



Curriculum Vitae

David J. Pepperl, Ph.D.
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Senior Consultant
Biologics Consulting Group, Inc.
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EXPERIENCE

Biologics Consulting Group, Inc., Senior Consultant

Montgomery Village, MD (Jan. 2004 to present)

- Design preclinical pharmacology and toxicology study protocols and nonclinical programs
- Develop and review strategic product development programs
- Identify, qualify and audit nonclinical toxicology contract research organizations (CROs)
- Source and manage preclinical pharmacology, pharmacokinetic and toxicology studies
- Serve as project or program manager, maintain timelines, budgets and milestones
- Facilitate communication and liaison between sponsor and nonclinical CROs
- Perform on-site study monitoring for pharmacology and toxicology studies
- Identify and develop efficacy models, source and manage pharmacology studies
- Prepare and review nonclinical regulatory documents including IND, Pre-IND and CTD submissions
- Review and revise nonclinical study reports for regulatory submissions
- Author, review and revise position papers, scientific manuscripts and technical reports

TherImmune Research Corporation, A subsidiary of Gene Logic, Inc. *Manager, Preclinical Development*, Drug Development Division

Gaithersburg, MD (Dec. 2000 - Dec. 2003).

- Served as Toxicologist and Project Manager for Preclinical development programs
- Managed preclinical drug and biologic development programs at TherImmune
- Provided nonclinical regulatory support and authored preclinical IND and pre-IND sections
- Developed Strategic Development plans for drug and biopharmaceutical products
- Identified, qualified and managed nonclinical pharmacology and toxicology laboratories
- Outsourced and managed nonclinical safety studies at outside contract service providers
- Served as on-site study monitor for client's crucial IND-enabling GLP toxicology studies
- Designed nonclinical pharmacology and toxicology studies
- Prepared and reviewed nonclinical study reports, position papers, scientific manuscripts and/or technical reports

SRA Life Sciences, *Manager of Pharmacology/Toxicology*

Falls Church, VA. (Sept. 1999 - Dec. 2000)

- Served as both project manager and a technical manager, providing technical expertise in the areas of pharmacology and toxicology.
- Served as client liaison with nonclinical CROs
- Designed pre-clinical pharmacology and toxicology studies, and performed on-site study monitoring on behalf of clients
- Assisted in the development of strategic product development plans.
- Prepared nonclinical pre-IND and IND submissions, and study monitoring reports
- Identified nonclinical CROs, sourced and managed nonclinical pharmacology and toxicology studies
- Prepared and reviewed study monitoring reports, preclinical assessments and study reports
- Authored scientific manuscripts and provided clients with concise information on specific models or scientific paradigms relevant to their product development plans.

SRA Life Sciences, *Research Scientist*

Rockville, MD (Dec. 1998 - Sept. 1999)

- Managed a hollow fiber bioreactor research laboratory and performed experiments aimed at studying the *in vitro* pharmacokinetic profiles of anti-viral compounds.
- Primary responsibility of performing contracted studies and basic research in the HIV area.
- Maintained lymphocyte and fibroblast cell lines for the study of anti-viral compounds, and followed the kinetics of HIV and CMV infection using hollow-fiber bioreactors as model systems.
- Developed and applied GFP reporter gene technology to study infection of CEM cells with recombinant HIV.

Receptor Biology, Inc., *Research Scientist*

Beltsville, MD (March 1998 - Sept. 1998)

- Developed and tested novel target systems for examining G-protein coupled receptor pharmacology and biology.
- Developed transiently-transfected cell lines for functional screening assays.
- Served as radiation safety monitor

Parke-Davis Pharmaceuticals, *Post-Doctoral Research Fellow*

Ann Arbor, MI (Aug. 1996 - Feb. 1998)

- Examined the expression and regulation of RGS proteins (regulators of G-protein signaling) in cultured cell models.
- Utilized slot blot analyses and RNase protection assays to examine the effect of amphetamine on gene expression in the rat brain



Pharmacia & Upjohn, Post-Doctoral Research Scientist

Kalamazoo, MI (June 1994 - July 1996)

- Studied the pharmacology and biology of dopamine receptor subtypes in vitro.
- Developed an in vitro yeast system to detect proteins interacting with the Dopamine D2L receptor.
- Identified a novel cDNA clone for a D2 receptor interacting protein
- Developed NT-2 cell models stably expressing specific dopamine receptor isoforms.

