

Meet Your Altascientists







Preclinical Experts



Clinical Experts



Bioanalytical Experts



Manufacturing and Analytical Experts



CRO Services Experts



Compliance and Quality
Assurance Experts

- Mike Broadhurst, Executive General Manager
- <u>lan Vanterpool</u>, General Manager
- <u>Francis Douville</u>, Vice President, Technical Operations
- <u>Dr. Norbert Makori</u>, BVM, MSc, PhD, DABT, Vice President, Toxicology
- Dr. Wendell P. Davis, DVM, DACVP, Vice President, Pathology
- <u>Dr. Jeffrey Burdick</u>, DVM, DSP, Site Director and Attending Veterinarian
- <u>Dr. Scott Boley</u>, PhD, DABT, Senior Scientific Advisor
- <u>Julie Forget</u>, DESS Tox, DABT, Senior Director, Safety Assessment
- <u>Dr. Alexander Walz</u>, PhD, Senior Director, Safety Assessment
- <u>Catherine (Catie) Selby</u>, MS, Director, *In Vivo* Operations
- <u>Isabel Tourigny</u>, Director, *In Vivo* Operations
- <u>Dr. Megan Haney</u>, DVM, PhD, DACLAM, Director, Veterinary Services, Attending Veterinarian
- <u>Dr. Simone Iwabe</u>, DVM, PhD, DACVO, Senior Veterinary Ophthalmologist
- <u>Carmela Parente</u>, Director, Preclinical Sponsor Liaison



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- <u>Emily Griffith</u>, DVM, Associate Director, Surgical Services
- Dr. Lisa Biegel, Senior Scientific Director, Preclinical Services
- Andy Fecht, Director of Environmental Health and Safety
- Shayna Halverson, Director, Quality Assurance
- <u>Dr. Francesca Barone</u>, DVM, PhD, Site Director
- <u>Dr. Kriscelle Mendoza</u>, MS, DVM, DACLAM, Veterinary Director/Attending Veterinarian
- Narine Lalayeva, MS, Director, Safety Assessment
- <u>Jean-Christophe Queudot</u>, Associate Director, Safety Pharmacology

PATHOLOGISTS/SCIENTISTS

- Dr. Keven Jackson, DVM, PhD, DACVP, Principal Pathologist
- Dr. Shunji Nakatsuji, PhD, DJSTP, DJCVP, Research Pathologist
- <u>Dr. Johanna Rigas</u>, DVM, MS, DACVP, Veterinary Clinical Pathologist
- <u>Dr. Elaine Debien</u>, DVM, DEC, MSc, DACVP, Principal Pathologist
- · Yafei Chen, MS, Senior Research Fellow
- Dr. Tara Arndt, DVM, DACVP, Senior Director



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PATHOLOGISTS/SCIENTISTS

- <u>Dr. Christina Ramirez</u>, PhD, DVM, DACVP, Research Pathologist
- <u>Dr. Divya Jose</u>, BVSc, MSc, MVestSC, DACVP, Senior Research Pathologist
- <u>Dr. Elinor Willis</u>, VMD, PhD, DACVP, Research Pathologist
- <u>Dr. Carolyn Gara-Boivin</u>, DVM, MSc, DACVP, Veterinary Clinical Pathologist

STUDY DIRECTORS

- <u>Dr. Camila Dores</u>, DVM MSc, PhD, DACVP, Associate Director, Pathology
- <u>Dr. Kelsey Brooks</u>, PhD, Scientist/Study Director, Safety Assessment
- <u>Dr. Stefan Nechev</u>, MD, DABT, Senior Toxicologist, Scientific Reviewer
- Dr. Li Zhan, MD, PhD, DABT, Research Scientist, Study Director
- Dr. Katherine Irby, PhD, Scientific Program Manager
- · Monserrath Camacho Ayala, MS, Scientist, Study Director
- <u>Dr. Rosemary Cook</u>, CVT, PhD, Scientist, Study Director

