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Joel M. Cohen, Sc.D., DABT

Principal

Dr. Cohen is a principal 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 has 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.

Areas of Expertise

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

Services

- Toxicology & Risk Sciences
- California Proposition 65
- Biocompatibility Analysis
- Alternative Analysis
- Food & Beverages
- Food Packaging
- Biocompatibility Support
- Toxicological Risk Assessment (TRA)
- Biological Evaluation Plans
- Medical Product Liability
- Extractable & Leachables
- Non-clinical Safety Assessment Support
- Impurity Assessments
- Permissible Daily Exposures
- Occupational Exposure Limit

Education

- Sc.D., Environmental Health, Harvard School of Public Health
- B.A., Anthropology, Environmental Sciences and Public Health, Tufts University

Selected 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, 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.

Carcinogenicity Assessment of California's Proposition 65-Listed Chemical: Evaluated the carcinogenicity potential of the Proposition 65-listed fragrance chemical beta-myrcene. Reviewed animal toxicity data, including carcinogenicity studies in rodents conducted by 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 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.

Patent Litigation Regarding Syringes Pre-filled with a Biological Drug Product: Evaluated the safety profile of a polymeric coating for application in a syringe pre-filled with a biological drug product. Reviewed toxicity data and protein adsorption properties of the polymeric coating, adhering to the biological safety assessment framework detailed in the ISO 10993 series of standards. Based opinions on whether a toxicologist, as a member of a biomedical product development team, would have considered the polymeric coating to be safe for use in the pre-filled syringe. These findings were prepared in a written declaration and also presented in an oral deposition.

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.

Selected Publications

Cohen, JM; Beck, BD; Rhomberg, LR. 2021. "Historical perspective on the role of cell proliferation in carcinogenesis for DNA-reactive and non-DNA-reactive carcinogens: Arsenic as an example." *Toxicology* 456:152783. doi: 10.1016/j.tox.2021.152783.

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

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.

Lewandowski, TA; **Cohen, JM.** 2016. "Skin sensitization risk assessment: Considering available data for weight of evidence assessments." *Regul. Toxicol. Pharmacol.* doi: 10.1016/j.yrtph.2016.09.007.