

CURRICULUM VITAE

**NAKISSA K SADRIEH, Ph.D**

5429 Alta Vista Road  
Bethesda, MD 20814  
(301) 493-0487

**BIRTHDATE:** August 31, 1964  
**MARITAL STATUS:** Married – Two children  
**NATIONALITY:** Naturalized American Citizen

**EDUCATION:**

| <b>INSTITUTION</b>                         | <b>DEGREE</b> | <b>FIELD</b>                | <b>YEAR</b> |
|--|---------------|-----------------------------|-------------|
| Rutgers University (NJ)                    | Ph.D., 1993   | Toxicology/<br>Pharmacology | 1987-1993   |
| Montclair State College (NJ)               | B.S., 1987    | Biology                     | 1985-1987   |
| Eastern Michigan University (MI)           |               | Biology                     | 1984-1985   |
| Faculte de Medecine Saint-Antoine (France) |               | Medicine                    | 1983-1984   |
| Faculte de Medecine de Bordeaux (France)   |               | Medicine                    | 1982-1983   |

**EXPERIENCE:**

**February 2002-present**

**Associate Director for Research Policy and Implementation, Office of Pharmaceutical Science, CDER, FDA.**

Responsibilities: 1) design, conduct and coordination of OPS-immediate office initiated research studies, 2) scientific support to the immediate office of OPS and to the Office Director, 3) evaluation of new technologies in drug development, 4) CDER expert on regulatory perspectives on nanotechnology products. 5) For about 2 years, in

addition to my usual responsibilities, I was also the acting Director of DAPR (Division of Applied Pharmacology Research). As such, I managed scientifically, fiscally and administratively a division of about 15 people, mostly Ph.Ds, and since I stopped this additional role a few months ago, I maintained 2 members of the staff on detail with me, in order to help me conduct my research projects; 6) member of the Therapeutic Inequivalence Action Coordinating Committee (TIACC), 7) project officer on contracts for OPS-initiated research projects.

Committees: Chair of the Rapid Response Team, RSR (Review Science Research) committee member, co-chair of the Pharmacology and Toxicology Coordinating Committee Research Subcommittee, Member of the Therapeutic Inequivalence Action Coordinating Committee Evaluation Team, chair of the CDER Nanotechnology Working Group, member of the FDA Nanotechnology Interest Group and the FDA Nanotechnology Task Force, member of the Interagency Oncology Task Force Nanotechnology Subcommittee, member of the Research Coordinating Committee. I also attend regularly most OPS committee meetings such as OPS CC, where I can bring my scientific expertise to the table. I am also a member of the steering committee of PQRI (Product Quality Research Institute).

**April 99-February 2002**

**Supervisory Pharmacologist/Toxicologist** in the Division of Medical Imaging and Radiopharmaceutical Drug products. Additionally, served as **ODE II Associate Director of Pharmacology and Toxicology** from October 2000 until February 2001.

Responsibilities: Supervised the work of 5 Ph.D. pharmacology and toxicology reviewers, conducted secondary and primary review of the pharmacology and toxicology section of drug applications, routinely met with Agency staff and drug sponsors during the drug development process to provide guidance on regulatory issues regarding the design and evaluation of non-clinical studies, represented the Agency at advisory committee meetings, and served on numerous committees (Pharmacology and Toxicology Coordinating Committee, Carcinogenicity Assessment Committee, PTCC Research

Subcommittee and PTCC Pharmacokinetic and Toxicokinetic subcommittee).

For the ODE II Associate Director of Pharmacology and Toxicology detail, I was responsible for reviewing action packages for 3 divisions and maintaining consistency between package inserts.

Lecture given for the course: Pharmacokinetics and toxicokinetics, in the fall of 1999.

Courses: Toxicokinetics/pharmacokinetics (1999), Fundamentals of genetic toxicology (2000), Toxicologic Pathology (2001), QT prolongation and drug development (2001), Supervising former peers (2000), Personnel Practices (2001), Leadership Skills I (2001).