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STUDY DIRECTORS

- Brian Klatt, Associate Scientific Director, Safety Pharmacology
- Breanna Colley, BA, Study Coordinator III
- <u>Jay Pennell</u>, MS, Principal Scientist, Study Director
- Bill Tuman, MS, Associate Scientific Director, PK
- <u>John MacMaster</u>, Scientist/Study Director, Safety Assessment
- <u>Tim Madsen</u>, Associate Director, General Toxicology
- Kyle Klepner, Senior Study Director
- <u>Kaileigh McGinley</u>, MS, RLAT, Senior Study Director
- Miri Pannu, MS, Associate Scientific Director
- <u>Jennifer Shenise</u>, Associate Scientist, Study Director
- Andrew Payne, PhD, Study Director
- Vanessa Plummer, BS, Study Director
- Gabriela Campoy, DVM, Scientist, Study Director
- <u>Dr. Nirmala Chinnappareddy</u>, BCSc, PhD, DABT, ERT, Study Director
- <u>Dr. Petronella Magunda</u>, BVSc, MPH, PhD, Associate Scientist/Study Director
- <u>Dr. Vishal Kothari</u>, PhD, Scientist, Study Director

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Mike Broadhurst

Executive General Manager Seattle, WA

Mike Broadhurst joined Altasciences in 2018. As Executive General Manager for Altasciences' preclinical facilities, Mike works closely with the executive management team to ensure the development and delivery of quality preclinical solutions that support both small and large molecules in all species, a scalable operational infrastructure, and streamlined processes.

With over 20 years of preclinical industry experience, Mike brings a breadth of knowledge to the Altasciences team. Prior to joining Altasciences, Mike was Senior Site Director at Charles River Laboratories, where he opened the company's first purpose-built toxicology facility in Canada, and later reopened a facility in Shrewsbury, MA.





Ian Vanterpool

General Manager Columbia, MO

Ian joined Altasciences in 2020, with experience leading large, complex operational divisions supporting multinational research organizations in the life science sector. With a growth mindset, Ian has led effective and agile teams by identifying talent and supporting his team's leadership potential.

He has a proven track record of collaborating with different disciplines in a global organization, designing improvement strategies that enhance operational efficiency and profitability, promote regulatory compliance, and deliver real value to the customer. He has a passion for quality improvement and problem resolution and has gained considerable experience managing and navigating scientific and technical teams through periods of significant change.





Francis Douville

Vice President, Technical Operations Seattle, WA

Francis Douville joined the Altasciences team in 2018 as Vice President, Technical Operations. Francis has over 25 years of industry experience in both laboratory science and *in vivo* operations. Prior to joining Altasciences, he occupied several different positions at Charles River Laboratories, from entry-level technician to scientist, up to Director of *In Vivo* and Laboratory Sciences Operations.

Francis' career extends beyond his beginnings in Montréal, Canada; he opened a CRO in Shanghai, China, and joined a U.S. preclinical facility on the west coast. Prior to moving to Seattle, Francis was part of the team at Charles River Laboratories that reopened an east-coast facility in Shrewsbury, MA.





Dr. Norbert Makori, BVM, MSc, PhD, DABT

Vice President, Toxicology Seattle, WA

Dr. Makori joined Altasciences in 2021 as Vice President of Toxicology. He has over 20 years of industry experience as a toxicologist (general and reproductive toxicology), including roles as a study director, and in management. Prior to joining Altasciences, Norbert led the General Toxicology department at Charles River Laboratories' site in Ashland, OH, for five years. Prior to that, he held the position of Leader of Toxicology and Immunotoxicology at WIL Research Labs.

Norbert also led the reproductive toxicology team at SNBL (now known as Altasciences' preclinical site in Seattle), before it became part of the Altasciences family. Norbert is a diplomate of the American Board of Toxicology (DABT), and has a doctorate in Comparative Pathology.





Dr. Wendell Davis, DVM, DACVP

Vice President, Pathology Seattle, WA

Dr. Davis joined Altasciences in 2022. He is a nonclinical development professional with extensive experience in toxicologic pathology and a proven track record of building and leading high functioning pathology groups in both the biotechnology and CRO sectors. He is a proven leader with a passion for building pathology capabilities and mentoring pathologists, research, and laboratory scientists.

