Katherine.Roach@gradientcorp.com

(617) 395-5034

(she/her)

Areas of Expertise

- Medical Device Biocompatibility
- Hemocompatibility Testing
- Immunotoxicology & Allergic Disease
- Inhalation Toxicology & Risk Assessment
- Nanotoxicology & Material Physicochemical Characterization
- Occupational Health & Safety
- Metals Toxicology
- Animal Models of Human Disease

Education

- Ph.D., Pharmaceutical and Pharmacological Sciences, West Virginia University
- M.P.H., Environmental and Occupational Health, West Virginia University
- B.S., Microbiology, Clemson University
- Diplomate of the American Board of Toxicology (DABT)

Katherine (Katie) A. Roach, Ph.D., M.P.H., DABT

Senior Toxicologist

Dr. Roach is a board-certified toxicologist specializing in medical device biocompatibility and human health risk assessment. At Gradient, she specializes in hemocompatibility and immunotoxicity to help companies with blood-contacting devices understand applicable regulations and standards, design studies, orchestrate appropriate testing and analyses, and interpret results to support medical device safety and regulatory approval. Dr. Roach has a unique scientific perspective from her background in identifying, understanding, and addressing complex biocompatibility issues that arise on the mechanistic/molecular level. Prior to joining Gradient, Dr. Roach worked for the Centers for Disease Control and Prevention (CDC) where she studied mechanisms of metal hypersensitivity in the context of workplace nanomaterial exposures. During her postdoctoral fellowship at the National Institutes of Occupational Safety and Health (NIOSH), she studied the immunology of mixed-type metal allergies in a novel transgenic mouse model.

Selected Projects

Biological Safety Evaluation: Developed and conducted biological safety evaluations for submission to the US FDA and EU Medical Device Regulation (MDR). Authored biological safety evaluations inclusive of *in vivo* and *in vitro* biocompatibility results, chemical characterization evaluations, toxicological risk assessments (TRAs), material and manufacturing analyses, and justifications for non-testing.

Medical Device Biocompatibility: Performed gap assessments to EU MDR and US FDA regulations and developed remediation strategies. Authored biological safety report inclusive of justifications for waiving endpoints using existing data and literature.

Medical Device Biocompatibility: Attended US FDA pre-submission meetings, authored responses to US FDA and EU Notified Body deficiencies, and developed strategies to achieve compliance to EU MDR, US FDA, and ISO 10993 expectations.

Toxicological Risk Assessment: Conducted TRAs for compounds identified in extracts from dialysis equipment under simulated use and exaggerated extraction protocols. 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.

Hemocompatibility Assessment: Developed and conducted blood safety evaluation strategies for a family of fluid administration sets. Authored biological safety evaluation plans, conducted literature reviews, wrote laboratory protocols, and compiled data reports inclusive of *in vivo* and *in vitro* hemocompatibility results.

Selected Publications and Presentations

Gauthier, AG; **Roach, KA.** 2025. "Risk-Based Framework for Evaluating Toxicological Potentiation Among Structurally Diverse, Non-grouped Extractables." Presented at the North American Biocompatibility Summit (NABS), Minneapolis, MN, September 10.

Roach, K; Khazaee, M; Mohar, I; Gauthier, A. 2025. "A prospective ICH S1B(R1) Weight-of-Evidence Carcinogenicity Assessment for GLP-1 Receptor Agonists and Two-Year Rat Bioassays." Abstract/Poster # 4703/J541. Presented at the Society of Toxicology (SOT) 64th Annual Meeting and ToxExpo, Orlando, FL, March 16-20.

Roach, K; Anderson, S; Waggy, C; Aldinger, J; Stefaniak, A; Roberts, J. 2024. "Assessment of dermal sensitization by nickel salts in a novel humanized TLR-4 mouse model." *J. Immunotoxicol.* 21(1).

Aldinger, J; **Roach, K;** Meighan, T; Roberts, J; Barber, T. 2024. "Induction of miR-21-PDCD4 signaling and transformation by freshly fractured crystalline silica in JB6 or BEAS-2B cells." *Appl. Vitro. Tox.* 10(4).

Roach, K; Kodali, V; Shoeb, M; Meighan, T; Kashon, M; Stone, S; McKinney, W; Erdely, A; Zeidler-Erdely, P; Roberts, J; Antonini, J. 2023. "Examination of the exposome in an animal model: The impact of high fat diet and rat strain on local and systemic immune markers following occupational welding fume exposure." *Toxicol. Appl. Pharmacol.* 464:116436.