

Tyler Nicholas, PhD, DABT

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Professional Summary

Board-certified toxicologist specializing in product stewardship toxicology with experience spanning nonclinical drug development, occupational toxicology, product quality toxicology, extractables and leachables, and process-related impurities. Provides strategic scientific leadership across CMC, EHS, Quality, and Regulatory Affairs in support of a portfolio of more than 200 development and commercial programs, translating toxicological evidence into health-based exposure limits and risk management strategies that protect patients and workers across the medicine lifecycle. Author of peer-reviewed publications on occupational exposure limits and pharmaceutical toxicology.

Education

2019	PhD, Toxicology University of Washington
2014	MS, Environmental Health University of Washington
2012	BS, Environmental Health University of Rochester

Certification

2023 – Present	DABT, Diplomate of the American Board of Toxicology American Board of Toxicology
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Experience

Industry Experience

2024 – Present	Senior Scientific Manager, Product Quality and Occupational Toxicology Genentech <i>Strategic & Scientific Leadership</i>
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- Lead occupational toxicology strategy across the 220+ program portfolio and serve as the point of contact for Occupational Exposure Band (OEB), Occupational Exposure Limit (OEL), and Safety Data Sheet (SDS) support.
- Support portfolio-wide product quality toxicology strategy spanning Acceptable Daily Exposures (ADE), Dose Regimen Correction Factors (DRCF), Toxicology-Based Limits (TBL), Extractables and Leachables (E&L), and quality excursions.
- Provide hands-on product quality and occupational toxicology support for 70–85 development and commercial programs.
- Personally authored 200+ product quality and occupational toxicology assessments informing decisions for hundreds of stakeholders across the Roche Group.
- Review and approve ADE, OEB, and OEL assessments used across the Roche Group; partner with program toxicologists to align supporting data and scientific interpretations.
- Developed Roche-wide scientific guidance and standardized methods for deriving ADE, DRCF, OEB, and OEL values.
- Conduct E&L and quality excursion assessments supporting container-closure selection, specifications, and health authority responses.
- Oversee external consultants supporting SDS and product quality toxicology assessments, including budgets, scientific direction, and deliverable approval.

Operational & Governance Leadership

- Manage assessment intake, program reviews, portfolio planning, and prioritization.
- Influence product quality strategy through enterprise technical governance committees, including the Process Impurities Technical Forum and the Critical Quality Attribute Forum.
- Co-developed a process improving cross-functional collaboration with Roche occupational toxicology colleagues.

People Leadership

- Recruited and supervised two interns, providing mentorship and technical oversight.

2021 – 2024

Toxicologist

Seagen (now Pfizer)

Project Toxicology

- Served as toxicologist for antibody-drug conjugate (ADC) programs, integrating nonclinical safety data into development strategy and cross-functional decisions.
- Designed and interpreted toxicology studies supporting regulatory submissions, technical reports, and peer-reviewed manuscripts.

- 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.

Product Quality and Occupational Toxicology

- Contributed to building Seagen's Product Quality and Occupational Toxicology capability in partnership with Chemistry, Manufacturing, and Controls (CMC), Environmental Health and Safety (EHS), Quality, and Regulatory Affairs.
- Aligned health-based exposure limit assessments between Seagen and Pfizer, maintaining scientific continuity during organizational integration.
- Personally authored 50+ ADE and TBL assessments supporting cleaning validation and specifications for process impurities and raw materials.
- Conducted E&L and quality excursion assessments supporting container-closure selection, specifications, and health authority responses.
- Conducted environmental risk assessments supporting management of the ecological impacts of pharmaceutical products.
- Oversaw external consultants supporting SDS and occupational toxicology assessments, including budgets, scientific direction, and deliverable approval.

2019 – 2021

Toxicologist

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

Graduate Research Assistant

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

Graduate Research Assistant

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

Undergraduate Research Assistant

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

Graduate Teaching Assistant, ENVH 305: Environmental Poisons and Public Health
University of Washington

2017

Graduate Teaching Assistant, ENVH 577: Risk Assessment
University of Washington

Awards and Honors

2024

Development Sciences Award for Collaborative Excellence

Genentech

- Contributed to a project that used *in silico* models for acute oral toxicity predictions to rule out dangerous goods classifications for small molecule shipments.

2021 – 2023

Impact Awards for Helping Patients, Scientific Excellence, and Fostering Teamwork

Seagen (now Pfizer)

- Fostered cross-functional collaboration across nonclinical sciences, environmental health and safety, and chemical manufacturing and controls teams.
- Derived toxicology-based limits for process impurities, enabling drug product specifications for a regulatory submission within a tight timeline.
- Conducted an extractable and leachable study to guide the selection of a new pharmaceutical container closure system within a tight timeline.
- Guided mass spectrometry method development for an extractable and leachable study for a marketed product within a tight timeline.