### **March 98-March 99**

·**Clinical Pharmacokinetics and Biopharmaceutics reviewer** in the division of Cardio-Renal drugs in the Center for Drug Research and Evaluation of the US Food and Drug Administration. My primary responsibilities included the primary review and evaluation of the scientific data included in the clinical pharmacology section of INDs and NDAs, the review and evaluation of biopharmaceutic studies and the knowledge and implementation of relevant guidances and policies issued by the FDA.

Courses: NONMEM training course for beginners, Basic statistics, ANOVA and Regression, Clinical Pharmacokinetics.

Committees: PTCC (Pharmacology-Toxicology Coordinating Committee) Research Subcommittee, CASE (Committee for the Advancement of Scientific Education), PK/TK subcommittee.

Awards: FDA 1999 Outstanding Achievement Award, Group Recognition Award, Quality Performance Award.

### **September 96-March 98**

·**Pharmacology/Toxicology reviewer** in the division of Medical Imaging and Radiopharmaceutical Drug Products in the Center for Drug Research and Evaluation of the US Food and Drug Administration. My primary

responsibilities were to evaluate and review pre-clinical animal pharmacology data, toxicology data and pharmacokinetic data included in INDs and NDAs.

Committees: Reviewer's Affairs Committee (HFD-160 RAC representative), Pharmacology Toxicology Coordinating Committee (PTCC) Research Subcommittee member, HFD-160 NDA Task Force chairperson, CASEval subcommittee member.

Classes: Clinical Pharmacokinetics and biopharmaceutics (one year graduate level class offered at NIH), Reproduction toxicology and the new ICH guidelines, Clinical Pathology, New reviewer workshop, Regulatory science, Successful negotiator.

Awards: recipient of 3 separate awards for review performance and quality.

#### **January 94-September 96**

· **Postdoctoral IRTA Fellow**, Laboratory of Experimental Carcinogenesis, Chemical Carcinogenesis Section, National Cancer Institute, National Institutes of Health. Project: Study of the metabolism and the mechanism of activation and carcinogenesis of heterocyclic amine food mutagens, with particular interest in the mammary carcinogenesis induced by this class of carcinogens. The Laboratory was interested in the effects of dietary constituents on the development and the histological characteristics of rat mammary tumors. My projects were focused on the characterization of the enzymatic pathways, including P450 and N-acetyltransferase, involved in the metabolic activation of heterocyclic amines in target organs, immunohistochemical analysis of normal and tumor tissues from rat mammary glands, detection and characterization of mutations in specific oncogenes such as p53 and neu in mammary gland tumors using molecular biology techniques and analysis of apoptosis and cell proliferation in rat mammary tissue.

· **Responsibilities:** developing research projects, designing experiments, developing methods, establishing and maintaining collaborations, writing manuscripts and training and supervision of students and technicians.

**September 87-October 93**

- **NIEHS Training Grant Fellow at Rutgers University**
- Dr. Paul E. Thomas, major advisor.
- **Doctoral Dissertation:** “Effects of Cyclosporin A on renal and hepatic cytochrome P450 isozymes”.

**June-August 1987**

- Warner-Lambert Company **Internship** in the Industrial Toxicology Department
- Responsibilities: Writing toxicological evaluations and creating a database for the benefit of industrial workers.

**1986-1987**

- Montclair State College **organic chemistry tutor** during undergraduate studies.

**HONORS:**

- NIEHS Training Grant Fellowship (1987- 1993).
- Graduated Summa Cum Laude from Montclair State College.
- Certificate of Merit Award from Eastern Michigan University.
- Sigma Xi Research Award.

