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Elaine Freeman, DABT

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Professional Profile

Ms. Freeman is a Board Certified Toxicologist (DABT) with over 20 years of experience in regulatory toxicology in the fields of pesticides, industrial chemicals, veterinary medicines, consumer products, and food safety. She has a comprehensive knowledge of toxicological requirements as well as a thorough understanding of the nuances of toxicological testing requirements for specific regulations.

Ms. Freeman is adept at project management and working with clients and regulators to develop strategic approaches to addressing human health concerns. She prepares chemical specific adjustment factor and human relevance frameworks for mode of action submissions. Ms. Freeman also prepares maximum tolerated dose assessments, has expertise in dermal absorption testing, and calculation of human dermal absorption factors and refined dermal equivalent doses, chemical hazard and risk prioritization systems for the oil and gas industry, consumer products and industrial chemicals. She monitors toxicological testing programs, conducts laboratory audits, prepares data evaluation reports and OECD study summaries.

Ms. Freeman prepares waivers from toxicological testing requirements for pesticides based on toxicology, structurally similar compounds and risk evaluations. She has experience with EPA's Endocrine Disruptor Screening Program including the submission of other scientifically relevant information (OSRI), study design and monitoring, weight of the evidence (WOE) evaluations, human risk evaluations, thyroid-specific mode of action testing and assessment, as well as ToxCast and EDSP21 evaluations. She conducts and evaluates QSAR assessments for new product development, re-registration, and impurity and metabolite of concern assessments.

Ms. Freeman has expertise in the Toxic Substances Control Act (TSCA) compliance including new chemical notifications (PMNs and LVEs), chemical reporting, regulatory interpretation, and training. She also has expertise in classification under the U.N.'s Globally Harmonized System (GHS) for Classification and Labeling as well as North American Hazard Communication regulations. She has experience with import tolerances, due diligence assessments, data compensation projects, and data gap analyses for pesticides active ingredients and inerts.

In her previous capacities, Ms. Freeman held positions in toxicology and product stewardship, was responsible for the full lifecycle of toxicology for pesticide and industrial chemicals in the US, Canada, and EU including registrations, re-registrations, tolerance petitions, waivers, testing orders, JMPR submissions, position papers and authoritative body representation.

Academic Credentials & Professional Honors

Dr.Sc, Regulatory Science, University of Southern California, 2026

M.S., Pharmacology and Toxicology, Duquesne University, 1998

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B.S., Microbiology, University of Pittsburgh, 1994

Prior Experience

Regional Manager North America - Expert Network, SAP, 2010-2011

Global Toxicology Leader / Product Stewardship Leader, Celanese, 2008-2010

Toxicologist, Chemtura, 2004-2008

Product Safety Representative / Toxicologist, Bayer Material Science, 2002-2004

Professional Affiliations

ToxForum, 2021-present

Allegheny-Erie Society of Toxicology (AESOT), 1995-2004; 2010-present. President-Elect 2022

National Society of Toxicology (SOT), 2005 - present Full Member, 1999-2005 Associate Member, 1996 Student Member. Risk Assessment Specialty Section Member 2010-present. Regulatory Specialty Section 2010-present.

American College of Toxicology (ACT), 2005-2009, 1999-2002 Associate Member, 1996 Student Member

Crop Life America Human Health and Risk Assessment Committee (HARC, HHRAC), 2005-2008; 2011-present

Allegheny-Erie Society of Toxicology (AESOT), 1995-2004; 2010-present. Executive Committee 2003, Counselor 2011-present. Awards Chairperson 2003, Education Committee 1998-2002, Communication Committee 1999-2001

International Society for Regulatory Pharmacology and Toxicology (ISRTP). 2011-present; Counselor 2015-2016; Treasurer 2016-present

American Chemistry Council (ACC) Regulatory Advocacy Information Network (RAIN), 2008-2010

Society for Chemical Hazard Communication (SCHC), 1995-2000; 2008-present; Assistant Chair Professional Development Committee 2010-present

Formaldehyde Council (FCI) and FormaCare, 2008-2010

Vinyl Acetate Council, 2008-2010

Executive Committee 2003, Counselor 2011-present. Awards Chairperson 2003, Education Committee 1998-2002, Communication Committee 1999-2001

Society for Chemical Hazard Communication (SCHC), 1995-2000; 2008-2019; Assistant Chair Professional Development Committee 2010-2019

Publications

Freeman E, Wilson, K. Case Study on the Use of Integrated Approaches for Testing and Assessment (IATA) for Chronic Toxicity and Carcinogenicity of Agrichemicals with Exemplar Case Studies - Ninth Review Cycle (2023). Organisation for Economic Co-operation and Development 2024

Talyor A, Freeman E. Nanotechnology Regulation Implementation in Industry. NanoTech 2017 presentation. Advanced Materials: TechConnect Briefs 2017.

