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Rachel Y. Chang, Ph.D., DABT

Senior Toxicologist

Dr. Chang is a toxicologist with experience in human health risk assessment and developmental toxicology. At Gradient, her primary responsibilities include toxicological risk assessment of extractables and leachables from medical devices, safety assessments of consumer products, benchmark dose (BMD) modeling, Proposition 65 support, and toxicological risk assessment in an occupational setting. Prior to joining Gradient, Dr. Chang earned her doctoral degree at the University of Washington. Utilizing mouse models and a combination of behavioral, molecular, and histological approaches, her research focused on autism-related neurological and behavioral effects from developmental exposure to traffic-related air pollution. She has authored several peer-reviewed research articles and guest lectured in a graduate-level toxicology class at the University of Washington.

Areas of Expertise

- Toxicological Risk Assessment (TRA) of Extractables & Leachables
- Medical Device Biocompatibility
- Consumer Product Safety
- California Proposition 65
- Developmental Toxicology

Services

- Toxicology & Risk Sciences
- Air Quality Sciences
- Product Safety Assessment
- California Proposition 65
- Biocompatibility Analysis
- Biocompatibility Support
- Toxicological Risk Assessment (TRA)
- Extractable & Leachables
- Non-clinical Safety Assessment Support
- Impurity Assessments
- Permissible Daily Exposures
- Occupational Exposure Limit

Education

- Ph.D., Environmental Toxicology, University of Washington
- B.S., Biochemistry, University of Washington
- Diplomate of the American Board of Toxicology

Selected Projects

Toxicological Risk Assessment (TRA) of Extractables and Leachables from Dialysis Equipment: Conducted TRAs for compounds identified in extracts from dialysis equipment under simulated use and an exaggerated extraction protocol. In accordance with ISO 10993-17, ICH M7, and US FDA guidance, identified toxicological data for relevant endpoints and derived chemical- and device-specific safety margins.

Toxicological Risk Assessment (TRA) of Extractables and Leachables from Inhalation Medical Device: Conducted fit-for-purpose TRAs associated with inhalation exposure to extractable compounds detected in components of a respiratory device. In accordance with ISO 10993-17 and US FDA guidance, identified toxicological data for relevant endpoints and derived chemical- and device-specific safety margins. For data-poor compounds, conducted weight-of-evidence analysis and applied read-across data.

Derivation of No Significant Risk Levels (NSRLs) and Maximum Allowable Dose Level (MADLs) for Proposition 65-Listed Chemicals: Evaluated the carcinogenicity and/or reproductive and developmental potential of Proposition 65-listed chemicals, using animal toxicity and toxicokinetic data and utilizing BMD modeling to derive NSRLs and/or MADLs.

Dermal Sensitization and Irritation Hazard Assessment from Consumer Product: Conducted a dermal sensitization and irritation hazard assessment for a consumer product based on available scientific literature and quantitative structure activity relationships/structural alerts.

Toxicological Weight-of-Evidence Analysis: Performed a weight-of-evidence evaluation on toxicological effects from long-term exposure to nitrate, nitrite, and hydrogen sulfide.

Neurotoxicity Literature Review for Pesticide Exposure: Performed a literature review of neurotoxicity studies conducted with a pesticide.

Selected Publications

Chang, RY; Alverson,AK; Cohen, JM. 2022. "A Rubric for Identifying Potentially Genotoxic Polycyclic Amines and Derivation of a Chemical Class-Specific TTC." *Winner of the MDCPSS Best Poster Award.* Presented at the Society of Toxicology 61st Annual Meeting, held March 27-31.

Chang, RY; Hadley, IG; Alverson, AK; Cohen, JM. 2021. "Expert Review of Cramer Class Predictions Under Three Toxtree Modules." Presented at the Society of Toxicology Annual Meeting, virtual, April.

Chang, RY; Mohar, I; Lewandowski, T. 2020. "Risk Assessment of 1,1,1-Trifluoroethane (HFA-143a) as a Potential Impurity in HFA-134a in Metered Dose Inhaler Products." Presented at the Society of Toxicology Annual Meeting, virtual, March.

Cohen, J; **Chang, RY.** 2020. "US FDA Partial Recognition of ISO 1993-18:2020-Implications for Toxicological Risk Assessment." *MDCPSS Newsl.* 11(1):12-14, Fall.