2021

Nominated: HERO Award for Collaborative Excellence

Exponent

- Contributed to a project that used an extractable and leachable study to evaluate impurity risks and enable regulatory approval of a medical device.

2018

Graduate Student Equity & Excellence Dissertation Fellowship

University of Washington

- One year of tuition and stipend awarded to predoctoral trainees from underrepresented backgrounds in the final year of graduate education.

2018

Student Travel Award

Society of Toxicology

- Funding awarded to predoctoral trainees delivering an oral or poster presentation at the Society of Toxicology annual meeting.

2016

Science Communication Fellowship

Pacific Science Center

- Participated in a program that prepared predoctoral trainees to develop a hands-on activity related to their research for teaching and engaging a general audience.

2015

NIH T32 ES007032-38: Environmental Pathology and Toxicology Training Grant

University of Washington

- Three years of tuition and stipend awarded to predoctoral trainees engaged in research on cellular and molecular mechanisms of toxicity.

- 2015
- Medical Aid and Accident Grant**
Washington State Department of Labor and Industries
- Funding awarded to predoctoral trainees engaged in research on regional and emerging needs in occupational health and safety.
- 2012
- Ronald E. McNair Graduate Fellowship**
University of Washington
- Two years of tuition and stipend awarded to master's or predoctoral trainees that participated in the Ronald E. McNair Post-Baccalaureate Achievement Program.
- 2012
- Student Life Award for Excellence in Creative Co-Sponsorship**
University of Rochester
- Organized a benefit concert for the American Cancer Society, co-sponsored by the Renaissance Scholars and the Society of Undergraduate Public Health Students.
- 2012
- Student Travel Award**
Council on Undergraduate Research
- Funding awarded to undergraduate trainees delivering a presentation at the National Conference on Undergraduate Research annual meeting.
- 2011
- Student Travel Award**
American Society for Microbiology
- Funding awarded to undergraduate trainees delivering a presentation at the Annual Biomedical Research Conference for Minoritized Scientists annual meeting.
- 2010
- Ronald E. McNair Post-Baccalaureate Achievement Program**
University of Rochester
- Participated in a national program that prepared undergraduate trainees from underrepresented backgrounds with potential to succeed in graduate education.
- 2008
- Renaissance Scholarship**
University of Rochester
- Selected from the top 1% of over 20,000 applications for a full-tuition, merit-based scholarship to attend the University of Rochester.

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 – Occupational Toxicology*. 2026. [PMID: 41960283](#).
- 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. [PMID: 41517894](#).
- 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. [PMID: 40293942](#).
- 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. [PMID: 39243930](#).
- 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. [PMID: 37678724](#).
- 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. [PMID: 33768701](#).
- 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. [PMID: 32574512](#).
- 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. [PMID: 31562762](#).
- 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. [PMID: 31124663](#).
- 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. [PMID: 29511286](#).

Presentations

Oral Presentations

- 01 **Nicholas T**, Boyes W, Scoville D, Kavanagh T, Altemeier W, Faustman E. The Effects of Gene × Environment Interactions on Silver Nanoparticle Toxicity in the Respiratory System: Towards an Adverse Outcome Pathway. *Predictive Toxicology Centers Progress Review*, Research Triangle Park, NC. 2019.
- 02 **Nicholas T**, Haick A, Workman T, Bammler T, Kavanagh T, Faustman E, Gharib S, Altemeier W. The Effects of Genotype × Phenotype Interactions on Transcriptional Response to Silver Nanoparticle Toxicity in Airway Epithelium Organotypic Culture Models. *PANWAT*, Bothell, WA. 2018.
- 03 **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 Airway Epithelium Organotypic Culture Models. *PANWAT*, Corvallis, OR. 2017.
- 04 **Nicholas T**, Haick A, Workman T, Griffith W, Nolin J, Kavanagh T, Faustman E, Altemeier W. Optimization of Airway Epithelium Organotypic Culture Models as a Platform for Adverse Outcome Pathway Assessment of Engineered Nanomaterials. *PANWAT*, Bothell, WA. 2016.
- 05 **Nicholas T**, Hazlehurst M, Spalt E, Curl C, Davey M, Burke G, Watson K, Vedal S, Kaufman J. 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*, Blaine, WA. 2015.

