

ToxSolutions

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SUMMARY: Board Certified Toxicologist with broad experience in the agricultural, pharmaceutical and chemical industries. Background includes international regulatory affairs, occupational health and product stewardship. Particular expertise in:

- Safety Evaluation
- Health / Environmental Risk Assessment
- Toxicology Study Design
- Exposure Assessment
- Regulatory Negotiations
- Registration Strategy
- Quality Improvement
- Management Presentations

**PROFESSIONAL
EXPERIENCE:**

ToxSOLUTIONS, Flemington, NJ

Regulatory Toxicology Consultant (1999 - Present)

Independent toxicology consultant to agricultural, pharmaceutical and chemical companies on product safety evaluation, risk assessment and occupational health issues.

- Conducted TSCA 8(e) audit of ~1500 toxicology studies and prepared criteria for submission of toxicity data to EPA for a Fortune 100 corporation.
- Prepared risk assessment of six chemicals emitted from digital printing equipment.
- Prepared safety assessment of chemicals imparted to drinking water for NSF 61 certification.
- Wrote safety pharmacology and pharmacokinetics summaries for IND submissions to FDA.
- Peer reviewed and explained a plant emissions risk assessment to the surrounding community.
- Evaluated potential chronic effects and proposed health surveillance of workers exposed during a production accident at an aerospace company.
- Developed a workplace exposure control program for a pharmaceutical production facility.
- Authored response to the UK Pesticide Safety Directorate on additional metabolism and carcinogenicity data requirements for reregistration of a product.
- Prepared HPV robust summaries on six related chemical compounds for submission to EPA.
- Wrote review of FDA PMN requirements for food contact substances.
- Critiqued the risk assessment of pharmaceutical degradation products for FDA submission, satisfying Agency concerns and allowing approval of NDAs.
- Wrote generic ISO and ANSI MSDSs for a group of similar consumer products.
- Negotiated fewer toxicology, ecotoxicology, phys/chem, and e-fate requirements for a pesticide reregistration in the EU with Rapporteur Member State (Dutch) Authorities.

UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY, Newark NJ

Assoc. Professor, School of Health Related Professions Toxicology Program (1999 - Present)

Part-time faculty member, teaching lecture, laboratory and seminar courses in toxicology. Also responsible for operation of the Student Internship Program and participates in the development / conduct of continuing education courses for the professional community.

AMERICAN CYANAMID COMPANY, Ag. Products Res. Division, Princeton, NJ

Senior Product Registration Manager, International Regulatory Affairs (1994 - 1999)

Managed registration of insecticide and fungicide products used in crop and public health outlets. Intl. Division consultant on regulatory toxicology and operator exposure. Developed successful regulatory strategies to resolve health and ecological risk issues

**PROFESSIONAL
EXPERIENCE:
(Continued)**

AMERICAN CYANAMID COMPANY (Continued)

- Key contributor to AHP Occupational Exposure Guidelines for determination of drug and agricultural product active ingredient permissible exposure levels.
- Developed first toxicology and ecotoxicology bridging strategy ever accepted by Japanese Authorities for an agricultural product registration, saving over \$2M.
- Company lead on pesticide exposure assessment methods used in the US and Europe.

Program Manager, Toxicology Department, Cyanamid Ag Research Center (1992 - 1994)

Designed, monitored and evaluated the complete spectrum of toxicology studies on crop protection chemicals, veterinary drugs and animal feed additives. Interpreted results, wrote summaries and rebuttals for submission to EPA, FDA and international agencies.

- Corporate consultant on environmental health risk assessment for acquisition of Shell Ag products business.
- Conceived FDA GRAS petition strategy for a critical animal drug incipient, successfully clearing a major hurdle to product registration.

Manager, Toxicology Operations (1989 - 1992)

Toxicology Program Manager (1983 - 1989)

Toxicology and Product Safety Department

Cyanamid Chemicals Group

Responsible for Chemicals Group \$1M toxicology testing program and safety evaluations in support of product registration and hazard communications activities. Supervised Associate and Assistant Toxicologists handling contract administration, quality assurance and MSDS / label preparation.

- Gave invited testimony before the NJ DEPE Commissioner on health risk assessment as the basis for environmental cleanup standards.
- Led industry response to revision of formaldehyde TLV by the ACGIH.

CELANESE CORPORATION, New York, NY

Staff Toxicologist, Department of Environmental, Health and Safety Affairs (1979 - 1983)

USAF AEROSPACE MEDICAL RES. LABORATORY, Wright-Patterson AFB, OH

Pharmacologist/Physiologist, Toxic Hazards Division (1975 - 1979)

EDUCATION:

Ph.D., Pharmacology The Ohio State University, College of Medicine (1975)
B.S., Cell Biology The Ohio State University (1970)

**BOARD
CERTIFICATION:**

Diplomate, American Board of Toxicology
Certified 1980 in General Toxicology, Re-certified 1985, 1990, 1995 and 2000

**PROFESSIONAL
MEMBERSHIPS
and
APPOINTMENTS**

Society of Toxicology
International Society of Regulatory Toxicology and Pharmacology
Society for Risk Analysis
American College of Toxicology
European Crop Protection Association Toxicology Expert Group (1996 - 1999)
New Jersey Environment Advisory Task Force (1993)
Chairman, Health and Safety Committee, Acrylonitrile Group (1991 - 1992)
Health Effects Advisory Board, NJ Haz. Substance Mgmt. Res. Center (1988 - 1992)
Board of Directors and Chair, Science Policy Comm., Formaldehyde Inst. (1989 - 1991)

PUBLICATIONS:

Over twenty publications and numerous scientific presentations on general toxicology, neurotoxicology, metabolism, carcinogenicity and cardiovascular pharmacology.