As a study pathologist and peer reviewer, he has experience evaluating small molecules, biologics, oligonucleotide, and an array of RNA therapeutics modalities across a range of preclinical species and routes of administration, in support of both early candidate selection and regulatory filings. Dr. Davis has co-authored over 25 publications, abstracts, and poster presentations. Prior to joining Altasciences, he held management roles in pathology and preclinical safety at Alnylam Pharmaceuticals, Charles River Laboratories, and Biogen Idec.

Dr. Davis also maintains an active role in the industry as a member of the Society of Toxicologic Pathology and as a diplomate member of the American College of Veterinary Pathologists.





Dr. Jeffrey Burdick, DVM, DSP

Site Director and Attending Veterinarian Scranton, PA

Dr. Burdick joined Altasciences in 2015. As site director and attending veterinarian, Jeffrey is fully involved in facility management at the Scranton preclinical site. He also manages the veterinary staff, animal care staff, necropsy team, and clinical pathology team.

Prior to joining Altasciences, he received his doctorate from the University of Pennsylvania, and completed an ACLAM residency program at GSK. Jeffrey has over 20 years of combined biomedical research experience in academic, pharmaceutical, and CRO settings.





Dr. Scott Boley, PhD, DABT

Senior Scientific Advisor Columbia, MO

Dr. Boley has advised sponsors on their nonclinical needs for the last 15 years and had managed toxicology programs for over 19 years. He has extensive expertise in drug development as well as the regulatory expectations for a variety of test article types and indications. As Senior Scientific Advisor, Scott works with clients and business development to better design the nonclinical programs in support of each sponsor's safety programs.

Scott is a diplomate of the American Board of Toxicology, holds a Bachelor of Science in Biochemistry and a doctorate in Biochemistry/Environmental Toxicology from Michigan State University, MI.





Julie Forget, dess tox, dabt

Senior Director, Safety Assessment Seattle, WA

Julie Forget joined Altasciences in 2018 as Director, Safety Assessment, and became Senior Director in 2022. With over 19 years of experience in the preclinical industry, Julie brings scientific depth and expertise to the study director team, with a focus on delivering quality science to clients, from protocol development to report delivery.

Prior to joining Altasciences, Julie's expertise as a study director covered a large spectrum of study designs, from discovery to IND/NDA-enabling studies. Julie was also part of the team that developed the safety assessment capabilities at a Charles River Laboratories facility on the east coast, which contributed to her experience as manager.





Dr. Alexander Walz, PhD

Senior Director, Safety Assessment Scranton, PA

Dr. Walz joined Altasciences in 2008. From initial client contacts to protocol design, from study monitoring to data interpretation, Dr. Walz works closely with his clients through all aspects of GLP regulated, preclinical studies. He also works closely with the study directors to provide excellent scientific support and guidance, as well as supports the needs of our clients throughout the preclinical development process.

Prior to joining Altasciences, Dr. Walz's work experience includes design, development, and testing of novel antigen formulations using proteomics and genomics at a biotechnology company, as well as applied research on heat stress at the USDA. He earned his doctorate in Molecular Biology at the University of Dresden/Germany, in conjunction with the University of Minnesota, with highest honors.





Catherine (Catie) Selby, MS

Director, *In Vivo* Operations Columbia, MO

Catie Selby has worked in biomedical research for 15 years in a variety of operational and research roles. Catie started her career as a research assistant in an academia role and moved to study director at Altasciences in 2012.

Since 2015, she has served as director of operations. In this capacity, she oversees scientific services, husbandry, quality control, training, clinical pathology and specimen management. Catie has a background in animal science, a Master of Science in swine reproduction, and experience in all aspects of study monitoring, study management, and staff development.





Isabel Tourigny

Director, *In Vivo* Operations Seattle, WA

Isabel joined Altasciences in 2019. As Director of Operations, Isabel is responsible for husbandry, necropsy, histology, sample management, and scientific services for large and small animals.

