

GARY W. WOLFE, Ph.D., DABT

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EXPERIENCE

August 2010-Present *Gary Wolfe Toxicology, LLC., Herndon, VA*
Principal Toxicologist

As a Principal Toxicologist, drug development plans for potential new pharmaceuticals primarily for FDA approval. Provides complete toxicology study designs to support drug development plans. Conduct study monitoring, planning, support, auditing, regulatory support including data interpretation and presentation. Preparation of IND, CTD, NDA, and pre-IND submissions for the FDA are also written. Position papers on specific topics are also prepared for client to support needs of the FDA. Also assist clients in identifying experts in the field to address specific issues.

Nov. 2008-Present *Aclairo Pharmaceutical Development Group, Inc., Vienna, VA*
Senior Consultant, Director of Scientific Writing

As a Senior Consultant, provide preclinical advice on scientific and regulatory issues in drug development, due diligence, and strategic planning for drug development. Provides complete toxicology plans, study monitoring planning and support, regulatory support including data interpretation and presentation, as well as preparation of IND, CTD, NDA, and pre-IND submissions for the FDA. Expert in planning, writing, and using position papers to forward client needs at the FDA.

As the Director of Scientific Writing, manage research/regulatory associates, consultants, and research fellows in the preparation of the nonclinical portion of regulatory submissions, scientific position papers, and management and monitoring of nonclinical studies placed at contract laboratories. Hires, trains, and mentors staff in writing of documents, monitoring of studies, and in their professional development.

Nov. 2005-Nov. 2008 *Summit Drug Development Services, LLC, Rockville, MD*
Vice President, Preclinical Services

As Vice President, served as the principal contact for and managed all aspects of the nonclinical drug development projects for Summit. Involved with implementing drug development strategies and plans, vendor selection and management, reviewing and authoring the pharmacology and toxicology

sections of regulatory documents, and preparation of scientific reports and other documents as needed.

Apr. 2003-Nov. 2005 ***Gene Logic Laboratories, Inc., Gaithersburg, MD***
(formerly TherImmune Research Corporation)
Vice President, Toxicology Services

As Vice President, was responsible for assurance of scientific integrity, contract compliance, communication with the client, new business development, effective management of resources, and the assurance of profitability. Supervised 10 toxicologists in the conduct of nonclinical toxicology studies, was Study Director of selected toxicology programs and the Principal Investigator for the NIEHS Reproductive Toxicity Test Systems Program.

Jan. 1999-Apr.2003 ***TherImmune Research Corporation, Gaithersburg, MD***
(formerly R.O.W. Labs)
Senior Vice President and Chief Scientific Officer

As Senior Vice President and Chief Scientific Officer, was responsible for assurance of scientific integrity, contract compliance, communication with the client, new business development, effective management of resources, and the assurance of profitability. Supervised 10 toxicologists in the conduct of preclinical toxicology studies, was Study Director of selected toxicology programs and the Principal Investigator for the NIEHS Reproductive Toxicity Test Systems Program. Also responsible for direct supervision of approximately 20 toxicology scientific staff (pathology, clinical pathology, report writing, veterinary medicine, and health and safety) as well as for all animal facility operations including compliance with FDA and USDA regulations and AAALAC International accreditation.

1993-1998 ***R.O.W. Sciences, Inc., Gaithersburg, MD***
Division Director of Toxicology

As Division Director, was responsible for all phases of toxicology studies conducted by R.O.W. Sciences in the company's Gaithersburg, Maryland laboratory (R.O.W. Labs). Served as Principal Investigator and/or Study Director for NIEHS Reproductive Toxicity Test Systems Program as well for other government and commercial toxicology studies. Responsibilities included preparation of protocols and amendments, interpretation of data, review and approval of all study and project reports, and directing, coordinating and monitoring all staff efforts in the laboratory. Other responsibilities included coordinating and monitoring the activities of off-site subcontractors, responding to Quality Assurance audits, overseeing and monitoring all phases of the study, and ensuring that the staff was properly trained. Direct supervision of approximately 10 toxicology scientific staff (pathology, clinical pathology, report writing, veterinary medicine, and health and safety) and for all animal facility operations including compliance with FDA and USDA regulations and AAALAC International accreditation.

