Tyler Nicholas, PhD, DABT

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Summary

Board-certified product stewardship toxicologist with experience across nonclinical, product quality, and occupational toxicology. Provides strategic scientific leadership across R&D and commercial programs, translating toxicological evidence into health-based exposure limits and risk management strategies that protect patients and workers across the medicine lifecycle.

Education

2019 **PhD, Toxicology** — University of Washington

2014 **MS, Environmental Health** — University of Washington

2012 **BS, Environmental Health** — University of Rochester

Certification

2023–Present **Diplomate of the American Board of Toxicology (DABT)** — American Board of Toxicology

Experience

Industry Experience

2026–Present **Senior Principal Scientist, Product Stewardship Toxicology** — Amgen

2024–2026 **Senior Scientific Manager, Product Quality and Occupational Toxicology** — Genentech

- Led occupational toxicology strategy, overseeing occupational exposure bands (OEBs), occupational exposure limits (OELs), and safety data sheets (SDSs).
- Guided product quality toxicology decisions involving acceptable daily exposures (ADEs), extractables and leachables (E&L), and quality excursions (QEs).
- Led risk assessment strategy for 70–85 programs in a 200+ program portfolio; authored 300+ risk assessments informing product stewardship decisions.
- Developed and harmonized scientific guidance across three R&D organizations within the Roche Group for deriving ADEs and OELs and assigning OEBs.
- Reviewed and approved ADE, OEL, and OEB assessments, collaborating with project toxicologists and pathologists to ensure scientifically defensible interpretations.
- Shaped product quality strategy through governance committees, including the Process Impurities Technical Forum and Critical Quality Attribute Forum.
- Directed external consultants supporting SDS and product quality risk assessments, overseeing budgets, scientific direction, and deliverable approval.
- Recruited and supervised two interns, providing scientific mentorship, technical guidance, and oversight of research projects from planning through completion.

2021–2024 **Scientist, Toxicology** — Seagen (acquired by Pfizer)

- Served as portfolio toxicologist for antibody-drug conjugate (ADC) programs, integrating nonclinical safety data into drug development strategy and decisions.
- Directed Good Laboratory Practice (GLP) studies at contract research organizations, ensuring protocol compliance, study quality, and effective execution.
- Investigated mechanisms of toxicity and emerging safety liabilities, presenting risk-based recommendations to project teams and governance committees.
- Helped establish product quality and occupational toxicology capabilities through cross-functional collaboration.

2019–2021 **Scientist, Toxicology** — Exponent

- Established toxicology-based limits for process impurities and raw materials, supporting pharmaceutical specifications and health authority submissions.
- Applied ISO 10993 guidance to extractables and leachables risk assessments for pharmaceuticals, medical devices, and combination products.
- Developed ISO 10993-aligned biocompatibility testing strategies and toxicological evaluations supporting medical device and combination product approvals.

Research Experience

2014–2019 **Research Assistant, Altemeier Lab** — University of Washington

- Developed organotypic airway cultures to model genotype-phenotype interactions on engineered nanomaterial toxicity across normal and asthmatic phenotypes.
- Integrated gene expression, high-content imaging, and biomarker assays to characterize barrier dysfunction, cytotoxicity, oxidative stress, and cytokine release.
- Quantified particle kinetics and dosimetry using inductively coupled plasma-mass spectrometry and modeled dose-response relationships in R.
- Combined RNA sequencing, pathway analysis, and Western blotting to identify and confirm transcriptional pathways and upstream regulators of toxicity.
- Applied in vitro-to-in vivo extrapolation and Adverse Outcome Pathway frameworks to translate mechanistic findings and predict respiratory toxicity.

2012–2014 **Research Assistant, Kaufman Lab** — University of Washington

- Characterized indoor, outdoor, and in-vehicle contributions to air pollution exposure in the Multi-Ethnic Study of Atherosclerosis and Air Pollution cohort.
- Quantified air pollutant concentrations in microenvironmental samples using ion-exchange chromatography.
- Analyzed time-weighted models in SAS to estimate the influence of individual microenvironments on participants' air-pollution exposure.

2010–2012 **Research Assistant, van Wijngaarden Lab** — University of Rochester

- Integrated analytical measurements and self-reported dietary data to characterize mercury exposure in the Seychelles Child Development Study cohort.
- Quantified mercury concentrations in fish from subsistence fishing communities using atomic absorption spectroscopy.
- Analyzed dose-simulation models in SAS to estimate the contribution of fish consumption to participants' mercury exposure.

