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Jiaru Zhang, M.P.H., DABT

Principal Scientist

Ms. Zhang is a principal scientist and toxicologist specializing in medical device safety evaluations, regulatory compliance for industrial and consumer products, and merger and acquisition due diligence. She successfully supports medical device approvals by producing robust biocompatibility safety evaluations and toxicological risk assessments using complicated extractable datasets that stand up to regulatory scrutiny. For regulatory compliance, Ms. Zhang has led large, multi-functional teams through Toxic Substances Control Act (TSCA) audits, thousands of Globally Harmonized System of Classification and Labelling of Chemicals (GHS) hazard evaluations, and new chemical registrations. Her decades of regulatory experience translates well for merger and acquisition due diligence, where her work assigns appropriate value to the acquisitions and mitigates liability for the buyer. In addition, she actively monitors regulatory updates and toxicology of emerging contaminants, such as n (1,3-dimethylbutyl)-n'-phenyl-p-phenylenediamine (6PPD) and microplastics. Prior to joining Gradient, Ms. Zhang worked at the Fox Chase Cancer Center and at the United Nations Convention of Long-Range Transboundary Air Pollution.

Areas of Expertise

- Medical Device Biocompatibility & Toxicological Risk Assessment
- Product Stewardship
- GHS Hazard Assessment, SDS, & Labeling
- Merger & Acquisition Due Diligence
- Alternatives Assessment
- TSCA Compliance
- PFAS Reporting
- 6PPD
- Microplastics

Services

- Biocompatibility Support
- Toxicological Risk Assessment
- Toxicology & Risk Sciences
- GHS Hazard Assessment
- Product Safety Assessment
- Chemical Portfolio Hazard/Risk Analysis
- Third-Party Profiling
- Alternatives Assessment
- Toxic Substances Control Act (TSCA)
- Environmental, Social & Governance (ESG)

Education

- M.P.H., Environmental Health Sciences & Policy, Columbia University Mailman School of Public Health
- B.S., Biology, Geography, Villanova University
- Diplomate of the American Board of Toxicology

Selected Projects

Medical Device Biocompatibility Approval: For a variety of devices, developed customized testing strategies and provided consulting support throughout the entire biological evaluation process to support compliance with the requirements of ISO 10993/18562, US FDA, and EU Medical Device Regulation (EU MDR). Leveraging existing data whenever possible, produced gap assessments and biological evaluation plans/reports that attributed to successful device approvals.

Medical Device Toxicological Risk Assessment: For a variety of devices and 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 gaps, identified robust read-across and used state-of-the-art modeling programs to assess potential hazards. For large datasets, identified efficient and defensible approaches to narrow the scope, and produced clinically relevant toxicological risk assessments. Our reports assisted in the US FDA and EU MDR product approvals.

Toxicological Hazard Evaluation, SDS, and Labeling: Managed a large team to provide GHS hazard evaluations of thousands of chemicals. Identified appropriate read-across in the absence of toxicological data. The hazard evaluations were used for compliant SDSs globally. Spearheaded the database automation of product-level hazard classifications. Collaborated with external IT firm to expand client's existing chemical compliance database by automating TSCA reporting requirements.

Alternative Assessment for 6PPD: Conducted alternative assessment (AA) for 6PPD in motor vehicle tires under California's Safer Consumer Products (SCP) Program. Working with a consortium, identified and evaluated potential alternatives to prioritized chemical, aiming to identify safer alternatives. Gradient's evaluation was submitted and accepted by regulators.

Merger and Acquisition: During an environmental due diligence for a buyer, confirmed known details, uncovered potential deal-breaking issues, and assessed level of effort for post-integration work. Our findings informed the representation and warranty insurance for this acquisition.

Selected Publications and Presentations

Lewandowski, TA; **Zhang, J;** Cohen, J. 2024. "The Role of Toxicology in Alternatives Assessment for Sustainable Chemistries: Challenges and Opportunities." Presented at the 12th Congress of Toxicology in Developing Countries (CTDC), Santiago, Chile, April 15-18.

Zhang, J. 2023. "What the Regulations Don't Tell You About Medical Devices: Differences in Expectations Between US FDA CDRH and EU MDR for E&L and Biocompatibility." Presented at the Pharma Ed Resources Extractables & Leachables Summit 2023, Philadelphia, PA, April 17, 18p.

Zhang, J; Marsh, C; Reid, K; Harmon, P. [Gradient; BASF]. 2022. "A Trade Name Market Differentiator: Case Studies Under the ChemFORWARD SAFER™ Program." Presented at the SETAC North America 43rd Annual Meeting, Pittsburgh, PA, November 13-17, 12p.