David W. Eaker, Ph.D., DABT

SENIOR CONSULTANT

CONTACT INFORMATION

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PROFESSIONAL PROFILE

Dr. David Eaker is a board-certified toxicologist in ToxStrategies' Pharmaceuticals practice with more than 35 years of professional experience. His expertise includes *in vitro* and in *vivo* toxicology for devices and drugs, large animal functionality and clinical suitability models, PK/PD, device biocompatibility, and design of overall preclinical/nonclinical strategies aimed at regulatory approval and market access. His work has supported drug-device combination products, device coatings and drug delivery, biologics delivery, quality and regulatory compliance (GLP, GDP, GMP), and direct engagements with global regulatory bodies.

Other specific areas of experience include materials characterization (extractables and leachables; degradation studies), overall toxicologic health hazard risk assessments, and engagement with applicable standards-setting bodies (e.g., ISO; AAMI). Dr. Eaker's work with innovation and product development teams throughout the product lifecycle has also included elements of medical materials science (polymers, elastomers, metals), product sustainability/recycling, sterilization modalities, and post-market support. He has supported hundreds of successful device and combination product 510(k), IDE, and PMA submissions, EU MDR CE submissions, China NMPA registrations, IND, NDA, and ANDA programs, inclusive of additional materials regulations (e.g., REACH, California Prop 65).

Dr. Eaker has also served as an Institutional Official (IO) under the US Federal Animal Welfare Act, overseeing responsible use of laboratory animals and AAALAC-accredited facilities.

EDUCATION, DEGREES EARNED, AND CERTIFICATIONS

Diplomate of the American Board of Toxicology (current to 2030)

Ph.D., Physical/Organic Chemistry, Florida State University, Tallahassee, FL

B.S., Organic Chemistry, University of North Carolina, Chapel Hill, NC (*with honors*)

HONORS AND AWARDS

US National Science Foundation Pre-Doctoral Fellow

University Teaching Fellow

Phi Beta Kappa (BS degree with honors)

SELECTED ADDITIONAL TRAINING

Predictive Toxicology Methodologies

Safety Pharmacology

Immunotoxicology and other sub-specialties

Incorporation of Pharmacokinetic and Pharmacodynamic Data into Risk Assessments

Structure Activity Relationships (SAR) in Toxicology

Integration of Mechanistic, Pathologic, and Toxicokinetic Data in Safety Assessment

International Harmonization of Nonclinical Toxicology Requirements

CURRENT PROFESSIONAL MEMBERSHIPS

Society of Toxicology (including Risk Assessment Specialty Section)

International Society of Regulatory Toxicology and Pharmacology

Association for the Advancement of Medical Instrumentation (AAMI)

American Association for Laboratory Animal Science (AALAS)

American Chemical Society (including Chemical Toxicology Section)

SELECTED PROFESSIONAL EXPERIENCE

Preclinical Development and Toxicology

- Product development, proof of concept studies, preclinical safety and efficacy
- Sustainable product design and development (green materials, processes); customer liaison
- Regulatory interactions (NDA, ANDA, IND, IDE, PMA, 510(k), 505(b)2 submissions and presentations)
- Toxicologic and clinical risk assessment, hazard evaluation, and risk communication
- Direct experience with medical devices and diagnostics, combination products, consumer products, over-the-counter and generic pharmaceuticals

Chemistry and Chemical Toxicology

- Physical/organic chemistry, mechanisms, kinetics, structure/activity relationships
- Analytical testing and interpretation
- Materials science, polymer, and elastomer formulations

Leadership and Management

- Continuous improvement techniques (lean processes, optimization)
- GLP/GDP/GMP/GCP regulatory compliance
- Development of technical guidance documents
- National and international Quality Systems (ISO 13485, ISO 17025)

PUBLICATIONS

Saltiel J, Gupta S, **Eaker DW**, Kropp AM, Ratheesh Kumar VK. 2018. Photochemistry and photophysics of the 3-styrylidenebenz[e]indanes. Photochem Photobiol 94(2):247-260; doi: 10.1111/php.12849.

Saltiel J, Choi J-O, Sears Jr DF, **Eaker DW**, O'Shea KE, Garcia I. 1996. Resolution of trans-1-(2-naphthyl)-2-phenylethene fluorescence in the presence of tri-n-butylamine into pairs of monomer and exciplex spectra. Selectivity in conformer quenching. J Am Chem Soc 118(32):7478-7485; doi: 10.1021/ja961340g.