**SOCIETIES:**

- Society of Toxicology (full member)

**LANGUAGES:**

- English
- French
- Farsi
- Spanish

**PUBLICATIONS (abstracts not included)**

1. Guo Z., Smith T.J., Wang E., **Sadrieh N.**, Ma Q., Thomas P.E. and Yang C.S., Effects of Phenyl Isothiocyanate, a Carcinogenesis Inhibitor, on Xenobiotic-Metabolizing Enzymes and Nitrosamine Metabolism in Rats, Carcinogenesis 13:12, 2205-2210, 1992.
2. **Sadrieh N.** and Thomas P.E., Characterization of cytochrome P450 isozymes involved in the covalent binding of Cyclosporin A metabolite(s) to liver microsomal proteins in vitro. Toxicol. Appl. Pharmacol. 127,222-232, (1994).

3. Witmer C., Faria E., Park HS., **Sadrieh N.**, Yurkow E., O'Connell S. Sirak A., and Schleyer H. In Vivo effects of Chromium. *Environ. Health Perspect.* 102, Suppl 3:169-176, (1994).
4. **Sadrieh, N.** and Snyderwine, E.G. (1995) Cytochromes P450 in the cynomolgus monkeys mutagenically activate 2-amino-3-methylimidazo[4,5-f]quinoline (IQ) but not 2-amino-3,8-dimethylimidazo[4,5-f]quinoxaline (MeIQx). *Carcinogenesis*, 16:1549-1555, (1995).
5. Ghosal A., **Sadrieh N.**, Levin W., and Thomas PE., Induction of Male specific Cytochromes P450 in Female Rats by Phenytoin (DPH) and Dexamethasone (DEX). *Arch. Biochem. Biophys.* 332(1):153-162, (1996).
6. **Sadrieh N.**, Davis C.D. and Snyderwine E.G., N-acetyl transferase enzymes in the human mammary gland activate heterocyclic amines to DNA-adducting metabolites. *Cancer Res.* 56:2683-2687 (1996).
7. Snyderwine EG, Turesky RJ, Turtletaub KW, Davis CD, **Sadrieh N**, Schutt HA, Nagao M, Sugimura T, Thorgeirsson UP, Adamson RH and Thorgeirsson SS. Metabolism of Food-Derived Heterocyclic Amines in Non-Human Primates. *Mutation Res.* 376(1-2):203-210 (1997)
8. Snyderwine EG, **Sadrieh N**, King RS, Schutt HA. Formation of DNA adducts of the food-derived mutagen 2-amino-9H-pyrido-[2,3-b]indole (A(alpha)C) and bioassay of mammary gland carcinogenicity in Sprague-Dawley rats. *Food Chem Toxicol.* 36(12):1033-41 (1998)
9. **Sadrieh N**, Brower B, Yu L, Doub W, Straughn A, Machado S, Pelsor F, Saint Martin E, Moore T, Reepmeyer J, Toler D, Nguyenpho A, Roberts R, Schuirmann DJ, Nasr M, and Buhse L. Stability, dose uniformity, and palatability of three counterterrorism drugs-human subject and electronic tongue studies. *Pharm. Res.* 22(10):1747-1756 (2005)
10. **Sadrieh N** and Brown S. Therapies require teamwork among FDA and developers; *Small Time* 5(8):22-23 (2005).
11. Treye Thomas, Karluss Thomas, **Nakissa Sadrieh**, Nora Savage, Patricia Adair, and Robert Bronaugh. Research Strategies for Safety Evaluation of Nanomaterials, Part VII: Evaluating Consumer Exposures to Nanoscale Materials, *Toxicological Sciences* Vol 91: 14-19 (2006).
12. M.-L. Chen, A. B. Straughn, **N. Sadrieh**, M. Meyer, P. J. Faustino, A. B. Ciavarrella, B. Meibohm, C. R. Yates, and A. S. Hussain; Effect of Sorbitol on Bioavailability and Bioequivalence of Drugs with Differential Intestinal Permeability; *Pharmaceutical Research*, (2006).