She has over 22 years of preclinical industry experience, and has worked in different environments, departments, and countries within large CROs.





Dr. Megan Haney, DVM, PhD, DACLAM

Director, Veterinary Services, Attending Veterinarian Columbia, MO

Dr. Haney joined Altasciences in 2019 and oversees the animal care program. In this capacity, she serves as Attending Veterinarian and manages the veterinary team.

She is involved in facility and operational management, in addition to oversight of surgical services, and assisting with model development. Prior to joining Altasciences, Dr. Haney received her veterinary doctorate from Kansas State University, KS, and completed a doctorate and ACLAM residency program at the University of Missouri, MO. She became a diplomate of the American College of Laboratory Animal Medicine after completing her board examination in 2020.





Dr. Simone Iwabe, DVM, PhD, DACVO

Senior Veterinary Ophthalmologist Scranton, PA

Dr. Iwabe is a board-certified veterinary ophthalmologist who joined Altasciences in 2020. She is responsible for conducting all the eye examinations, intravitreal and subretinal injections, ocular surgeries, and imaging procedures (fundus photography and OCT). Her expertise includes in gene therapy, retinal diseases, glaucoma, OCT, ERG, and ocular safety testing.

Simone received a Master of Science and a doctorate in Comparative Ophthalmology at the Autonomous National University of Mexico (UNAM), Mexico City. She is a diplomate of the American College of Veterinary Ophthalmologists (ACVO), and a member of the Association for Research in Vision and Ophthalmology (ARVO).





Carmela Parente

Director, Preclinical Sponsor Liaison

Carmela Parente joined Altasciences in 2022 with more than 27 years of industry experience in regulatory preclinical toxicology. She has provided expert input for the study design and interpretation of toxicological data, having conducted over 250 studies on pharmaceutical products, including acute, subacute and repeat dose, chronic, and reproductive toxicology. Prior to joining Altasciences, she held study director roles at Charles River Laboratories, subsequently moving into management positions.

As Director of Safety Assessment, she focused on scientific management and supporting staff, ensuring client satisfaction and delivery of high-quality and GLP-compliant reports. Additional roles included IACUC Chair, Process Improvement Lead, and Key Sponsor Portfolio Manager. In her current role, she provides leadership to, and oversight of, the preclinical program management team, as well as supporting sponsors through complete preclinical services support with subsequent clinical support.

Carmela is passionate about helping our clients get critical medicines to patients quickly by providing excellent client service with a personalized approach.





Emily Griffith, DVM

Associate Director, Surgical Services Columbia, MO

Emily Griffith joined Altasciences in 2018 as a Staff Veterinarian, and is now Associate Director of Surgical Services. Emily oversees and manages the surgical staff, and assists with protocol and model development. Prior to joining our site, she received her doctoral degree from the University of Missouri's College of Veterinary Medicine, and worked as a clinical veterinarian in a private companion animal practice.





Dr. Lisa Biegel, PhD

Senior Scientific Director, Preclinical Services Columbia, MO

Dr. Biegel joined Altasciences in 2022 and has more than 30 years of industry experience in regulatory toxicology at major organizations. She has provided expert input for the study design and interpretation of toxicological data, having conducted over 200 studies on pharmaceutical and agricultural products, including acute, subacute and repeat dose, chronic, and reproductive toxicology.

Dr. Biegel has authored or co-authored more than 25 peer-reviewed publications and presented at numerous conferences on toxicology, and other topics. Prior to joining Altasciences, she held research and study director roles at DuPont and Covance/Labcorp, subsequently moving into global management positions. In her most recent role as Vice President, Global Safety Assessment, Study Direction, Reporting and Data Management, she focused on scientific management and supporting staff development, ensuring timely communication, client satisfaction and delivery of high-quality and GLP-compliant reports and SEND datasets for regulatory submissions.