Saltiel J, Choi J-O, Sears Jr DF, **Eaker DW**, Mallory FB, Mallory CW. 1994. Effect of spectra shifts on the resolution of trans-1-(2-naphthyl)-2-phenylethene conformer UV spectra based upon principal component analysis with self-modeling. J Phys Chem 98(50):13162-13170; doi: 10.1021/j100101a012.

Saltiel J, Sears Jr DF, Choi J-O, Sun Y-P, **Eaker DW**. 1994. Fluorescence, fluorescence-excitation, and UV absorption spectra of trans-1-(2-naphthyl)-2-phenylethene conformers. J Phys Chem 98(1):35-46; doi: 10.1021/j100052a008.

Saltiel J, **Eaker DW**. 1984. Principal component analysis applied to 1-phenyl-2-(2-naphthyl)ethene fluorescence. Four components not two. J Amer Chem Soc 106(24):7624-7626; doi: 10.1021/ja00336a054.

Goerner H, **Eaker DW**, Saltiel J. 1981. Analysis of the decay of 1-phenyl-2-(2-naphthyl)ethene triplets. A nanosecond laser pulse study. J Amer Chem Soc 103(24):7164-7169; doi: 10.1021/ja00414a021.

Saltiel J, **Eaker DW**. 1980. Lifetime and geometry of 1-phenyl-2-(2-naphthyl)ethene triplets: Evidence against the triplet mechanism for direct photoisomerization. Chem Phys Lett 75(2):209-213; doi: 10.1016/0009-2614(80)80498-2.

Whitten DG, **Eaker DW**, Horsey BE, Schmehl RH, Worsham PR. 1978. Photochemical reactions in organized monolayer assemblies.10. Photochemical and thermal reactions of porphyrins and organic surfactants in monolayer assemblies. Modification of reactivity in condensed hydrophobic microenvironments. Ber der Bunsengesell Phys Chem 82(9)858-867; doi: 10.1002/bbpc.19780820904.

Worsham PR, **Eaker DW**, Whitten DG. 1978. Photochemical reactions in organized monolayer assemblies. 11. Ketone photoreactivity as a probe of the microenvironment: Photochemistry of the surfactant ketone 16-oxo-16-p-tolyhexadecanoic acid in monolayers, micelles, and solution [Letter to Editor]. J Amer Chem Soc 100(22):7091-7093; doi: 10.1021/ja00490a066.

POSTERS, ABSTRACTS, AND PRESENTATIONS

Eaker DW. Accelerating successful product development and market access: New collaboration opportunities. Invited Speaker and Session Chair, Medical Device R&D Summit, Palm Beach, FL, 2015.

Eaker DW. Impact of changes to the FDA biocompatibility guidance: An industry perspective. Invited Speaker, MedCon 2014, FDA and Xavier Health, Cincinnati, OH, May 2014.

Eaker DW. Global regulatory harmonization efforts for review and approvals of combination medical devices. Invited Speaker, ANTEC 2014, Society of Plastics Engineers, Las Vegas, NV, April 2014.

Eaker DW. Biocompatibility Testing: Alternate approaches, toxicologic risk assessment. Medical Device and Manufacturing 1998, Anaheim, CA, 1998.

Eaker DW. Biocompatibility testing of medical devices, toxicologic risk assessment. Medical Device and Manufacturing 1998, St. Paul, MN, 1998.

Eaker DW. Appearance before the Federal Trade Commission, Environmental Product Claims and Labeling Guidelines, December 1995.

Frazier LM, **Eaker DW**. Searching for toxicity data using computerized databases. EPOCH-Envi Short Course Lecture, Duke University, Durham, NC, June 1994.

Eaker DW, Brown WL. Using consumer input to enhance quality management. Invited Lecture, Food Development and Marketing USA, Newark, NJ, November 1991.

Eaker DW. New challenges for nutrition labeling. Invited Lecture, ADS 1991 Mid-Year Meeting, Miami, FL, April 1991.

Eaker DW. Smoke aerosol filtration, theory and experiment. Invited Symposium Lecture, 44th TCRC, Winston-Salem, NC, October 1990.

Kay DL, Heavner DL, Nelson PR, Jennings RA, **Eaker DW**, Robinson JH, DeLuca PO, Risner CH. Effects of relative humidity on nonsmoker response to environmental tobacco smoke. INDOOR AIR 90: 5th International Conference on Indoor Air Quality and Climate, Toronto, Canada, July 1990.

Eaker DW, Saltiel J. Evidence against the triplet mechanism for the direct photoisomerization of 1-phenyl-2-(2-naphthyl)ethene. Florida Section ACS Meeting, Tampa, FL, May 1980.