Association, Arlington, VA, September 2007

QT Analysis, **Yaning Wang**, representative speaker from FDA, sponsored by Pharmaceutical Education and Research Institute (PERI), Inc., Development Strategies & Clinical Trial Methods for Oncologic Products Including Clinical Applications for Biomarkers, Arlington, VA, June 2007

Application of Mathematic Disease Model in Oncology for Survival Prediction, **Yaning Wang**, Walter Reed Army Institute of Research, February 22, 2007

Risk Factors of Survival: Meta-Analyses of Non-Small Cell Lung Cancer Trials, **Yaning Wang**, Drug Information Association, Sharing Knowledge to Improve Clinical Drug

Development and Regulatory Decisions: Data/models of Diseases, Drugs, Placebo, Baseline, and Dropouts, Washington, January 2007

Quantitative Methods in Oncology Drug Development--FDA Perspective, **Yaning Wang**, 2006 AAPS Annual meeting, San Antonio, TX, October 2006

Value of Disease Model to Drug Development, **Yaning Wang**, 2006 AAPS Annual meeting PPDM Open Forum, San Antonio, TX, October 2006

Visualization of Differences Among NONMEM Estimation Methods, **Yaning Wang**, 2006 AAPS Annual meeting, San Antonio, TX, October 2006 (Selected as Research Highlight in J. Clin. Pharmacol. 2007; 47; 531)

The Importance of Early Interaction with FDA: EOP2A Experiences, **Yaning Wang**, East Coast Population Analysis Group: Workshop & Conference Tuesday, July 25, 2006

Pharmacometric Submission and Review: Expectation and Practices, **Yaning Wang**, representative speaker from FDA and session chairperson, sponsored by Drug Information Association, EXPOSURE/RESPONSE BEST PRACTICE: Design, Analysis and Review, Philadelphia, December 2005

Case Study: A Quantitative Approach to Assess A Genomic Design and A Biomarker Titration Design for A Phase III Clinical Study, **Yaning Wang**, Clinical Pharmacology Subcommittee Advisory Committee for Pharmaceutical Science, November 14, 2005

Application of Exposure-Response Analysis to Optimize Risk/Benefit Ratio for Combination Therapy, **Yaning Wang**, Office of Clinical Pharmacology and Biopharmaceutics Annual Science Day Meeting, Rockville, MD, October 2005

Application of A Model-Based Analysis to Improve the Drug Development Plan for A Life-Threatening Disease, **Yaning Wang**, Robert Powell, Nhi Beasley, Patrick Marroum and Joga Gobburu, Office of Clinical Pharmacology and Biopharmaceutics Annual Science Day Meeting, Rockville, MD, October 2004

Regulatory Application of Exposure-Response: Impacts of Biomarker Data, **Yaning Wang**, representative speaker from FDA, sponsored by BioScience Forum, a Special Symposium for Application of Biomarkers to the Drug Discovery and Development Process, Millbrae CA, June 2004

Regulatory Guidance: Application of Exposure-Response and How We Review, **Yaning Wang**, representative speaker from FDA and session chairperson, sponsored by Drug Information Association, Pharmacokinetic and Pharmacodynamic Application in the Drug Development Process, Washington DC, March 2004

Simulations using Trial Simulator, Shashank Rohatagi and **Yaning Wang**, pre-

conference short course in 3rd Annual Clinical Trial Simulation in Drug Development, Best practice for creating cost-effective modeling and simulation practice, Washington DC, August 2002

Pharmacokinetic and pharmacodynamic comparison of two inhaler formulations of beclomethasone dipropionate, **Yaning Wang** and Guenther Hochhaus, Winner of oral presentation in Research Showcase of the College of Pharmacy at University of Florida, Spring 2003

Application of an ex vivo receptor binding method in determining the pulmonary targeting of beclomethasone dipropionate in rats, **Yaning Wang** and Guenther Hochhaus, selected for the oral presentation in the Graduate and Professional Student Forum at the University of Florida, Spring 2002

The pulmonary targeting of beclomethasone dipropionate in rats, **Yaning Wang** and Guenther Hochhaus, Finalist of oral presentation in Research Showcase of the College of Pharmacy at University of Florida, Spring 2002

Assessment of matrix effects in quantitative LC/MS/MS: Application to the analysis of inhaled steroids, **Yaning Wang** and Guenther Hochhaus, oral presentation, Graduate Student Seminar Series, College of Pharmacy, Spring 2001

Posters:

Optimization of Benefit/Risk Ratio for Combination Therapy with Exposure-Response Analysis and Clinical Trial Simulation, **Yaning Wang**, 2006 AAPS Annual meeting, San Antonio, TX, October 2006

Visualization of Differences Among NONMEM Estimation Methods, **Yaning Wang**, 2006 AAPS Annual meeting, San Antonio, TX, October 2006

Application of A Model-Based Analysis to Improve the Drug Development Plan for A Life-Threatening Disease, **Yaning Wang**, Robert Powell, Nhi Beasley, Patrick Marroum and Joga Gobburu, 11th Annual FDA Science Forum, Washington DC, April 2005

A Clinical Trial Simulation Approach for Designing Studies Investigating the Similarity in PK-PD Relationships Between Different Patient Populations, N. Seth Berry, **Yaning Wang**, He Sun, and Peter Lee, 10th Annual FDA Science Forum, Washington DC, August 2004

Pharmacokinetic (PK) and pharmacodynamic (PD) comparison of HFA and CFC-beclomethasone dipropionate in asthma control, **Yaning Wang** and Guenther Hochhaus, 4th Retrometabolism Based Drug Design and Targeting Conference, Palm Coast Resort, Florida, May 2003

Pulmonary targeting of beclomethasone dipropionate (BDP) in rats, **Yaning Wang** and Guenther Hochhaus, 2002 AAPS Annual meeting, Toronto, Canada, November 2002