13. **Sadrieh N** and Espandiari P, Nanotechnology and the FDA: What are the scientific and regulatory considerations for products containing nanomaterials? *Nanotechnology Law and Business*, 3:3, (2006).
14. **Sadrieh N** and Miller TJ, Nanotechnology: Regulatory Perspective for Drug Development in Cancer Therapeutics, Book Chapter in *Nanotechnology in Cancer Therapy*, CRC Press, (2007).
15. Yang Y, Brownell CR, **Sadrieh N**, May JC, Del Grosso AV, Lyon RC, Faustino PJ. Validation of an in vitro method for the determination of cyanide release from ferric-hexacyanoferrate: Prussian blue. *J Pharm Biomed Anal.* 2007 Mar 12;43(4):1358-63. Epub 2006 Dec 14.
16. Yongsheng Yang, Charles R. Brownell, **Nakissa Sadrieh**, Joan C. May, Alfred V. Del Grosso, David A. Place, Eldon E. Leutzinger, Eric P. Duffy, Ruyi He, Florence Houn, Robbe C. Lyon and Patrick J. Faustino. Accepted. In press. *J. of Toxicology-Clinical Toxicology* 2007.
17. Patrick J. Faustino, Yongsheng Yang, Joseph J Progar, Charles R Brownell, **Nakissa Sadrieh**, Joan C May, Eldon Leutzinger, David A Place, Eric P Duffy, Florence Houn, Sally A Loewke, Vincent J Mecozzi, Christopher D Ellison, Mansoor A Khan, Ajaz S Hussain, Robbe C Lyon, Quantitative determination of Cesium binding to ferric hexacyanoferrate: Prussian Blue, *Journal of Pharmaceutical and Biomedical Analysis* 47(2008) 114-125.
18. Maziar Kakhi, Suneela Prodduturi, Anna M. Wokovich, William H. Doub, Lucinda F. Buhse, **Nakissa Sadrieh**; Risk Analysis of Transdermal drug delivery systems; *Pharmaceutical Engineering*, 27(6), Article # 6, 1-11 (2007)
19. Anna M. Wokovich, Stanley A. Brown, Fraser J. McMaster, William H. Doub, Bing Cai, **Nakissa Sadrieh**, Mei Ling Chen, Stella Machado, Meiyu Shen and Lucinda Buhse; Evaluation of substrates for 90 degree peel adhesion: a collaborative study I. Medical tapes. *Journal of Biomedical Materials Research: Part B-Applied Biomaterials*. Volume 87B, Issue 1, pages 105-113, October 2008.
20. Jun Zhang, Ronald P Brown, Martin Shaw, Vishal S Vaidya, Yuzhao Zhou, Parvaneh Espandiari, **Nakissa Sadrieh**, Melvin Stratmeyer, Joe Keenan, Cormac G Kilty, Joseph V Bonventre and Peter Goering; Immunolocalization of Kim-1, RPA-1, RPA-2 in Kidney of Gentamicin-, Mercury-, or Chromium-treated rats: relationship to renal distributions of iNos and Nitrotyrosine; *Toxicological Pathology*, 2008
21. **Nakissa Sadrieh** and Katherine M Tyner; Characterization considerations for nanomaterial-based drugs; *American Pharmaceutical Review*, 11(3), 70-74, 2008.