Dr. Biegel received a PhD in toxicology from Texas A&M University, TX. In her current role, she provides leadership and oversight to the study direction and reporting teams, as well as strategic scientific input for the site. She is passionate about helping our clients get critical medicines to patients as quickly as possible, while maintaining a focus on study quality, animal welfare, and employee development.





Andy Fecht

Director of Environmental Health and Safety Columbia, MO

Andy Fecht joined Altasciences in 2022 as Director of Environmental Health and Safety. In this role, Andy oversees the site's compliance with local, state, and federal environmental, health and safety regulations.

Prior to joining Altasciences, Andy spent 20 years at Teva Pharmaceuticals in operations and safety management, where he implemented a best-in-class EHS program that was deployed across Teva's North American active pharmaceutical ingredient manufacturing facilities.





Shayna Halverson

Director, Quality Assurance Seattle, WA

Shayna Halverson joined Altasciences in 2006. As the manager, quality assurance, at our preclinical facility, she works closely with the site's management team to maintain a pulse on quality and compliance with FDA GLP regulations, as well as sites across Altasciences to ensure a consistent approach. Shayna has been in the industry for over 13 years, and previously worked as a technician handling NHPs.





Dr. Francesca Barone, DVM, PhD

Site Director Sacramento, CA

Dr. Barone joined Altasciences in 2023. As Site Director she is responsible for research operations, including *in vivo* study management, technical operations, and veterinary services.

Dr. Barone promotes collaboration with other sites, and works closely with the clients in the early phases of drug development. Prior to joining Altasciences, she completed a postdoctoral fellowship at the National Institute of Health, and worked extensively with large animal models in biomedical research leading project design, implementation, and IND applications.





Dr. Kriscelle Mendoza, MS, DVM, DACLAM

Veterinary Director, Attending Veterinarian Sacramento, CA

Dr. Mendoza joined Altasciences in 2019, and is Director of Veterinary Services at Sacramento. She has over 10 years' experience working within laboratory animal husbandry, research, and medicine.

Dr. Mendoza completed a laboratory animal residency at Louisiana State University in 2019, and her Doctor of Veterinary Medicine at Iowa State University in 2017. She is a diplomate of the American College of Laboratory Animal Medicine, and has a Master of Pharmaceutical Sciences.





Narine Lalayeva, MS

Director, Safety Assessment, Seattle, WA

Narine joined Altasciences in 2005. She has over 19 years of experience conducting GLP and non-GLP studies with small and large molecules, with expertise in the conduct and direction of GLP preclinical toxicology studies, as well as the more specialized field of developmental and reproductive toxicology (DART).

She has targeted experience in general toxicology (single dose, multi dose, chronic, IND-enabling), DART (NHP and small animal), vaccine studies (small animals), intrathecal, and model development (diabetic NHP model). She has also been instrumental in the development of Altasciences' DART background dataset.

In her current role, Narine's focus has expanded to the development of a robust study director training program. In addition, Narine is in charge of the development of a new client satisfaction charter. This charter will enhance client experience with Altasciences by expanding on a foundation for building strong client relationships, fostering trust, and ensuring a positive experience throughout the project lifecycle.





Jean-Christophe Queudot

Associate Director, Safety Pharmacology, Seattle, WA

Jean-Christophe Queudot joined Altasciences in 2019 as Principal Scientist, Safety Pharmacology, and became Associate Director in 2023. With over 16 years of experience in the preclinical industry from toxicology to safety pharmacology, Jean-Christophe brings scientific guidance and expertise to the study director team and clients to refine the study design to reach the goal of the studies in compliance with the guidelines.

Prior to joining Altasciences, Jean-Christophe worked for different CROs in Europe and United States, and covered a large spectrum of study designs form early discovery to IND/NDA-enabling studies.





Dr. Keven Jackson, DVM, PhD, DACVP

Principal Pathologist Seattle, WA

Dr. Jackson joined Altasciences in 2002, and offers 36 years of pathology experience and 18 years of experience in toxicological pathology. He has a Doctor of Veterinary Medicine from Louisiana State University, anatomic pathology residency training, and a doctorate in Veterinary Microbiology from the Washington State University.