Poster Presentations

- 01 **Nicholas T**, Beaulieu A, Moudgal C, Morinello E, Graham J. Considerations for Establishing Health-Based Exposure Limits for Small Molecule Kinase Inhibitors. *ACT*, Austin, TX. 2024.
- 02 **Nicholas T**, Beaulieu A, Moudgal C, Morinello E, Graham J. Establishing Health-Based Exposure Limits for Protein Kinase Inhibitors: Considerations and Best Practices. *Development Sciences Offsite [Internal Meeting]*, Monterey, CA. 2024.
- 03 **Nicholas T**, de Zafra C. Protecting Patient and Worker Safety Through a Product Quality and Occupational Toxicology (PQOT) Group at Seagen. *Science Day [Internal Meeting]*, Bothell, WA. 2023.
- 04 **Nicholas T**, de Zafra C. Building a Product Quality and Occupational Toxicology (PQOT) Group at Seagen. *Science Day [Internal Meeting]*, Bothell, WA. 2022.
- 05 **Nicholas T**, Boyes W, Scoville D, Kavanagh T, Altemeier W, Faustman E. The Effects of Gene × Environment Interactions on Silver Nanoparticle Toxicity in the Respiratory System: Towards an Adverse Outcome Pathway. *SOT*, Anaheim, CA. 2020.
- 06 **Nicholas T**, Haick A, Workman T, Bammler T, Kavanagh T, Faustman E, Gharib S, Altemeier W. The Effects of Genotype × Phenotype Interactions on Transcriptional Response to Silver Nanoparticle Toxicity in Airway Epithelium Organotypic Culture Models. *SOT*, Baltimore, MD. 2019.
- 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 Airway Epithelium Organotypic Culture Models. *SOT*, San Antonio, TX. 2018.

- 08 **Nicholas T**, Haick A, Workman T, Griffith W, Nolin J, Kavanagh T, Faustman E, Altemeier W. Optimization of Airway Epithelium Organotypic Culture Models as a Platform for Adverse Outcome Pathway Assessment of Engineered Nanomaterials. *SOT*, Baltimore, MD. 2017.
- 09 **Nicholas T**, Haick A, Workman T, Griffith W, Nolin J, Kavanagh T, Faustman E, Altemeier W. Optimization of Airway Epithelium Organotypic Culture Models as a Platform for Adverse Outcome Pathway Assessment of Engineered Nanomaterials. *WC10*, Seattle, WA. 2017.
- 10 **Nicholas T**, Hazlehurst M, Spalt E, Curl C, Davey M, Burke G, Watson K, Vedal S, Kaufman J. Using Time-Weighted Models to Predict Ambient Sources of Traffic-Related Air Pollution Exposure in the Multi-Ethnic Study of Atherosclerosis and Air Pollution. *ISEE*, Seattle, WA. 2014.
- 11 **Nicholas T**, Zareba G, Watson G, van Wijngaarden E. Using Dose-Simulation Models to Predict Dietary Sources of Mercury Exposure in the Seychelles Child Development Study. *NCUR*, Ogden, UT. 2012.
- 12 **Nicholas T**, Zareba G, Watson G, van Wijngaarden E. Using Dose-Simulation Models to Predict Dietary Sources of Mercury Exposure in the Seychelles Child Development Study. *ABRCMS*, St. Louis, MO. 2011.

Service

Academic Service

- 2023 – Present **Affiliate Assistant Professor, Environmental and Occupational Health Sciences**
University of Washington
- 2021 – Present **Member, External Advisory Committee**
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**
International Consortium for Innovation and Quality in Pharmaceutical Development
- 2021 – 2023 **Councilor, Pacific Northwest Association of Toxicologists**
Society of Toxicology
- 2019 – 2021 **Councilor, Out Toxicologists and Allies Special Interest Group**
Society of Toxicology

Community Service

2016 – 2019	Science Communication Fellowship Program Pacific Science Center
2008 – 2012	Medical Emergency Response Team University of Rochester

Professional Memberships

2023 – Present	American Board of Toxicology
2016 – Present	Society of Toxicology

Other Accomplishments

Athletics

2024	San Francisco Half Marathon
2019	TCS New York Marathon (Fundraised \$2,700 with Team for Kids)
2019	RMI Expeditions Mt. Rainier Summit Climb
2017	Portland Marathon
2016	Vancouver Marathon
2015	Seattle Rock 'n' Roll Marathon
2014	Seattle Half Marathon
2014	Seattle Rock 'n' Roll Half Marathon
2013	Seattle Marathon

Music

2019 – Present

Bass Clarinet and Ukelele

Independent Practice

2012 – 2019

First Chair Bass Clarinetist

University of Washington Symphony Orchestra

2008 – 2012

First Chair Bass Clarinetist

University of Rochester Symphony Orchestra