Marcie Wood, Ph.D.

PRINCIPAL SCIENTIST

SENIOR VICE PRESIDENT, PHARMACEUTICALS

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PROFESSIONAL PROFILE

Dr. Marcie Wood is Senior Vice President and Principal Scientist of ToxStrategies' Pharmaceuticals practice. She is a toxicologist with more than 20 years of experience in drug discovery and development, including seven years at the U.S. Food and Drug Administration (FDA). She has nonclinical experience with biologic, biosimilar, and small-molecule products for a wide variety of pulmonary, allergy, rheumatology, oncology, ophthalmology, neurology, and pain indications, as well as multiple routes of administration (e.g., inhalation, oral, intravenous, subcutaneous, intra-articular, intranasal, and dermal), in developing nonclinical sections (pharmacology, pharmacokinetics, toxicology) of regulatory documents (e.g., preIND, IND, BLA/NDA), and regulatory agency interactions.

In the Center for Drug Evaluation and Research (CDER) at FDA, Dr. Wood served as both pharmacology/toxicology supervisor and reviewer in the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP). As a supervisor, she was responsible for providing leadership and guidance to the Division's team of pharmacology/toxicology reviewers with respect to the evaluation of nonclinical data submitted in pre-Investigational New Drug Applications (INDs), INDs, and New Drug Applications (NDAs)/Biologics License Applications (BLAs), ensuring that the regulatory recommendations of the team were scientifically sound and in line with applicable guidance documents. She also evaluated and presented recommendations on challenging scientific and regulatory issues to CDER senior management, including nonclinical hold deficiencies, complete responses to clinical holds, and other issues with the potential to influence clinical development; represented the Division's nonclinical expertise at internal, industry, and Advisory Committee (AC) meetings; and provided recommendations to the Executive Carcinogenicity Assessment Committee (ECAC) on dose selection for rodent carcinogenicity studies and carcinogenicity study outcomes. Dr. Wood also participated in Pharmacology and Toxicology Coordinating Committee (PTCC) meetings and interacted with other CDER review divisions to address cross-division review issues.

As a reviewer, Dr. Wood was responsible for reviewing nonclinical data packages (i.e., pharmacology, pharmacokinetics, and toxicology) of biologic, biosimilar, and small-molecule products submitted in support of the safety of pulmonary, allergy, and rheumatology indications (e.g., allergic rhinitis, asthma, chronic obstructive pulmonary disease, cystic fibrosis, idiopathic pulmonary fibrosis, rheumatoid arthritis, lupus, etc.). She prepared comprehensive written reports of nonclinical data, including inhalation toxicology data, and provided regulatory conclusions and recommendations for preINDs, INDs, and NDAs/BLAs, including recommendations for approved product labeling. Dr. Wood also worked on multidisciplinary teams, addressed cross-discipline review issues (e.g., excipients, impurities, and leachables and extractables), and participated in meetings with industry representatives to provide regulatory advice and guidance on nonclinical drug development programs.

Dr. Wood spoke at FDA educational courses on nonclinical considerations for the review of inhalation drug products and participated in the Oligonucleotide Subcommittee of the PTCC. Prior to her time at the FDA, Dr. Wood was a research scientist in the areas of neurodegenerative disorders and addiction at the Roskamp Institute, in Sarasota, Florida, for over four years.

EDUCATION AND DEGREES EARNED

2004 Ph.D., Toxicology, University of Kentucky, Lexington, KY

1997 B.S., Molecular Biology, Grove City College, Grove City, PA

SCIENTIFIC ADVISORY PANELS, COMMITTEES, AND WORKGROUPS

2013–2016 FDA Pharmacology and Toxicology Coordinating Committee (PTCC)

2009–2016 FDA Oligonucleotide PTCC Subcommittee

PROFESSIONAL HONORS/AWARDS

2015 CDER Team Excellence Award, Idiopathic Pulmonary Fibrosis Drugs Review Team

2014 FDA Group Recognition Award, IND Toolchest Working Group — Design, development, and implementation of an internet-based navigational tool, enabling submission of investigator-initiated IND applications

2012 CDER Team Excellence Award, Toxicology for Non-Toxicologists Organizing Committee

2012 CDER Team Excellence Award, Kalydeco (Ivacaftor) Review Team

1999 International Behavioral Neuroscience Society Travel Award

1999 Neurobehavioral Teratology Society Travel Award

PROFESSIONAL ASSOCIATIONS

2018–Present Society of Toxicology, member

2016–Present BioSafe General Membership

2015–Present American College of Toxicology, member

PROFESSIONAL EXPERIENCE

Pharmacology/Toxicology Supervisor at US FDA

Provided leadership and guidance to a team of PhD-level reviewers that evaluated nonclinical data submitted in support of the safety of DPARP drug products, including:

- Secondary review of more than 100 IND reviews (small molecules, biologics, and biosimilars) and 20 NDA/sNDA/BLA reviews (including approved NDAs for the inhalation products Striverdi Respimat, Breo Ellipta, Arnuity Ellipta, and Bevespi Aerosphere, as well as Mitigare, Otezla, and Ofev, and approved BLAs for Nucala and Cinqair)
- Secondary review of nonclinical regulatory advice provided for more than 150 meeting requests for small molecules and biologics (Type A, B, and C meetings), as well as biosimilars (Biosimilar Initial Advisory and Type 2, 3, and 4 meetings)

Evaluated and presented recommendations on challenging scientific and regulatory issues to CDER Senior Management, including nonclinical hold deficiencies and complete responses to clinical holds, as well as other nonclinical issues that affected clinical development.

Represented DPARP's nonclinical expertise at internal, industry, and Advisory Committee (AC) meetings.

Wrote, reviewed, and made recommendations for nonclinical sections of AC meeting documents.

Presented at a joint CBER/CDER/CDRH workshop to FDA employees on "Nonclinical Considerations for Inhalation Combination Products".

Invited speaker at the Association for Inhalation Toxicologists — International Society for Aerosols in Medicine Joint 2014 Conference in Princeton, NJ.

Hired and trained new reviewers, supported professional development of established reviewers, and managed a high-volume team workload, with the support of a Senior Team Leader.

Gained familiarity with scientific and regulatory issues relevant to development of drugs for other indications, including oncology, dermatology, gastroenterology, metabolism and endocrine, and neurology drugs, as well as drugs for rare diseases, through attendance at PTCC meetings and interactions with other review divisions within CDER.

Pharmacology/Toxicology Reviewer at US FDA

Reviewed and evaluated a wide range of nonclinical pharmacology and toxicology data (including inhalation toxicology studies) in INDs and NDAs/BLAs, to support development of small molecules, biologics, and biosimilars.

Completed the primary nonclinical NDA review of Kalydeco for cystic fibrosis in an expedited timeframe, as well as the primary nonclinical NDA review of Dymista for allergic rhinitis.

Prepared comprehensive written reports of nonclinical data, which included regulatory conclusions and recommendations to be conveyed to Sponsors, including recommendations for approved drug product labeling (e.g., Daliresp, Dymista, and Kalydeco).

Worked in multidisciplinary teams for drug product review and addressed cross-discipline issues (e.g., excipients, impurities, and leachables and extractables with Chemistry and Manufacturing Control colleagues).

Met with industry representatives in formal meeting settings to provide regulatory advice and guidance on nonclinical drug development programs.

Mentored and supported junior reviewers on nonclinical scientific and regulatory aspects of drug development.

Taught at a CDER course for non-toxicologist FDA employees on “Inhalation Toxicology”.

Served as Acting Team Leader and Acting Supervisory Interdisciplinary Scientist to support continuity of Division operation.

Research

Co-investigator for research programs for traumatic brain injury (TBI) and drug addiction, with the goal of identifying potential molecular targets for therapeutic intervention.

Designed, planned (coordinated study schedules and staff), and conducted *in vitro* and *in vivo* studies, and analyzed and summarized study data (molecular biology, genomic, proteomic, behavioral, pharmacokinetic).

Trained and supervised junior research staff.

BOOK CHAPTERS

Kimzey A, Mease K, Mounho-Zamora B, **Wood M**. 2021. 13. Biosimilar products—A review of past and current regulatory approval standards for preclinical safety studies. In: Translational Medicine: Optimising Preclinical Safety Evaluation of Biopharmaceuticals. CRC Press: Boca Raton, FL.

Kimzey AL, Piche M-S, **Wood M**, Weir AB, Lansita J. 2018. 11.19 — Immunophenotyping in drug development. In: Comprehensive Toxicology, 3rd Ed. Vol. 11, pp. 399–427.

MANUSCRIPTS

Jackson JW, Frederick C Streich Jr, Pal A, Coricor G, Boston C, …, **Wood M**, et al. 2024. An antibody that inhibits TGF-β1 release from latent extracellular matrix complexes attenuates the progression of renal fibrosis. Sci Signal 17(844):eadn6052; doi: 10.1126/scisignal.adn6052.

Kayihan GC, **Wood M**, Mouzon B, Ferguson S, Margenthaler E, Mathura V, Mullan M, Crawford F. 2010. Gulf war agents trigger discrete transcriptional changes in human neuronal cells. Toxicol Environ Chem 92:1783–1799.

