

Donald F. Schmitt, M.P.H.
Senior Managing Scientist

Professional Profile

Mr. Donald Schmitt is a Senior Managing Scientist in Exponent's Health Sciences Center for Chemical Regulation and Food Safety. Mr. Schmitt has 30 years of corporate and consulting experience in toxicology, risk assessment, and regulatory affairs. He has significant experience in evaluating the safety of foods and food ingredients, additives and contaminants, feed additives, human and veterinary drugs, medical devices, cosmetics, and environmental and occupational exposures. He has developed regulatory strategies for FDA-regulated products in support of regulatory compliance, product defense, product development and claims, and pre-market approval. Mr. Schmitt has conducted pre-clinical toxicity evaluations of drugs, medical devices, and biologics for both the government and private sectors. He has designed, contracted, and monitored pre-clinical safety studies required for regulatory clearance of new food additives, cosmetic ingredients, and human and veterinary drugs for clients. He has provided technical support and assisted in the preparation of a variety of reports and submissions to regulatory authorities including Generally Recognized as Safe (GRAS) affirmation petitions, food contact notifications (FCNs), new dietary ingredient notification (NDIs), direct and indirect food additive petitions, health claims petitions, clinical study Investigator Brochures, and Investigational New Drug and New Drug Applications (INDs/NDAs). He has experience in quality assurance programs and conduct of GLP and GCP audits.

Academic Credentials and Professional Honors

M.P.H., Environmental Health Sciences, The Johns Hopkins University, 1993

M.B.A., Finance, Loyola University, 1983

B.A., Biology, Northwestern University, 1976

Publications

Lamb J, Hentz, K, Schmitt D, Tran N, Junker K. A one-year oral toxicity study of sodium stearoyl lactylate (SSL) in rats. *Food Chem Toxicol* 2010; 48:2663–2669.

Alexander DD, Schmitt DF, Tran NL, Barraji LM, Cushing CA. Partially hydrolyzed 100% whey protein infant formula and atopic dermatitis risk reduction: A systematic review of the literature. *Nutr Rev* 2010; 68(4):232–245.

Schmitt D, Tran N, Riefler S, Jacoby J, Merkel D, Marone P, Naouli N. Toxicologic evaluation of modified gum acacia: mutagenicity, acute and subchronic toxicity. *Food Chem Toxicol* 2008; 46(3):1048–1054.

Spiegel J, Rose R, Karabell P, Frankos V, Schmitt D. Safety and benefits of Fructooligosaccharides as food ingredients. *Food Technol* 1994; 48(1):85–89.

Schmitt D, Frankos V, Westland J, Zoetis T. Toxicologic evaluation of cellulon fiber; genotoxicity, pyrogenicity, acute and subchronic toxicity. *J Am Coll Toxicol* 1991; 10(5):541–554.

Frankos V, Schmitt D, Haws L, McEvily A, Iyengar R, Miller S, Munro I, Clydesdale F, Forbes A, Sauer R. Generally Recognized as Safe (GRAS) evaluation of 4-Hexylresorcinol for use as a processing aid for prevention of Melanosis in shrimp. *Reg Toxicol Pharmacol* 1991; 14:202–212.

Greener Y, Gillies B, Wienckowski D, Schmitt D, Woods E, Youkilis E. Assessment of the safety of chemicals administered intravenously in the neonatal rat. *Teratology* 1987; 35(2):187–194.

Greener Y, McCartney M, Jordan L, Schmitt D, Youkilis E. Assessment of the systemic effects, primary dermal irritation, and ocular irritation of Chlorhexidine Acetate solutions. *J Am Coll Toxicol* 1985; 4(6):309–319.

Greener Y, Jesmok G, Grove N, Schmitt D, Wienckowski D, Woods E. Assessment of potential toxic effects of treated Hemofil (T-AHF) injection in rats and mice and on the systemic hemodynamics in dogs. *J Toxicol Environ Health* 1985; 15:801–811.

Presentations and Abstracts

Alexander DD, Schmitt D, Tran N, Barraji L, Cushing CA. Partially hydrolyzed 100% whey infant formula and atopic dermatitis risk reduction: A systematic review of the literature. Experimental Biology, Program Abstract (Poster), New Orleans, LA, 2009.