University of Arizona, Graduate Assistant, Dept. of Pharmacology and Toxicology,

Tucson, AZ (Aug. 1989 - June 1994)

- Developed an in vitro cAMP-responsive reporter gene assay for studying α_2 adrenergic receptor pharmacology and function.
- Compared the pharmacology and signaling of distinct adrenergic receptor subtypes
- Examined the pharmacology of a peripheral-type benzodiazepine receptor in COS-7 cells.

Michigan State University, Laboratory Technician, Biochemistry Dept.

East Lansing, MI (May 1988 - Aug. 1989)

- Responsibilities included large-scale growth and maintenance of mammalian Vero cells, Herpes Simplex Virus (HSV-1) purification, and molecular biological studies of HSV-1

Michigan State University, Laboratory Assistant, Biochemistry Department

East Lansing, MI (April 1986 - May 1988)

- Purified cGMP phosphodiesterase from retinal ROS using chromatographic and electrophoretic techniques and performed second messenger assays and routine laboratory maintenance

EDUCATION

Ph.D., *Pharmacology and Toxicology*. University of Arizona, Tucson, AZ (1994)

B.S., *Biochemistry*, Michigan State University, East Lansing, MI (1988).

CONTINUING EDUCATION

- *Biotechnology Derived Therapeutics: Pharmacology and Toxicology Perspectives in Nonclinical Development*, Charles River Laboratories Symposia, September, 2005
- *Immunogenicity Testing for Therapeutics*, Barnett International, September, 2005
- *Preclinical and Clinical Trials for Medical Device and Combination Products*, Minneapolis, MN, March, 2004.
- *Vaccine Development Minicourse*, Am. College of Toxicology, November, 2003, Washington DC
- *Combination Products: Gaining regulatory approval while overcoming manufacturing and quality challenges*, Barnett International Course, July 30-31, 2003, Washington, DC.
- *Project Management Bootcamp*©, Dominion Project Management, November-December, 2002.

- *Worldwide Preclinical Development of Biotechnology-Derived Products: The Science and the Regulations*, Drug Information Association, October, 2002.
- *Pharmacokinetics in Toxicological Science*, American College of Toxicology Mini Course, November, 2000.
- *Pharmacokinetics and Special Populations*, American College of Toxicology Mini Course, November, 2000.
- *Project Management Success Factors*, Drug Information Association, July 2001.
- *Social Styles Training*, Wilson Learning Corp., April, 2000.
- *Good Laboratory Practices*, PERI, February 28-March 2, 2000.
- *A Primer of Drug Metabolism, Pathology, and Toxicology in the Non-Clinical Safety Assessment of New Pharmaceuticals*, PERI, October 4-7, 1999.

PROFESSIONAL SOCIETIES

American College of Toxicology (ACT), 2000-present
National Capital Area Society of Toxicology, 2000-2001
Drug Information Association (DIA), 2002-2004

INVITED SEMINARS AND TEACHING

- Villa Julie College, Stevenson, MD, November, 2005
- American Chinese Pharmaceutical Assn., 2005 Regional Conference, October, 2005
- Immunogenicity Testing for Therapeutics, Barnett International, September, 2005
- PERI Biologics Drug Development, April 11-13, 2005, Bethesda, MD
- Combination Products, Barnett International, March 25-26, 2004, Philadelphia, PA
- Medical Device and Combination Products, March 11-12 2004, Minneapolis, MN
- Combination Products, Barnett International, July 30-31, 2003, Washington, DC.
- PERI, Biologics Drug Development, March, 2003, Arlington, VA.
- Combination Products, Barnett International, November 19, 2002, Philadelphia, PA.
- National Institute of Health, 1996.
- Berrien County, Michigan Math/Science Center, September, 1995.
- Michigan Society for Neuroscience, May 1995, Ann Arbor, Michigan.