22. Anna M. Wokovich, Stanley A. Brown, Meiyu Shen, William H. Doub, Bing Cai, **Nakissa Sadrieh**, Mei Ling Chen, Stella Machado, Lucinda F. Buhse. Evaluation of substrates for 90° peel adhesion - A collaborative study. II. Transdermal drug delivery systems. *Journal of Biomedical Materials Research: Part B - Applied Biomaterials*. Volume 88B, Issue 1, p 61-65, January 2009.
23. P Espandiari, B Rosenzweig, J Zhang, Y Zhou, R Holland, L Schnackenberg, VS Vaidya, PL Goering, RP Brown, JV Bonventre, K Mahjoob; D Portilla, RD Beger, K Thompson, J Hanig, **N Sadrieh**, Age-Related Differences in Susceptibility to Cisplatin Induced Renal Toxicity, *Journal of Applied Toxicology*, accepted, 2009.
24. Anna M Wokovich, Katherine Tyner, William H Doub, **Nakissa Sadrieh**, and Lucinda F Buhse, Particle size determination of sunscreens formulated with various forms of titanium dioxide; accepted Feb 19, 2009 in *Drug Development and Industrial Pharmacy*.
25. Katherine M Tyner, Anna M Wokovich, William H Doub, Lucinda F Buhse, Stephanie S Watson, Li-Piin Sung, and **Nakissa Sadrieh**. Comparing methods for detecting and characterizing metal oxide nanoparticles in unmodified commercial sunscreens, *Nanomedicine* 4(2), 145-159, 2009.
26. Katherine M Tyner and **Nakissa Sadrieh**, Considerations when submitting nano-therapeutics to FDA/CDER for regulatory review; *Methods in Molecular Medicine* (book chapter).
27. **Nakissa Sadrieh**<sup>\*,†</sup>, Anna M. Wokovich<sup>‡</sup>, Neera V. Gopee<sup>§</sup>, Jiwen Zheng<sup>¶</sup>, David Parmitter<sup>¶</sup>, Paul H. Siitonen<sup>§</sup>, Christy R. Cozart<sup>§</sup>, Anil K. Patri<sup>¶</sup>, Scott E. McNeil<sup>¶</sup>, Paul C. Howard<sup>§</sup>, William H. Doub<sup>‡</sup>, and Lucinda F. Buhse<sup>‡</sup>.; Lack of Dermal Penetration of Titanium Dioxide (TiO<sub>2</sub>) from Sunscreen Formulations containing Nano- and Sub-Micron-Size TiO<sub>2</sub> Particles; *Toxicological Sciences*, 2009
28. Banu Zolnik and **Nakissa Sadrieh**, Regulatory perspective on the impact of ADME assessment of nanoscale material containing drugs; *Advanced Drug Delivery Reviews*; 2009
29. tissue levels of Cis and Gen
30. Kim-1 levels in kidneys of rats-kinetic study.

**Invited Speaker**

1. July 1996: National Institutes of Health, National Cancer Institutes, Division of Basic Sciences, Women Postdoctoral Fellow Forum. Title of seminar: "N-acetyltransferase expression and metabolic activation of food-derived heterocyclic amines in the human mammary gland".
2. ILSI April 2004; FDA perspective on nanotechnology.
3. ChABSA June 2004; Nanotechnology: regulatory considerations for drug development.
4. ILSI-HESI annual meeting, New Orleans, January 2005;
5. Nanobusiness conference, May 2005, New York, NY.
6. MHRA-sponsored conference on Nanotechnology: impact on Health and Regulation, London, UK, October 2005.
7. PDA nanopharmaceutical conference, London, UK, November 2005
8. NIST Measurement and Standards needs in Nanobiotechnology, Houston, Texas, January 2006.
9. Nanotech 2006, NCI/NSTI symposium on cancer and nanotherapeutics, Boston, May 2006.
10. American College of Veterinary Pathologists, symposium on nanotechnology, Tucson, AZ, December 2006.
11. Rutgers University, Piscataway NJ, speaker in Course on nanotechnology drug delivery, December 2006.
12. ISPE, Paris, France, April 2007
13. University of Nottingham, Nottingham, England, May 2007.
14. Gordon Conference, Colby College, New Hampshire, June 2007.
15. America Academy of Nanomedicine September 2008-Potomac, MD
16. European Science Foundation conference on nanomedicine; September 2008 Barcelona, Spain
17. American Association of Pharmaceutical Science, November 2008-Atlanta
18. Parenteral Drug Association/FDA joint conference September 2008, Washington DC
19. Society of Toxicology March 2009- Baltimore