1988.1993 ***Hazleton Washington, Inc., Vienna, VA***
Associate Director, Department of Toxicology

GLP Study Director for numerous clients conducting nonclinical programs in multiple species in the support of INDs and NDAs. Responsibilities included preparation of protocols and amendments, interpretation of data, review and approval of all study and project reports, and directing, coordinating,

and monitoring all staff efforts in the laboratory. Supervised the technical and administrative operations of the Scientific Resources Unit within the Department of Toxicology. Supervised approximately 30 professional and 10 clerical/support staff in the preparation of all reports for toxicology studies conducted at the Vienna, VA, and Rockville, MD facilities of Hazleton.

1985.1988

Hazleton Laboratories America, Inc., Rockville, MD

Director, Department of Toxicology and Experimental Carcinogenicity

GLP Study Director for numerous clients conducting nonclinical programs in multiple species in the support of INDs and NDAs. Served as the Principal Investigator on several toxicology programs for the National Toxicology Program, Department of the Army, and the Denver Water Department. Responsibilities included preparation of protocols and amendments, interpretation of data, review and approval of all study and project reports, and directing, coordinating, and monitoring all staff efforts in the laboratory. Responsible for technical and administrative matters in the conduct of toxicology studies as well as several NIH basic research programs. Served as the Site Coordinator for the Rockville operation, an 88,000 square foot laboratory, of Hazleton Laboratories.

1981.1985

Hazleton Laboratories America, Inc., Vienna, VA

Senior Staff Scientist

GLP Study Director for numerous clients conducting nonclinical programs in multiple species in the support of INDs and NDAs. Responsibilities included preparation of protocols and amendments, interpretation of data, review and approval of all study and project reports, and directing, coordinating, and monitoring all staff efforts in the laboratory. Laboratory Supervisor of Chronic Rodent Toxicology III Section which involved the supervision of approximately 20 technicians in the conduct of approximately 25 chronic and 15 subchronic studies.

1978-1981

Hazleton Laboratories America, Inc.

Staff Scientist

GLP Study Director for numerous clients conducting nonclinical studies in multiple species in the support of INDs and NDAs. Responsibilities included preparation of protocols and amendments, interpretation of data, review and approval of all study and project reports, and directing, coordinating, and monitoring all staff efforts in the laboratory. Laboratory Supervisor of the Acute Toxicology Section, which involved the supervision of approximately 5 technicians in the conduct of numerous acute and teratology studies.

EDUCATION

- 1974 B.A., Biology, Thiel College
- 1976 M.S., Pharmacology and Toxicology, Purdue University
- 1978 Ph.D., Pharmacology and Toxicology, Purdue University

PUBLICATIONS

Wolfe, G.W., Bousquet, W.F., and Schnell, R.C.: Circadian variations in response to amphetamine and chlorpromazine in the rat. *Communications in Psychopharmacology*, 1, 29-37, 1977.

Wolfe, G.W. and Schnell, R.C.: Annual differences in daily variations in hepatic drug metabolizing enzyme activity and plasma hormone levels in the rat. *Pharmacology*, 19, 116-120, 1979.

Wolfe, G.W. and Schnell, R.C.: Influence of hormonal factors on daily variations in hepatic drug metabolism in male rats. *J Interdiscipl Cycle Res* 10, 173-183, 1979.

Wolfe, G.W. and Schnell, R.C.: Influence of hormonal factors on daily variations in hepatic drug metabolism in male rats. *J Interdiscipl Cycle Res* 10, 173-183, 1979.

Steinberg, M., Wolfe, G.W., and McCreesh, A.H.: Correlating the inflammatory response between animal and human skin. *J Toxicol, Cut Ocular Toxicol*, 1(1), 33-48, 1982.

Wolfe, G.W. and Steinberg, M.: Rationale for TLV's, selected nuisance dusts: are short-term tests predictive? *J Appl Toxicol*, 8(6). 381-382, 1988.

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Matsuzawa, T., Saito, T., Imamura, K., Yoshida, T., Okamiya, H., Hanada, T., Nii, A., Ozaki, H., Kanai, K., Sakai, T., Trutter, J.A., Wolfe, G.W.: Acute, subacute and chronic toxicity studies of Emonapride (YM-09151), *The Clinical Report*, 23(13), 7-22, 1989.

Wolfe, G.W., Nishida, N., Mayahara, H.: Twenty-six-week dietary toxicity study in rats with Manidipine Hydrochloride [CV-4093(2HCl)], *Jpn Pharmacol Ther*, 17(S4), June 1989.