Dr. Shunji Nakatsuji, PhD, DJSTP, DJCVP

Research Pathologist Seattle, WA

Dr. Nakatsuji joined Altasciences in 2015 as a pathologist with 30 years' experience in the pharmaceutical industry in Japan, including 10 years at Astellas. Dr. Nakatsuji received a Bachelor of Science and a Master of Science in Agricultural Sciences from Kobe University, and a doctorate in Veterinary Pathology from Osaka Prefecture University.

He is a diplomate of both the Japanese College of Veterinary Pathologists (DJCVP), and the Japanese Society of Toxicologic Pathologists (DJSTP). He has been an active member of the INHAND working group of the Society of Toxicologic Pathology since 2010.





Dr. Johanna Rigas, DVM, MS, DACVP

Veterinary Clinical Pathologist Seattle, WA

Dr. Rigas joined Altasciences in 2021 and is a board-certified veterinary clinical pathologist with extensive experience in clinical pathology laboratory development and management, clinical diagnostic pathology, and teaching veterinary medical programs.

Dr. Rigas completed a residency in veterinary clinical pathology, after earning a Doctor of Veterinary Medicine from Oregon State University. She also holds a Master of Biology from Portland State University, with thesis work performed in biomedical research at Oregon Health & Science University.







Dr. Elaine Debien, DVM, DES, MSC, DACVP

Dr. Debien joined Altasciences in 2022, with over 10 years of toxicologic pathology experience in a GLP environment. She obtained her doctorate and a Master of Veterinary Sciences/Pathology at the Université de Montréal, where she also completed her residency program in veterinary anatomic pathology. She is a member of the Society of Toxicologic Pathology and a diplomate of the American College of Veterinary Pathologists.

Prior to joining Altasciences, Dr. Debien was Senior Veterinary Pathologist at Charles River Laboratories, where she developed experience and interest for gene therapy, biotherapeutics, and intrathecal toxicity studies in NHPs, and carcinogenicity studies in transgenic mice.





Yafei Chen, MS

Senior Research Fellow Columbia, MO

Yafei Chen joined Altasciences in 2021. Prior to joining, he held study director and study monitor roles at CROs and pharmaceutical companies, including AstraZeneca and Janssen. Yafei has 18 years of experience in general toxicology, safety pharmacology, and investigative biomarkers.

Yafei is experienced in providing expert input into the study design and interpretation of toxicological data, ensuring timely communication and delivery of high-quality and GLP compliant reports for regulatory submissions. He is proficient in providing expert input into the study design and interpretation of toxicological data.

A graduate from Peking Union Medical College, with a Master of Science in Clinical Biochemistry, Yafei's research work includes renal, neuro, and immunotoxicity, with a current passion for developing and promoting gene therapy models in miniature swine.





Dr. Tara Arndt, DVM, DACVP

Senior Director, Clinical Pathology Seattle, WA

Dr. Arndt joined Altasciences in 2023. She is a dual board-certified ACVP veterinary anatomic and clinical pathologist with extensive experience in regulatory toxicological pathology, including discovery and preclinical development. Dr. Arndt completed a clinical pathology residency program at the University of California, Davis, and became a diplomate of ACVP in 2007 (clinical pathology). She obtained dual ACVP board certification in 2013 (anatomic pathology) after briefly training at the University of Guelph, Ontario Veterinary College in Canada.

Dr. Arndt served as Senior Toxicologic Clinical Pathologist at Labcorp (previously Covance) for almost a decade before joining Altasciences. She is an active member of several impactful ASVCP, ACVP, STP, and ESTP committees and working groups, has chaired and presented at international symposia, and has authored or co-authored several manuscripts and book chapters on diagnostic and toxicologic clinical pathology.

When not working, you will likely find her somewhere in the great outdoors, focusing on wildlife and landscape photography, ecology, and conservation.