Freeman E, Nusz J. Chemical Alternatives Assessment: Where do I start? Abstract, Society of Toxicology Annual Meeting, 2016.

Freeman E. Overview of regulations affecting industrial products in North America including VOC, HMIS, NFPA 704, OSHA proposed GHS, OSHA HAZCOM, ANSI HAZCOM and UN and Global GHS. Presentation to Wurth International, 2011.

Freeman E. Overview of GHS regulations. C4U Meeting, 2010.

Freeman E, Cardona R, Clayton V, Wanner U, Long S. Assessment of the relevance of carboxin soil metabolites. Abstract, Society of Toxicology Annual Meeting, 2008

Freeman E, Cardona R, Wanner U, Long S. The use of structure activity relationships (SAR) in characterizing the toxicological hazards of plant metabolites Abstract, Society of Toxicology Annual Meeting, 2007

Freeman E, Milchak M. ChemADVISOR, Inc Correlation Coefficients for an Aquatic Toxicity Database. Abstract, Society of Toxicology Annual Meeting, 2000

Freeman E, Milchak M, DiPasquale J, Dobson T. ChemADVISOR, Inc creation of an aquatic toxicity database. Abstract, Society of Toxicology Annual Meeting, 1999

Freeman E, Long SF. The beneficial effects of Nandrolone on cardiomyopathic Hamsters: Electrophysiological, molecular, and physiological parameters. Abstract, Society of Toxicology Annual Meeting, 1998

Freeman E. Effects of nandrolone decanoate on cardiomyopathic and normal hamsters, Thesis 1998

Parsons P, Freeman E, Weidling R, Williams GL, Gill P, Byron N. Using existing knowledge for the risk evaluation of crop protection products in order to guide exposure driven data generation strategies and minimise unnecessary animal testing. Critical Reviews in Toxicology Volume 51, 2021 - Issue 7. DOI: 10.1080/10408444.2021.1987384

Talyor AA, Freeman EF, van der Ploeg MJC. Regulatory developments and their impacts to the nano-industry: A case study for nano-additives in 3D printing. Ecotoxicology and Environmental Safety 207 (2021) 111458. DOI: 10.1016/j.ecoenv.2020.111458

McArdle ME, Freeman EL, Staveley JP, Ortego LS, Coady KK, Weltje L, Weters A, Wheeler KR, Bone AJ. Critical Review of Read-Across Potential in Testing for Endocrine-Related Effects in Vertebrate Ecological Receptors. Environmental Toxicology and Chemistry—Volume 39, Number 4—pp. 739–753, 2020. DOI: 10.1002/etc.4682

Loccisano AE, Freeman E, Riffle B, Doi A, Frericks M, Ferger I, Fabian E. Afidopyropen: Challenges and impact of a toxicokinetic study designed to identify a point of inflection for dose-proportionality. Reg Tox and Pharm. 124 doi: 10.1016/j.yrtph.2021.104962.

Mealey KL, Owens KG, Freeman E. Canine and feline P-glycoprotein deficiency: What we know and where we need to go. J Vet Pharmacol Therap. 2022;00:1–16. DOI: 10.1111/jvp.13102

Project Experience

TSCA worker exposure assessments for new and existing chemicals.

Review and strategic evaluation of ToxCast and EDSP21 High Throughput Screening (HTP) data in support of international registration review for industrial and crop protection chemicals.

Toxicology lead for global regulatory toxicology and due diligence for acquisition of a FIFRA active ingredient including assessment of current and future potential issues regarding the asset.
Several assessments of the mode of action and human relevance of thyroid tumors in rats including mechanistic study design and monitoring. Including risk-based assessment to address the need for comparative thyroid assays.