Wolfe, G.W., Chikaato, M., Mayahara, H.: Twenty-six-week oral toxicity study in dogs with Manidipine Hydrochloride [CV-4093(2HCl)], *Jpn Pharmacol Ther*, 17(S4), June 1989.

Lauer, W. C., Johns, F. J., Wolfe, G. W., Myers, B. A., Condie, L. W., and Borzelleca, J. F., Comprehensive Health Effects Testing Program for Denver's Potable Reuse Demonstration Project. *J Toxicol Environ Health*, 30, 305-321, 1990.

Chapin, R.E., Delaney, J.C., Kaiser, L.B., Wang, Y., Lanning, L.L., Davis, B., Collins, B., and Wolfe, G.W. The Effects of 4-Nonylphenol in Rats: a Multigenerational Reproduction Study. *Toxicol Sci*, 52(1), 80-91, 1998.

Nehrebechjy, L., Wang, Y., Quance, J., Kariya, J., Wolfe, G.W., and Bishop, J. Craniofacial

Malformations Observed in F₁ Pups of Sprague-Dawley (SD) Rats Administered Propylthiouracil (PTU) in Drinking Water. *Teratology*, 63(6), 257, 2001.

Witt, K.L., Tice, R.R., Wolfe, G.W., and Bishop, J. B. Genetic damage detected in CD-1 mouse pups exposed perinatally to 3'-azido-3'-deoxythymidine or dideoxyinosine via maternal dosing, nursing, and direct gavage: II. Effects of the individual agents compared to combination treatment. *Environ Mol Mut* 44(4), 321-8, 2004.

Bishop, J.B., Witt, K. L., Tice, R.R., and Wolfe, G.W. Genetic damage detected in CD-1 mouse pups exposed perinatally to 3'-azido-3'-deoxythymidine and dideoxyinosine via maternal dosing, nursing, and direct gavage. *Environ Mol Mut*, 43(1), 3-9, 2004.

Levin, E.D., Brunssen, S., Wolfe, G.W., and Harry, G.J. Neurobehavioral assessment of mice after developmental AZT exposure. *Neurotoxicol Teratol*, 26(1), 65-71, 2004.

Blystone, C.R., Kissling, G.E., Bishop, J.B., Chapin, R.E., Wolfe, G.W., and Foster, P.M.D. Determination of the Di-(2-Ethylhexyl)Phthalate NOAEL for Reproductive Development in the Rat: Importance of the Retention of Extra Animals to Adulthood. *Toxicol Sci*, 116(2), 640-646, 2010.

BOOK CHAPTERS

Lauer, W., Wolfe, G., and Condie, L., Health Effects on Recycled Drinking Water from Secondary Wastewater. In: Yang, R.S.H., ed., *Toxicology of Chemical Mixtures: From Real Life Examples to Mechanisms of Toxicologic Interactions*. Orlando, Florida: Academic Press, Inc., 63-82, 1994.

Wolfe, G. Preclinical Safety Study Design Templates and Estimated Costs. In: Cavagnaro, Joy A., ed., *Preclinical Safety Evaluation of Biopharmaceuticals*. Hoboken, New Jersey: John Wiley & Sons, Inc., 851-912, 2008.

PRESENTATIONS

Wolfe, G.W.: Temporal variations in hepatic drug metabolism in the rat. *The Pharmacologist*, 20, 275, 1978.

Wolfe, G.W. and Schnell, R.C.: Influence of hormonal factors on daily variations in hepatic drug metabolism in male rats. *J Interdiscipl Cycle Res* 10, 173-183, 1979.

Steinberg, M., Wolfe, G.W., and McCreesh, A.H.: Correlating the inflammatory response between animal and human skin. *J Toxicol, Cut Ocular Toxicol*, 1(1), 33-48, 1982.

Wolfe, G.W. and Steinberg, M.: Rationale for TLV's, selected nuisance dusts: are short-term tests predictive? *J Appl Toxicol*, 8(6), 381-382, 1988.

Wolfe, G.W., Rodwin, M., French, J.E., and Parker, G.A.: Thirteen-week subchronic toxicity study of Crotonaldehyde in F344 rats and B6C3F₁ mice. *The Toxicologist*, 7(1), 209, 1987.

Wolfe, G.W., Rodwin, M., French, J.W., and Parker, G.A.: Thirteen-week subchronic toxicity study of Butyraldehyde in F344 rats and B6C3F₁ mice. *The Toxicologist*, 7(1), 209, 1987.

