

Joel M. Cohen, Sc.D., DABT

Senior Toxicologist

jcohen@gradientcorp.com



Dr. Cohen is a senior toxicologist with specialties in computational toxicology and human health risk assessment. At Gradient, his primary responsibilities include non-clinical safety assessments of medical device and pharmaceutical components, consumer product safety evaluation, physiologically based pharmacokinetic (PBPK) modeling, and particulate matter inhalation exposure assessment and dose modeling.

Before joining Gradient, Dr. Cohen earned his doctoral degree at the Harvard School of Public Health, applying *in vitro* cellular models to study the fate, transport and toxicity of nanoparticles in the lung. He has authored several peer-reviewed articles and one patent, and presented his work to academic and general audiences. He was a Visiting Scientist in the Molecular and Integrative Physiological Sciences Program in the Department of Environmental Health at the Harvard T.H. Chan School of Public Health through 2020.

Representative Projects

Toxicological Risk Assessment (TRA) of Extractables and Leachables from Dialysis Equipment:

Conducted toxicological risk assessments for compounds identified in extracts from dialysis equipment. In accordance with ISO 10993-17, ICH M7, and US FDA guidance, Gradient identified toxicological data for relevant endpoints and used these data to derive chemical- and device-specific safety margins. For this work, Gradient partnered with an analytical testing laboratory. The client used our TRAs to support a safety evaluation of the medical device.

Non-clinical Safety Assessment of Biopharmaceutical Impurities: Conducted human health hazard and risk assessments for potential impurities in a cell-based cancer treatment. Some of the evaluated impurities included chemical process impurities, residual viral vector, plasmid DNA, and continuous cell line residuals. We provided the client with detailed monographs on each impurity and, when possible, a permissible exposure limit for the impurity. These monographs were used by the client as manufacturing guidance and as supporting documents for regulatory applications and meetings.

Carcinogenicity Assessment of California's Proposition 65-Listed Chemical: Evaluated the carcinogenicity potential of the Proposition 65-listed fragrance chemical beta-myrcene. We reviewed animal toxicity data, including carcinogenicity studies in rodents conducted by the National Toxicology Program (NTP), and applied a linear no-threshold response extrapolation to derive a no significant risk level (NSRL). Our method was based on the anticipated approach that could be taken by the California Office of Environmental Health Hazard Assessment (CalOEHHA) and current best practices for carcinogenicity risk assessment. We also considered uncertainties in the animal carcinogenicity data and the relevance of findings to the potential for carcinogenicity in humans.

PBPK Exposure Assessment: Evaluated the significance of lead present in a variety of consumer products for comparison with Proposition 65-proposed lead limits. Performed lead modeling using the Leggett plus model to quantify the overall impact on blood lead and bone lead concentrations of intermittent intake of lead from the product as compared to the impact of a daily intake of lead at the proposed Proposition 65 limits.

Areas of Expertise

- Medical Device Biocompatibility
- Extractables and Leachables
- Pharmaceutical Non-Clinical Safety
- Consumer Product Safety
- Proposition 65
- Skin Sensitization
- Inhalation Toxicology
- Alternatives Assessment
- Nanotechnology

Education

Sc.D., Environmental Health, Harvard School of Public Health

B.A., Anthropology, Environmental Sciences and Public Health, Tufts University

Selected Publications

Cohen, J; Chang, RY. Fall 2020. "US FDA partial recognition of ISO 10993-18:2020 - Implications for toxicological risk assessment." *MDCPSS Newsl.* 11(1):12-14.

ASTM Standard WK59975, accepted for publication December 2019, "New Guide for the Derivation of Health Based Exposure Limits (HBELs)," *ASTM International*, West Conshohocken, PA.

Cohen, JM; Rice, JW; Lewandowski, TA. 2018. "Expanding the toolbox: Hazard-screening methods and tools for identifying safer chemicals in green product design." *ACS Sustain. Chem. Eng.* 6(2):1941-1950.

Petito Boyce, C; Sax, SN; **Cohen, JM.** 2017. "Particle size distributions of lead measured in battery manufacturing and secondary smelter facilities and implications in setting workplace lead exposure limits." *J. Occup. Environ. Hyg.* 14 (8) :594-608.

DeLoid, GM; **Cohen, JM;** Pyrgiotakis, G; Demokritou, P. 2017. "Preparation, characterization, and in vitro dosimetry of dispersed, engineered nanomaterials." *Nat. Protoc.* 12(2):355-371.



Science and Strategies for Health and the Environment www.gradientcorp.com

One Beacon Street, 17th Floor, Boston, MA 02108 | 617-395-5000