PUBLICATIONS

1. Gehm, B.D., R.M. Pinke, S. Laquerre, J.G. Chafouleas, D.A. Schultz, **D.J. Pepperl** and D.G. McConnell. Activation of bovine rod outer segment phosphatidylinositol-4,5 biphosphate phospholipase C by calmodulin antagonists does not depend on calmodulin. *Biochemistry* **30**: 11302-11306, 1991.
2. Parola, A.L., D.G. Stump, **D.J. Pepperl**, K.E. Krueger, J.W. Regan and H.E. Laird. Cloning and expression of a pharmacologically unique peripheral-type benzodiazepine receptor isoquinoline binding protein. *J. Biol. Chem.* **266**: 14082-14087, 1991.

3. Kedzie, K.M., C.A. Balfour, G.Y. Escobar, S.W. Grimm, Y. He, **D.J. Pepperl**, J.W. Regan, J.C. Stevens, and J.R. Halpert. Molecular basis for a functionally unique cytochrome P450IIB1 variant. *J. Biol. Chem.* **266**: 22515-22521, 1991.
4. Svensson, S.P.S., T.J. Bailey, **D.J. Pepperl**, N. Grundstrom, S. Ala-Uotila, M. Scheinin, J.O.G. Karlsson and J.W. Regan. Cloning and expression of a fish α_2 adrenoceptor. *Br. J. Pharmacol.* **110**: 54-60.
5. **Pepperl, D.J.** and J.W. Regan. Selective coupling of α_2 -adrenergic receptor subtypes to cAMP-dependent reporter gene expression in transiently transfected JEG-3 cells. *Mol. Pharmacol.* **44**: 802-809, 1993.
6. Regan, J.W., T.J. Bailey, J.E. Donello, K.L. Pierce, **D.J. Pepperl**, D. Zheng, K.E. Kedzie, C.E. Fairbairn, A.M. Bogardus, D.F. Woodward and D.W. Gil. Molecular cloning and expression of Human EP3 receptors: evidence of three variants with differing carboxyl termini. *Br. J. Pharmacol.* **112**: 377-385, 1994.
7. Regan J.W., T.J. Bailey, **D.J. Pepperl**, K.L. Pierce, A.M. Bogardus, J.E. Donello, C.E. Fairbairn, K.M. Kedzie, D.F. Woodward and D.W. Gil. Cloning of a novel human prostaglandin receptor with characteristics of the pharmacologically defined EP2 subtype. *Mol. Pharmacol.* **46**: 213-220, 1994.
8. Woodward D.F., **D.J. Pepperl**, T.H. Burkey and J.W. Regan. 6-Isopropoxy-9-oxoxanthene-2-carboxylic acid (AH6809), A human EP(2) receptor antagonist, *Biochem. Pharmacol.* **50**(10): 1731-1733, 1995.
9. **Pepperl, D.J.**, S. Shah-Basu, D. VanLeeuwen, J.G. Granneman and R.G. MacKenzie. Regulation of RGS mRNAs by cAMP in PC12 cells, *Biochem. Biophys. Res. Commun.*, **243**: 52-55, 1998.

REVIEW ARTICLES

- Pepperl, D.J.** and J.W. Regan. The Adrenergic Receptors. *CRC Handbook of Receptors and Channels: Vol. 1. G-Protein Coupled Receptors*, S.J. Peroutka, (ed.), CRC Press Inc., pp. 45-78, 1993.