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(she/her)

Areas of Expertise

- Medical Device Regulations
- Biocompatibility & Risk Assessment
- Pharmaceutical Non-clinical Safety Assessment
- Developmental & Reproductive Toxicology
- Environmental Toxicology

Education

- Ph.D., Environmental Toxicology, University of North Carolina at Chapel Hill
- M.S., Environmental Toxicology, University of North Carolina at Chapel Hill
- B.S., Biological Science, *magna cum laude*, Virginia Tech
- Diplomate of the American Board of Toxicology (DABT)

Cassandra J. Meakin, Ph.D., DABT

Senior Toxicologist

Dr. Meakin is a board-certified toxicologist with expertise in biological safety evaluations and toxicological risk assessments for medical devices and pharmaceuticals. Her work involves evaluating human health risks associated with chemical exposures and supporting regulatory compliance for US and international agencies, including the US FDA, the EU, and others. She has extensive experience assessing data in alignment with ISO 10993, ICH, and other global standards. Before joining Gradient, Dr. Meakin earned a doctorate from the University of North Carolina at Chapel Hill and completed a postdoctoral fellowship at Rutgers University. She has authored several peer-reviewed publications and remains active in the scientific community through leadership roles in the Society of Toxicology and other professional organizations.

Selected Projects

PFAS Exposure Assessment: Reviewed scientific literature and US EPA and National Toxicology Program (NTP) evaluations of health effects, including immunotoxicity, cancer, and reproductive outcomes, from exposure to per- and polyfluoroalkyl substances (PFAS).

Biological Safety Assessment: Conducted biological safety assessments on routine materials and manufacturing changes. Authored justifications for waiving testing, when feasible, or designed test plans to minimize cost while re establishing safety.

Chemical Equivalency Study: Designed and conducted chemical equivalency studies in accordance with ISO 10993-18, Annex C for limited- and prolonged-duration medical devices to support manufacturing changes.

Medical Device Biological Safety Evaluation: Developed and conducted biological safety evaluation strategies for implantable medical port and catheter system medical devices. Authored biological safety evaluation plans and reports inclusive of *in vivo* and *in vitro* biocompatibility results, chemical characterization evaluations to address drug compatibility, toxicological risk assessments, material and manufacturing analyses, and justifications for non-testing.

Biological Safety Evaluation: Developed and conducted biological safety evaluation strategies for a contrast media delivery system. Authored biological safety evaluation plans and reports inclusive of *in vivo* and *in vitro* biocompatibility results, chemical characterization evaluations to address drug compatibility, toxicological risk assessments, material and manufacturing analyses, and justifications for non-testing.

Selected Publications and Presentations

Meakin, C; Borton, L. 2026. "Identification of Chemicals of Endocrine and Reproductive Concern in Medical Device Extractables and Leachables Datasets." Presented at the Society of Toxicology (SOT) 65th Annual Meeting and ToxExpo, San Diego, CA, March.

Kearing, S; **Meakin, C;** Borton, L. 2026. "Integrating Total Organic Carbon (TOC) Analysis into Chemical Characterization for Toxicological Risk Assessment: A Case Study Evaluating the Relationship Between TOC and Gravimetric Residues." Presented at the Society of Toxicology (SOT) 65th Annual Meeting and ToxExpo, San Diego, CA, March.

Kearing, S; **Meakin, C;** Borton, L. 2025. "What Value Does Total Organic Carbon (TOC) Analysis Provide to Chemical Characterization Data? A Case Study Examining the Capabilities of TOC and Where They Intersect with Gravimetric Analysis for Residue Determination." Presented at the North American Biocompatibility Summit (NABS), Minneapolis, MN, September.

Pruett, R; **Meakin, C;** Drury, N; Goodman, J. 2024. "Evaluation of neural reflex activation as a potential mode of action for respiratory and cardiovascular effects of fine particulate matter." *Inhal. Toxicol.* 36(3):125-144.

Meakin, C; Aleksunes, L. 2022. "High-throughput screening of toxicants that modulate extravillous trophoblast migration." *Toxicol. Lett.* 375:1-7.