Teaching Experience

2018 **Teaching Assistant, ENV H 305: Environmental Health** — University of Washington

2018 **Teaching Assistant, ENV H 577: Risk Assessment** — University of Washington

Publications

01 **Nicholas T**, Morinello E, Moudgal C, Beaulieu A, Graham J. Considerations for Establishing Occupational Exposure Limits for Small Molecule Kinase Inhibitors in Drug Development. *Frontiers in Toxicology*. 2026.

02 Graham J, Anand S, Bercu J, Besenhofer L, de Zafra C, Feng Y, Glowienke S, Hillegass J, Hutchinson R, Jolly R, Masuda-Herrera M, **Nicholas T**, Olszova D, Schmitz M, Semmelmann F, Tien E. Assessment and Control of Host Cell Proteins in Biologics: Survey of Industry Practices and a Vision for Harmonization. *Biotechnology and Bioengineering*. 2025.

03 Abdelhamed S, Zhang X, Zeng W, Grogan B, Schilperoort L, James R, Burley K, Sarrett S, Bou L, Raha P, Olson D, Sigurjonsson H, Dominguez M, **Nicholas T**, Fishburn J, Lim A, Diolaiti D, Gupta P, Abrahams C, Carosino C, Heiser R, Gardai S, Levengood M. Preclinical Development of PF-08046032: A Novel, Investigational CD25-Directed Antibody-Drug Conjugate Optimized for Selective Depletion of Regulatory T Cells in Advanced Malignant Tumors. *Molecular Cancer Therapeutics*. 2025.

04 Graham J, Anand S, Bercu J, Besenhofer L, de Zafra C, Feng Y, Fisher C, Hillegass J, Hutchinson R, Jolly R, Moudgal C, **Nicholas T,** Olszova D, Schmitz M, Semmelmann F. Safety Assessment of Protein A and Derivation of a Parenteral Health-Based Exposure Limit. *Regulatory Toxicology and Pharmacology*. 2024.

05 Zareba G, Harrington D, Scrimale T, Lesperance A, Watson G, van Wijngaarden E, Shamlaye C, **Nicholas T**, Myers G, Thurston S. Relationship of Mercury and Selenium in Ocean Fish Frequently Consumed in the Seychelles: A Comparison to Levels in Ocean Fish Consumed in the US. *Neurotoxicology*. 2023.

06 **Nicholas T**, Boyes W, Scoville D, Workman T, Kavanagh T, Altemeier W, Faustman E. The Effects of Gene × Environment Interactions on Silver Nanoparticle Toxicity in the Respiratory System: An Adverse Outcome Pathway. *WIREs Nanomedicine and Nanobiotechnology*. 2021.

07 **Nicholas T**, Haick A, Workman T, Griffith W, Nolin J, Kavanagh T, Faustman E, Altemeier W. The Effects of Genotype × Phenotype Interactions on Silver Nanoparticle Toxicity in Organotypic Cultures of Murine Tracheal Epithelial Cells. *Nanotoxicology*. 2020.

08 **Nicholas T**, Haick A, Bammler T, Workman T, Kavanagh T, Faustman E, Gharib S, Altemeier W. The Effects of Genotype × Phenotype Interactions on Transcriptional Response to Silver Nanoparticle Toxicity in Organotypic Cultures of Murine Tracheal Epithelial Cells. *Toxicological Sciences*. 2020.

09 **Nicholas T**, Kavanagh T, Faustman E, Altemeier W. The Effects of Gene × Environment Interactions on Silver Nanoparticle Toxicity in the Respiratory System. *Chemical Research in Toxicology*. 2019.

10 Hazlehurst M, Spalt E, **Nicholas T**, Curl C, Davey M, Burke G, Watson K, Vedal S, Kaufman J. Contribution of the In-Vehicle Microenvironment to Individual Ambient-Source Nitrogen Dioxide Exposure: The Multi-Ethnic Study of Atherosclerosis and Air Pollution. *Journal of Exposure Science and Environmental Epidemiology*. 2018.

Presentations

Oral Presentations

01 **Nicholas T**, et al. *The Effects of Gene × Environment Interactions on Silver Nanoparticle Toxicity in the Respiratory System: Towards an Adverse Outcome Pathway*. Pacific Northwest Association of Toxicologists (PANWAT) Annual Meeting, Corvallis, OR, 2019.

02 **Nicholas T**, et al. *The Effects of Genotype × Phenotype Interactions on Transcriptional Response to Silver Nanoparticle Toxicity in Airway Epithelium Organotypic Culture Models*. PANWAT Annual Meeting, Bothell, WA, 2018.