Ferguson S, Mouzon B, Kayihan G, **Wood M**, Poon F, Doore S, Mathura V, Humphrey J, O-Steen B, Hayes R, Roses A, Mullan M, Crawford F. 2010. Apolipoprotein E genotype and oxidative stress response to traumatic brain injury. Neuroscience 168:811–819.

Crawford F, **Wood M**, Ferguson S, Mathura V, Gupta P, Humphrey J, Mouzon B, Laporte V, Margenthaler E, O’Steen B, Hayes R, Roses A, Mullan M. 2009. Apolipoprotein E-genotype dependent hippocampal and cortical responses to traumatic brain injury. Neuroscience 159:1349–1362.

Abdullah L, Luis C, Paris D, Ait-Ghezala G, Mouzon B, Allen E, Parrish J, Mullan MA, Ferguson S, **Wood M**, Breitner JC, Crawford F, Mullan MJ. 2009. High serum A-beta levels and vascular risk factors in first-degree relatives of Alzheimer’s disease cases. Molec Med 15:95–100.

Laporte V, Ait-Ghezala G, Volmar CH, Ganey C, Ganey N, **Wood M**, Mullan M. 2008. CD40 ligation mediates plaque-associated tau phosphorylation in β-amyloid overproducing mice. Brain Res 1231:132–142.

Crawford F, **Wood M**, Ferguson S, Mathura V, Faza B, Wilson S, Fan T, O’Steen B, Ait-Ghezala G, Hayes R, Mullan M. 2007. Genomic analysis of response to traumatic brain injury in a mouse model of Alzheimer’s disease (APPsw). Brain Res 1185:45–58.

Crawford FC, **Wood ML**, Wilson SE, Mathura VS, Hollen TR, Geall F, Kolippakkam DN, Mullan MJ. 2006. Cocaine induced inflammatory response in human neuronal progenitor cells. J Neurochem 97:662–674.

Wood M, Ananthanarayanan M, Jones B, Wooten-Kee R, Hoffman T, Suchy FJ, Vore M. 2005. Hormonal regulation of hepatic organic anion transporting polypeptides. Molec Pharmacol 68:218–225.

Cao J, **Wood M**, Liu Y, Hoffman T, Hyde J, Park-Sarge OK, Vore M. 2004. Estradiol represses prolactin-induced expression of Na+/taurocholate cotransporting polypeptide in liver cells through estrogen receptor-{alpha} and Stat5a. Endocrinol 145:1739–1749.

Mottino AD, Veggi LM, **Wood M**, Velez Roman JM, Vore M. 2003. Biliary secretion of glutathione in estradiol 17β-D-glucuronide-induced cholestasis. J Pharmacol Experiment Therapeut 307:306–313.

Cao J, Gowri PM, Ganguly TC, **Wood M**, Hyde JF, Talamantes F, Vore M. 2001. PRL, placental lactogen, and GH induce Na+/taurocholate-cotransporting polypeptide gene expression by activating signal transducer and activator of transcription-5 in liver cells. Endocrinol 142:4212–4222.

Booze RM, Welch MA, **Wood ML**, Billings KA, Apple SR, Mactutus CF. 1999. Behavioral sensitization following repeated intravenous nicotine administration: Gender differences and gonadal hormones. Pharmacol Biochem Behav 64:827–839.

Booze RM, **Wood ML**, Welch MA, Berry S, Mactutus CF. 1999. Estrous cyclicity and behavioral sensitization in female rats following repeated intravenous cocaine administration. Pharmacol Biochem Behav 64:605–610.

CONFERENCE AND MEETING PRESENTATIONS

Oral Presentations

Wood M, Mease K, Lueth J. Study monitoring: Expert approaches for a successful nonclinical program. Exhibitor-Hosted Session, Society of Toxicology 64th Annual Meeting, Orlando, FL, March 2025.

Mihalchik AL, Choksi NY, Lea I, **Wood ML**. Modern strategies to evaluate drug impurities. Session presented at Society of Toxicology 62nd Annual Meeting, Nashville, TN, March 2023.

Fryzek J, Bylsma L, Mease K, Movva N, Welsh BT, **Wood M**. Nonclinical toxicology and real-world epidemiology essential for a successful rare disease product launch. Presentation at World Orphan Drug Congress. Virtual Conference, August 2020.

Welsh B, **Wood M,** Lansita J. Exhibitor Session: Strategies for successful pre-IND and IND submissions. Society of Toxicology 57th Annual Meeting, San Antonio, TX, 2018.

Wood, M. Review of marketed inhaled biologics. The 32nd Annual Meeting of the British Society of Toxicological Pathology (BSTP), Knutsford, Cheshire, UK, 2017.

Wood, M. Regulatory perspective on inhaled biotherapeutics. Charles River 23rd Annual Biotech Symposium, Carlsbad, CA, 2017.