Several assessments of the mode of action and human relevance of thyroid tumors in rats including mechanistic study design and monitoring.

Mode of action and human relevance of liver tumors in mice and rats and lung tumors in mice using the IPCS Human Relevance Framework including mechanistic study design and monitoring.

Global project management and toxicological testing lead for international biopesticide registration including dossiers for Australia and New Zealand, waiver from the requirements for toxicological testing for the European Union, as well as study placement and monitoring.

Assessment of the product stewardship and regulatory implications of locating a 3D Printer in an office setting.

Evaluation of toxicological data from literature, toxicological reports, publically available information, and internal databases for fragrance compounds. Identification of NOAELs for oral repeated dose systemic toxicity, acute and subchronic inhalation toxicity and reproductive toxicity for use in threshold of toxicological concern (TTC) evaluations.

QSAR modeling conducted using DEREK and review of OECD Toolbox QSAR modeling in determination of toxicological relevance of impurity and metabolite of concern relevance for FIFRA registration.

Chemical specific adjustment factor (CSAF) based on human, rat, dog and mouse pharmacokinetic data in support of EPA FIFRA pesticide reevaluation.

Design and support of dermal triple pack testing (in vivo rat, in vitro rat and in vitro human) in support of deriving a refined dermal equivalent dose for pesticides.

Waivers from immunotoxicity and neurotoxicity testing requirements under FIFRA based on review and evaluation of toxicological database, review of similar compounds, and point of departure and margin of safety in dietary and occupational health risk assessments.

Project management and toxicological support for inert pesticide submission under FIFRA.

Review, evaluation, design and integration of toxicological animal testing, target animal testing and residue testing for a veterinary API as well as laboratory animal dose selection and protocol review.

Dietary risk assessment to determine level of detection and influence on acceptable ADI for a veterinary API.

Success PMN and LVE submissions under amended TSCA (2017).

Project manager and regulatory lead for single submitter and joint PMN submissions to EPA TSCA. Included toxicological study evaluation, evaluation of potential degradation product, and overall summary document identification of endpoints for risk assessment.
Design of hazard-based classification and screening systems for internal and publicly available

prioritization projects for industrial chemicals, pesticide inerts and consumer products.

Review and evaluation of available guideline toxicology study to address whether effects on mammalian and ecological endocrine biological pathways are adequately assessed. Includes the Hypothalamus Pituitary Gonadal (HPG), Hypothalamus Pituitary Thyroid (HPT), Hypothalamus Pituitary Adrenal (HPA) Somatotropic, Vitamin D, Peroxisome proliferation activation receptor and retinoid signaling axis and pathways.

Acute toxicology and companion animal testing support for pet “spot-on” products in accordance with FIFRA and evaluation of the necessity for child protective packaging.
Refinements of inter- and intra-species uncertainty factors (CSAF) based on pharmacokinetic and pharmacodynamic data.

Toxicological re-analysis and statistical modeling for a veterinary API safety assessment.

Toxicological support for FDA GRAS and food contact submissions. Included representation of client at FDA meeting to discuss toxicological database, presentation of genotoxic weight of the evidence evaluations to FDA, participation in GRAS panel meetings, preparation of toxicological sections of GRAS dossiers, and identification of surrogate compounds for toxicological assessment.

Participated in a team that designed a relative risk ranking system to allow prioritization of products/chemicals in use based upon both hazard and exposure. The approach identified patterns of chemical use/exposures to both occupational and environmental receptors related to activities throughout the oil and gas exploration and production life cycle.

Assessment and recommendations for labelling of over the counter pet products (not FIFRA or FDA-regulated) in accordance with the Consumer Product Safety Act, the Federal Hazardous Substances Act (FHSA) and FHSA regulation including the evaluation for the necessity for child protective packaging.

EDSP Tier I submission of other scientifically relevant information (OSRI), study monitoring, data evaluation reports, and weight of the evidence submissions for pesticides.

Review and evaluation of a disposable device for measuring gluten in foods, and the components, for compliance with the FDA, EPA TSCA, Consumer Products Safety Commission Federal Hazardous Substances Act (CPSC FHSA), EPA waste regulations and State specific regulations, as well as product stewardship concerns.