Schmitt D, Frankos V, Richardson D. Toxicologic evaluation of Sanguinaria extract. 11th Annual Meeting of the American College of Toxicology, Program Abstract (Poster), Savannah, GA, 1990.

Youkilis E, McCartney M, Schmitt D, Woods E. Subchronic intravenous toxicity evaluation of Methionine-Enkephalin. 25th Annual Meeting of the Society of Toxicology, Program Abstract (Poster), New Orleans, LA, 1986.

Prior Experience

Manager, Regulatory Affairs and Technical Support, Global Drug Metabolism, Monsanto /Pharmacia / Pfizer, Inc., 1996–2003

Coordinator, Regulatory Affairs, Environment, Health & Safety Department, Amoco Corporation, 1993–1995

Manager (Consultant), ENVIRON Corporation, 1988–1993

Senior Laboratory Supervisor, Baxter Healthcare Corporation, 1980–1988

Toxicologist, G.D. Searle & Co., 1977–1980

Assistant Biologist, IIT Research Institute, 1976–1977

Project Experience

Food Ingredients, Additives, and Contaminants

Developed a GRAS affirmation petition for a product manufactured by a novel bacterial fermentation process, with proposed food use as a suspending/thickening agent. Designed, placed and monitored (audited) pre-clinical studies required for FDA approval.

Critically reviewed the scientific database supporting proposed structure-function claims for a carbonated beverage product. The database was comprised of clinical, animal, and in vitro studies. Prepared a report reviewing the scientific-based strength of evidence supporting the claims using current FDA guidance.

Managed an expert panel review of scientific data supporting a proposed qualified health claim for an infant formula product. Managed the preparation of a report reviewing the scientific-based strength of evidence supporting the claims using current FDA guidance.

Prepared several food contact notifications (FCNs) for rinse-aid products and managed submission/approval process with FDA.

Critically reviewed the scientific database of a soluble fiber source traditionally used as an over-the-counter pharmaceutical agent now proposed for use as a soluble dietary fiber source in ready-to-eat cereal. The database was comprised of human, animal, and in vitro studies addressing general toxicity, vitamin and mineral absorption and availability, allergenicity, carcinogenicity, and reproductive effects. Prepared a GRAS affirmation petition in support of its safety for the proposed use.

Evaluated the safety of a chemical agent found in OTC pharmaceutical products for use as a processing aid in seafood. Reviewed the composition, manufacture, and efficacy of the agent

and completed a GRAS petition incorporating an evaluation of information on its toxicity in humans and animals and supporting its safe use in seafood.

Critically reviewed and interpreted pre-clinical toxicity data and compiled GRAS affirmation petitions and direct and indirect food additive petitions for new food additives and uses.

Reviewed scientific data on an enzyme and its bacterial production strain and prepared regulatory submissions for both food (GRAS) and drug (OTC) approvals.

Pharmaceutical/Medical Devices

Prepared the toxicology, pharmacology, and PK/TK sections of clinical study Investigator Brochures and Investigational IND's/NDA's. An example of one NDA was for a drug that holds promise for dramatically decreasing the high percentage of reocclusion that occurs in angioplasty patients.

Assembled several expert panels to address the safety of antimicrobial agents for use in oral hygiene products (e.g., toothpaste and oral rinse). One agent was an extract from a plant source. The evaluations included a review of the pre-clinical and clinical toxicologic database, analysis of consumer exposure, and determination of the margin of safety associated with the proposed oral uses. Several regulatory submissions, expert reports, and publications were prepared for submission to the FDA and U.K. regulatory authorities.

Reviewed the toxicologic database on acetone and assessed the exposure and associated human health risk of acetone residuals on a peridental device.

Products of Biotechnology

Prepared regulatory submissions in support of feed additive products, plants, and dietary supplements prepared by use of genetic modification/biotechnological methodology. Assembled expert panels to address the safety of these products for their proposed uses.

Professional Affiliations

- Society of Toxicology
- Midwest Regional Chapter of the Society of Toxicology
- American College of Toxicology
- Institute of Food Technologists