Wood, M. Determination of adversity in inhalation toxicology studies: US regulatory perspective. The 31st Annual Meeting of the British Society of Toxicological Pathology (BSTP) – Association of Inhalation Toxicologists Joint Conference, Alderley Edge, Cheshire, UK, 2016.

Wood, M. FDA, CBER/CDER/CDRH: Combination products: A cross-center workshop. Nonclinical considerations for inhalation combination products, 2015.

Wood M. Toxicology study designs and considerations to support first in human trials: The regulatory perspective. Association of Inhalation Toxicologists — International Society for Aerosols in Medicine Joint Conference, Princeton, NJ, 2014.

Wood M. Inhalation toxicology. FDA, CDER: Toxicology for non-toxicologists continuing education course, 2011.

Wood M. Estrus cyclicity and behavioral sensitization in female rats following repeated intravenous cocaine administration. Satellite Symposium of the 8th Annual Meeting of the International Behavioral Neuroscience Society, Nancy, France, 1999.

Poster Presentations

Mihalchik AL, Choksi NY, **Wood ML**. Toward best practices for read-across in evaluation of drug impurities, extractable, and leachable compounds. Poster presented at Society of Toxicology 62nd Annual Meeting, Nashville, TN, March 2023.

Mihalchik A, **Wood M**. Considerations for standardization and derivation of pediatric and neonatal tolerable exposure limits for extractable and leachable compounds from medical devices. Society of Toxicology 61st Annual Meeting, San Diego, CA, March 2022.

Kimzey A, Welsh B, **Wood M**. Case studies demonstrating the process and challenges of deriving exposure-based limits for impurities in pharmaceutical drug products administered directly to the CNS. American College of Toxicology, Virtual Annual Meeting, 2021.

Kimzey AL, Welsh BT, Chesney AR, Fonck C, O'Neill C, **Wood ML.** Derivation of a health-based exposure limit for cesium using non-clinical and clinical data. American College of Toxicology, Virtual Annual Meeting, 2020.

Wood M, Mouzon B, Reed J, Ferguson S, Mathura V, Roses A, Mullan MJ, Crawford F. Identification of novel therapeutic targets for traumatic brain injury by proteomic analysis of response to injury in ApoE3 and ApoE4 transgenic mice. 26th Army Science Conference, Orlando, FL, 2008.

Wood ML, Mathura V, Laporte V, Humphrey J, Poon F, Mouzon B, Ferguson S, Margenthaler E, Gupta P, Brewster K, O' Steen B, Hayes R, Roses A, Mullan MJ, Crawford F. Genomic variations in the inflammatory response of APOE transgenic mice following traumatic brain injury. Society for Neuroscience Annual Meeting, Washington, DC, 2008.

Wood ML, Ferguson S, Mathura V, Humphrey J, Mouzon B, O'Steen B, Hayes R, Mullan M, Crawford F. Genomic response of apoe transgenic mice to traumatic brain injury. Society for Neuroscience Annual Meeting, San Diego, CA, 2007

Wood ML, Ait-Ghezala G, Wilson SE, Berhane B, Mullan MJ, Crawford FC. Characterization of a chromosome 8 gene disrupted by translocations in Tourette Syndrome patients from two unrelated families. Society for Neuroscience Annual Meeting, Washington, DC, 2005.

Wood M, Ananthanarayanan M, Suchy F, Vore M. Regulation of organic anion transporting polypeptides by prolactin and growth hormone. American Association for the Study of Liver Diseases (AASLD) 55th Annual Meeting, Boston, MA, 2004.

Wood M, Vore M. Regulation of sodium taurocholate cotransporting protein (ntcp) by prolactin (PRL) and growth hormone (GH) in young rat hepatocytes. AASLD 54th Annual Meeting, Boston, MA, 2003.

Wood M, Vore M. Prolactin and growth hormone activation of signal transducer and activator of transcription-5b in primary cultures of young rat hepatocytes. Gordon Research Conference on Prolactin, Ventura, CA, 2002.

Wood ML, Hauser KF, Booze RM, Welch MA, Strupp BJ, Mactutus CF. Prenatal intravenous cocaine alters Purkinje cell development in neonatal rats. Society for Neuroscience Annual Meeting, Miami Beach, FL, 1999.

Wood ML, Booze RM, Lehner AF, Tobin T, Mactutus CF. Brain levels of cocaine and metabolites in rat fetuses, as a function of uterine position, after maternal IV administration. Neurobehavioral Teratology Society/Teratology Society Meeting, Keystone, CO, 1999.

Wood ML, Mactutus CF, Welch MA, Berry S, Booze RM. The dopamine transporter and dopamine receptor subtypes in female rats following repeated daily IV cocaine administration. Society for Neuroscience Annual Meeting, Los Angeles, CA, 1998.