Walker, R., Seefeld, M., and Wolfe, G.: Acute and subacute toxicity of the anti-convulsant CI-953. *The Toxicologist*, 8(1), 84, 1988.

Sonowane, B., Rubenstein, R., Bathija, A., De Rosa, C., Wolfe, G., and Albert, E.N.: Subchronic toxicity studies in rats with *m*- and *p*-Xylenes. *The Toxicologist*, 8(1), 210, 1988.

Myers, B., Billups, L., Irwin, R., Burka, L., and Wolfe, G.: Prechronic (14-Day) toxicity of Methylene Bis (thiocyanate) orally administered to Fischer 344 rats and B6C3F₁ mice. *The Toxicologist*, 9(1), 223, 1989.

Terrill, J.B., Robinson, M., Wolfe, G.W., Billups, L.H.: Subacute and subchronic oral toxicity of *p*-Chlorotoluene in the rat. *The Toxicologist*, 10(1), 60, 1990.

Czeh, E., Myers, B., Ulland B., Irwin, R., Burka, L., Wolfe, G.: Subchronic toxicity of Methylene bis (thiocyanate) orally administered to B6C3F₁ mice. *The Toxicologist*, 10(1), 174, 1990.

Myers, B., Cardy, R., Irwin, R., Burka, L., Wolfe, G.: Subchronic toxicity of Methylene bis (thiocyanate) orally administered to F344 rats. *The Toxicologist*, 10(1), 174, 1990.

Wolfe, G., Myers, B., Lemen, J., Lauer, W., Johns, F., Condie, L., Borzelleca, J.: Preliminary report of findings of a health effects for Denver's potable reuse demonstration project. *The Toxicologist*, 10(1), 176, 1990.

Billups, L.H., Terrill, J.B., Wolfe, G.W., Robinson, M.: Subchronic oral toxicity of 1,3-Dichloropropane in the rat. *The Toxicologist*, 10(1), 297, 1990.

Lauer, W. C., Johns, F. J., Wolfe, G. W., Myers, B. A., Condie, L. W., and Borzelleca, J. F., Comprehensive Health Effects Testing Program for Denver's Potable Reuse Demonstration Project. *J Toxicol Environ Health*, 30, 305-321, 1990.

Terrill, J.B., Robinson, M., Wolfe, G.W., and Billups, L.H., Subacute and Subchronic Oral Toxicity of *p*-Chlorotoluene in the Rat. *J Am Coll Toxicol* 9(5), 487-495, 1991.

Bercz, J.P., Robinson, M., Jones, L., Page, N.P., Parnell, M.J., and Wolfe, G.W., Subacute Toxicity Studies of 2,4,6-Trichlorophenol in Sprague-Dawley Rats. *J Am Coll Toxicol* 9(5), 497-506, 1991.

Wolfe, G.W., Quander, R., Kiorpes, A., Hall, B., Palmer, T., and Ball, D., Subchronic Toxicity Studies of Aditoprim in Beagle Dogs. *The Toxicologist*, 13(1), 313, 1993.

Delaney, J.C., Wolfe, G.W., Jamieson, H.M., and Chapin, R.E.: Reproductive Effects of Ethoxyquin in S-D rats assessed by a continuous breeding protocol. *The Toxicologist*, 15(1), 165, 1995.

Jamieson, H.M., Delaney, J.D., Wolfe, G.W., and Chapin, R.E.: Reproductive Effects of Dicyclopentadiene S-D rats assessed by a continuous breeding protocol. *The Toxicologist*, 15(1), 166, 1995.

Wolfe, G.W., Delaney, J.C., Lanning, L.L., and Chapin, R.E.: Reproductive Effects of Thiophenol in S-D rats assessed by a continuous breeding protocol. *The Toxicologist*, 30(1), 119, 1996.

Delaney, J.D., Wolfe, G.W., Lanning, L.L., and Chapin, R.E.: Reproductive Effects of Caffeine S-D rats assessed by a continuous breeding protocol. *The Toxicologist*, 30(1), 121, 1996.

Kaiser, L.B., Wolfe, G.W., Lanning, L., Chapin, R., Klinefelter, G., and Hunter, E.S.: Short term reproductive and developmental effects of sodium bromate in S-D rats when administered in the drinking water. *The Toxicologist*, 30(1), 121, 1996.