03 **Nicholas T**, et al. *The Effects of Genotype × Phenotype Interactions on Silver Nanoparticle Toxicity in Airway Epithelium Organotypic Culture Models*. PANWAT Annual Meeting, Corvallis, OR, 2017.

04 **Nicholas T**, et al. *Optimization of Airway Epithelium Organotypic Culture Models as a Platform for Adverse Outcome Pathway Assessment of Engineered Nanomaterials*. PANWAT Annual Meeting, Bothell, WA, 2016.

05 **Nicholas T**, et al. *Using Time-Weighted Models to Predict Ambient Sources of Traffic-Related Air Pollution Exposure in the Multi-Ethnic Study of Atherosclerosis and Air Pollution*. Cascadia Annual Symposium on Environmental, Occupational, and Population Health, Blaine, WA, 2015.

Poster Presentations

01 **Nicholas T**, et al. *Considerations for Establishing Health-Based Exposure Limits for Small Molecule Kinase Inhibitors*. American College of Toxicology (ACT) Annual Meeting, Austin, TX, 2024.

02 **Nicholas T**, et al. *The Effects of Gene × Environment Interactions on Silver Nanoparticle Toxicity in the Respiratory System: Towards an Adverse Outcome Pathway*. Society of Toxicology (SOT) Annual Meeting, Virtual, 2020.

03 **Nicholas T**, et al. *The Effects of Genotype × Phenotype Interactions on Transcriptional Response to Silver Nanoparticle Toxicity in Airway Epithelium Organotypic Culture Models*. SOT Annual Meeting, Baltimore, MD, 2019.

04 **Nicholas T**, et al. *The Effects of Genotype × Phenotype Interactions on Silver Nanoparticle Toxicity in Airway Epithelium Organotypic Culture Models*. SOT Annual Meeting, San Antonio, TX, 2018.

05 **Nicholas T**, et al. *Optimization of Airway Epithelium Organotypic Culture Models as a Platform for Adverse Outcome Pathway Assessment of Engineered Nanomaterials*. SOT Annual Meeting, Baltimore, MD, 2017.

06 **Nicholas T**, et al. *Optimization of Airway Epithelium Organotypic Culture Models as a Platform for Adverse Outcome Pathway Assessment of Engineered Nanomaterials*. Tenth World Congress on Alternatives and Animal Use, Seattle, WA, 2017.

07 **Nicholas T**, et al. *Using Time-Weighted Models to Predict Ambient Sources of Traffic-Related Air Pollution Exposure in the Multi-Ethnic Study of Atherosclerosis and Air Pollution*. International Society for Environmental Epidemiology (ISEE) Annual Meeting, Seattle, WA, 2014.

08 **Nicholas T**, et al. *Using Dose-Simulation Models to Predict Dietary Sources of Mercury Exposure in the Seychelles Child Development Study*. National Conference on Undergraduate Research (NCUR) Annual Meeting, Ogden, UT, 2012.

09 **Nicholas T**, et al. *Using Dose-Simulation Models to Predict Dietary Sources of Mercury Exposure in the Seychelles Child Development Study*. Annual Biomedical Research Conference for Minority Students (ABRCMS) Annual Meeting, St. Louis, MO, 2011.

Service

Academic Service

2023–Present **Affiliate Assistant Professor, Department of Environmental and Occupational Health Sciences** — University of Washington

2021–Present **Member, External Advisory Committee, Department of Environmental and Occupational Health Sciences** — University of Washington

2016–2018 **Member, Provost's Advisory Council for Students** — University of Washington

2016–2018 **Member, Dean's Advisory Council for Students** — University of Washington

Professional Service

2022–Present **Member, Impurities and Biologics Impurities Working Groups** — IQ Consortium

2016–Present **Member, Society of Toxicology**

- Councilor, Pacific Northwest Association of Toxicologists (2021–2023)
- Councilor, Out Toxicologists and Allies Special Interest Group (2019–2021)

Community Service

2016–2019 **Fellow, Science Communication Program** — Pacific Science Center

2008–2012 **Member, Medical Emergency Response Team** — University of Rochester

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Awards and Honors

2024 **Development Sciences Award for Collaborative Excellence** — Genentech

2021–2023 **Impact Award** — Seagen (acquired by Pfizer)

2018 **Final Year Dissertation Fellowship** — University of Washington

2015 **Environmental Pathology and Toxicology Training Grant** — University of Washington

2015 **Medical Aid and Accident Grant** — Washington State Department of Labor and Industries

2012 **Ronald E. McNair Graduate Fellowship** — University of Washington

2008 **Renaissance Scholarship** — University of Rochester