



Alex.Gauthier@gradientcorp.com

(617) 395-5016

Alex G. Gauthier, Ph.D.

Senior Toxicologist

Dr. Gauthier is a toxicologist specializing in medical device biocompatibility, toxicological risk assessment, pharmaceutical nonclinical safety assessment, and large animal safety and efficacy studies. Prior to joining Gradient, Dr. Gauthier was a medical device biocompatibility scientist and toxicologist at a leading medical technology company, and a preclinical toxicology study director at a global contract research company. Dr. Gauthier did his postdoctoral fellowship at Massachusetts Eye and Ear/Harvard Medical School, where he investigated sex-specific differences and autologous stem cell therapy in clinical trial patients with corneal disease. He earned his doctorate in toxicology at St. John's University, where he investigated novel therapies for ventilator-associated pneumonia, acute lung injury, and cystic fibrosis.

Selected Projects

Medical Device Biocompatibility: Conducted biological safety protocol development and evaluations for various lines of medical devices in accordance with ISO 10993 for submission to US FDA and European Medical Device Regulation (EU MDR).

Toxicological Risk Assessment: Conducted a toxicological risk assessment on talc as a material additive for components used in ventilator devices. Utilized material and physical characterization techniques to determine worst-case talc content in device components.

Pharmaceutical Impurity Risk Assessment: Conducted risk assessment of pharmaceutical impurities in a drug delivery system. Performed ICH M7(R2) genotoxicity assessment using *in silico* prediction tools.

Pharmaceutical Nonclinical Safety Testing: Evaluated and recommended testing strategies for a peptide drug product according to ICH M6(R1) and ICH M3(R2).

Consumer Product Safety Assessment: Developed biological safety and risk evaluation strategies for wearable medical devices compliant to US FDA regulations. Performed literature and predicate device review for comparative research.

Areas of Expertise

- Medical Device Biocompatibility
- Toxicological Risk Assessment of Extractables & Leachables
- Material Characterization
- Supplier Change Assessment
- Pharmaceutical Nonclinical Safety Assessment

Education

- Ph.D., Toxicology, St. John's University
- B.S., Biochemistry, Hofstra University

Selected Publications and Presentations

Gauthier, AG; Dugan, TW; Gadol, HJ. 2024. "Application of a 3D QSAR Approach for the Re-evaluation of Organophosphorus Compounds for Cohort of Concern Identification." Presented at the Society of Toxicology (SOT) 63rd Annual Meeting and ToxExpo, Salt Lake City, UT, March 10-14.

Jurkunas, U; Yin, J; Johns, L; Li, S; Negre, H; Shaw, K; Samarakoon, L; Ayala, A; Kheirkhan, A; Katikireddy, K; **Gauthier, A;** Ong Tone, S; Kaufman, A; Ellender, S; Hernandez Rodriguez, D; Daley, H; Dana, R; Armant, M; Ritz, J. 2023. "Cultivated autologous limbal epithelial cell (CALEC) transplantation: Development of manufacturing process and clinical evaluation of feasibility and safety." *Sci. Adv.* 9(33):eadg6470. doi: 10.1126/sciadv.adg6470.

Gauthier, AG; Lin, M; Zefi, S; Kulkarni, A; Thakur, GA; Ashby, CR; Mantell, LL. 2023. "GAT107-mediated $\alpha 7$ nicotinic acetylcholine receptor signaling attenuates inflammatory lung injury and mortality in a mouse model of ventilator-associated pneumonia by alleviating macrophage mitochondrial oxidative stress via reducing MnSOD-S-glutathionylation." *Redox Biol.* 60:102614. doi: 10.1016/j.redox.2023.102614.

Gauthier, AG. 2023. "Considerations for Toxicological Risk Assessment of Hindered Phenolic Antioxidants in Accelerated Aged Devices." Presented at the Society of Toxicology (SOT) 62nd Annual Meeting and ToxExpo, Nashville, TN, March 19-23.

Gauthier, AG; Wu, J; Lin, M; Sitapara, R; Kulkarni, A; Thakur, GA; Schmidt, EE; Perron, JC; Ashby Jr, CR; Mantell, LL. 2021. "The positive allosteric modulation of $\alpha 7$ -nicotinic cholinergic receptors by GAT107 increases bacterial lung clearance in hyperoxic mice by decreasing oxidative stress in macrophages." *Antioxidants* 10(1):135. doi: 10.3390/antiox10010135.