Delaney, J.C., Wolfe, G.W., Kaiser, L., Lanning, L., Klinefelter, G., Hunter, E.S., and Chapin, R.E.: Short term reproductive and developmental effects of chlorodibromomethane in S-D rats when administered in the drinking water. *The Toxicologist*, 36(1), 257, 1997.

Kaiser, L.B., Wolfe, G.W., Lanning, L., Klinefelter, G., Hunter, E.S., and Chapin, R.E.: Short term reproductive and developmental effects of dibromacetonitrile in S-D rats when administered in the drinking water. *The Toxicologist*, 36(1), 257, 1997.

Kaiser, L.B., Wolfe G.W., Lanning, L.L., Klinefelter, G., Hunter, E.S., and Chapin, R.E. Short Term Reproductive and Developmental Effects of Bromoacetonitrile and Hexachloroacetone in the S-D Rat when Administered in the Drinking Water. *The Toxicologist*, 42(1S), 100, 1998.

Wolfe G.W., Mowry, R.M., Lanning, L.L., Kaiser, L.B., and Chapin, R.E. Reproductive Effects of Elmiron in S-D Rats Assessed by the Continuous Breeding Protocol. *The Toxicologist*, 42(1S), 101, 1998.

Delaney, J.C., Wolfe, G., W., Lanning, L.L., and Chapin, R. E. Reproductive Effects of Methacrylonitrile in S-D Rats Assessed by the Continuous Breeding Protocol. *The Toxicologist*, 42(1S), 100, 1998.

Chapin, R.E., Davis, B.J., Delaney, J.C., Kaiser, L.B., Wang, Y., Lanning, L.L., and Wolfe, G.W. Multigenerational Study of 4-Nonylphenol in Rats. *The Toxicologist*, 42(1S), 100, 1998.

Layton, K.A., Wolfe, G.W., Wang, Y., Bishop, J., and Chapin, R.E. Reproductive Effects of Isoeugenol in Sprague-Dawley Rats When Assessed by the Continuous Breeding Protocol. *The Toxicologist*, 60(1), 384-385, 2001.

Wolfe, G.W., Pepperl, S.G., Wang, Y., Bishop, J., and Chapin, R.E. Sodium Bromate: Reproductive Assessment by Continuous Breeding When Administered to Sprague-Dawley Rats in the Drinking Water. *The Toxicologist*, 60, 385, 2001.

Patel, R., Wolfe, G.W., Rousell, S., Cherian, G., Ko, K., Moore, R.W., Bishop, J., and Chapin, R.E. Reproductive Effects of Dibutylphthalate in Sprague-Dawley Rats When Assessed in a Multigenerational Study. *The Toxicologist*, 60, 385, 2001.

Nehrebechjy, L., Wang, Y., Quance, J., Kariya, J., Wolfe, G.W., and Bishop, J. Craniofacial Malformations Observed in F₁ Pups of Sprague-Dawley (SD) Rats Administered Propylthiouracil (PTU) in Drinking Water. *Teratology*, 63(6), 257, 2001.

Muir, B., Bishop, J., Murphy, L., Pepperl, S., and Wolfe, G. Multigenerational Reproductive Assessment of AZT/3TC Administered to CD-1[®] Mice by Gavage. *The Toxicologist*, 90(1), 1245, 2006.

Wang, Y., Miller, P., Bassett, B., Manetz, S., Wolfe, G., and Purmal, A. Carcinogenicity Variation of p-Cresidine While Used as a Positive Control Chemical in the P53 Mouse Short-Term Carcinogenicity Test. *The Toxicologist*, 90(1), 2091, 2006.

Foster, P.M., Bishop, J., Chapin, R.E., Kissling, G.E., And Wolfe, G.W. Determination of the Di-(2-Ethylhexyl)phthalate (DEHP) NOAEL for Reproductive Development In the Rat: Importance of Retention of Extra F₁ Animals. *The Toxicologist*, 90(1), 2101, 2006.

PROFESSIONAL AFFILIATIONS

American Board of Toxicology (DABT)

Diplomate 1981

Recertified 1984, 1987, 1990, 1993, 1996, 1999, 2002, 2005, 2008

Society of Toxicology (SOT)

Full Member 1981-Present

Teratology Society

Full Member 2000-Present

National Capital Area Chapter, SOT

Full Member 1985-Present

American College of Toxicology (ACT)

Full Member 1981-Present