Barry S. Levine, DSc, DABT

Levine Tox Consulting

Consultants in Toxicology and Nonclinical Development

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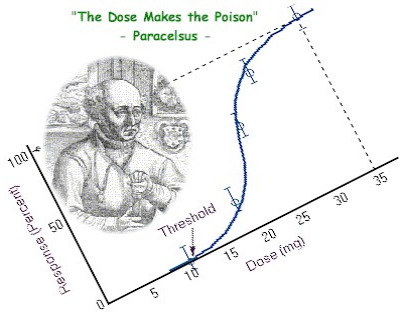
CONSULTING SERVICES

- **Nonclinical Drug Development**
  - Strategic Planning – Technical + Budgetary
  - Toxicology/Safety Assessment
  - Small Molecules, Generics, Biologics, and Biosimilars
  - Medical Devices (Biocompatibility)
  - Scientific Program Management including Contract Research Organization Interactions and Study Monitoring
- **Regulatory filings** (FDA, EMA, Health Canada)
  - Nonclinical Sections of Common Technical Documents (CTDs), Investigator's Brochures, etc.
- **Other Consultation Areas**
  - Product Liability/Forensic Toxicology (Expert Witness Testimony)
  - Government Contracts
  - Clinical Pathology of Laboratory Animals



EDUCATION AND CERTIFICATION

- **Diplomate, American Board of Toxicology**, 1980
- **D.Sc. (Doctor of Science), Toxicology**, Harvard School of Public Health, 1976
- **M.Sc., Toxicology**, Harvard School of Public Health, 1974
- **M.S., Medicinal Chemistry**, University of Illinois, 1972
- **B.S., Pharmacy**, University of Illinois, 1971

EXPERIENCE

40+ Years of Experience in Toxicology/Nonclinical Development
evaluating various classes of therapeutic agents within:

- Pharmaceutical Industry
- Contract Research Organizations
- Academia

- **Principal, Levine Tox Consulting**, Chicago, IL, 2008 – present
- **Director, Preclinical Development,** Hospira, Lake Forest, IL, 2004-2008
- **Previous posts included director level positions in toxicology** at pharmaceutical companies and contract research organizations

  - PharmaMar USA, Cambridge, MA
  - Vertex Pharmaceuticals, Cambridge, MA
  - Toxicology Research Laboratory (a Contract Research Organization) University of Illinois at Chicago, Chicago, IL
  - BioReliance Corp. (formerly Microbiological Assoc.), Bethesda, MD

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ANCILLARY INFORMATION

- **Pharmaceutical Industry Experience**
  - Development, placement and monitoring of nonclinical development programs for drugs & biologics at 15+ CRO facilities (toxicology - general, DART, genotoxicity, PK; bioanalytical; safety pharmacology)
  - Nonclinical development representative on drug development & due diligence teams
  - Toxicology qualification of impurities in drug substances and drug products
  - Preparation of nonclinical sections of regulatory filings (FDA, EMA, Health Canada)
  - Development and oversight of a Bioethics Program on animal use in research
- **Director of GLP Toxicology Laboratories.** Eighteen years of experience within the pharmaceutical industry and contract research organizations
  - General toxicology, developmental and reproductive toxicology, pharmacokinetics
  - Rats, mice, dogs, nonhuman primates (Rhesus, Cynomolgus, Baboons, Stumptails), rabbits, goats, ferrets
- **Government Contracts** - Principal Investigator (NCI, NIH, US Army, World Health Organization)
- **Academic Teaching Experience** - Fifteen years; Professor of Pharmacology & Director, Toxicology Research Laboratory, University of IL at Chicago. Lectures/courses given to graduate & medical students
- **Legal Experience** - Twenty years including expert witness testimony
- **President, Society of Toxicology, Midwest Regional Chapter**, 1991-1992
- **Chair, Animal Clinical Chemistry Division, American Association of Clinical Chemistry**, 1984 -1986
- **56 publications, 76 abstracts, 2 book chapters, numerous technical reports**

SCIENTIFIC SOCIETY MEMBERSHIPS

- **Society of Toxicology**
- **American College of Toxicology**
- **Society of Toxicologic Pathology**
- **Society of Forensic Toxicologists**

JOURNAL/GRANT APPLICATION REVIEWER

- **Journals:** *Toxicology Mechanisms and Methods* (Editorial Board), *Cancer Chemotherapy and Pharmacology, Pharmaceutical Biology, Phytomedicine, Pharmacology and Toxicology, Intl. Journal of Pharmacognosy*
- **Grant Applications:** National Cancer Institute, National Institutes of Health, Great Lakes Protection Fund
- **Peer Review Panel:** Toxicological Profile of RDX, US Dept. Health and Human Services

INVITED PRESENTATIONS

- ***Relationship Between Dosing Vehicles, Dose Volume, and Stress*,** Humane Society of the United States Workshop entitled "Refinement in Toxicology Testing," New Orleans, LA, 1999
- ***Conduct of GLP Toxicology Studies*,** One week course presented to Chinese govt. scientists (course co-director and speaker), National Institute of Military Medical Sciences, Beijing, China, 1993
- ***Preclinical Toxicology Studies of New Drugs and Vaccines*,** U.S. Army Medical Research & Development Command Drug Development Symposium, Frederick, MD, 1993
- ***Principles of Toxicology*,** American Industrial Hygiene Assoc. Course, Berkeley, CA, 1987