Dr. Christina Ramirez, DVM, PhD, DACVP

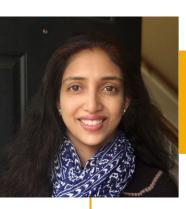
Research Pathologist Seattle, WA

Dr. Ramirez joined Altasciences in 2024, bringing with her a broad spectrum of experience including experimental pathology, diagnostic pathology, genetic disease research, and diagnostic genetic testing.

A board-certified veterinary anatomic pathologist, she has a doctorate in Molecular and Cellular Biology from the University of Washington, as well as a doctorate in Veterinary Medicine from Washington State University.

Dr. Ramirez completed a residency in Veterinary Anatomic Pathology at the University of Missouri, and became a diplomate of the American College of Veterinary Pathology in 2014.





Dr. Divya Jose, BVSc, MSc, MVestSC, DACVP

Senior Research Pathologist Seattle, WA

Dr. Jose joined Altasciences in 2024, bringing four years of experience in regulatory toxicologic pathology. She obtained her veterinary degree from Kerala Agricultural University, India, and has a Master of Veterinary Science in Animal nutrition, and Veterinary Anatomic pathology from University of Saskatchewan, Canada. She completed residency in Veterinary Anatomic Pathology at Western College of Veterinary medicine, Canada, and became a Diplomate of the American College of Veterinary Pathologists in 2021. She is an active member of ACVP and STP.

Prior to joining Altasciences, Dr. Jose served as a Veterinary Anatomic Pathologist at Charles River Laboratories, where she has developed an interest in reproductive toxicology.





Dr. Elinor Willis, VMD, PhD DACVP

Research Pathologist Scranton, PA

Dr. Willis joined Altasciences in 2024. She received a Doctor of Veterinary Medicine and a Doctorate in virology and immunology from the University of Pennsylvania, focusing on antiviral immunity and vaccines. She completed a residency in veterinary anatomic pathology at UPenn and became a Diplomate of the American College of Veterinary Pathologists in 2023.

Dr. Willis recently completed a postdoctoral fellowship with the University of Pennsylvania's Comparative Pathology Core. Her experience includes immunology, infectious diseases, vaccines, cellular therapies, and humanized mouse models.





Dr. Carolyn Gara-Boivin, DVM, MSc, DACVP

Veterinary Clinical Pathologist Columbia, MO

Dr. Gara-Boivin joined Altasciences in 2024. She earned her Doctor of Veterinary Medicine and Master of Science in Veterinary Sciences/Clinical Pathology from the University of Montréal, where she also completed a residency in Veterinary Clinical Pathology. In 2012, Dr. Gara-Boivin became a Diplomate of the American College of Veterinary Pathologists (Clinical Pathology).

With 12 years of experience as an Associate Professor of Clinical Pathology at the University of Montréal, Dr. Gara-Boivin has made valuable contributions to the field through numerous publications and co-authorships, as well as presentations at international conferences. Her research is focused on coagulation and anticoagulants, urinalysis, and establishing hematological reference values in exotic species.





Dr. Camila Dores, DVM, MSc, PhD, DACVP

Associate Director, Pathology, Columbia, MO

Dr. Dores joined Altasciences in 2023. An expert in anatomic pathology, with extensive experience in research/comparative pathology, she received a doctorate from Sao Paulo State University in Brazil in 2005.

Dr. Dores earned a Master of Science in a combined program between Sao Paulo State University and The Baker Institute at Cornell University, where she studied equine embryonic stem cells. She also obtained a doctorate in Comparative Biology and Experimental Medicine, studying tissue and cellular xenografting, spermatogonia stem cells, and 3D culture systems at the University of Calgary, Canada. Dr. Dores completed the Anatomic Pathology Residency program at Oregon State University, achieving American College of Veterinary Pathologists (ACVP) board certification in 2019.

She has worked in academia as an associate professor and director of biopsy and necropsy services at St. George's University, as well as a research pathologist in other laboratories. She is passionate about biomedical research and has multiple published manuscripts.





Dr. Kelsey Brooks, PhD

Scientist, Study Director Seattle, WA

Dr. Brooks joined Altasciences in 2019, with a focus on chromosome segregation abnormalities during early embryo development. Prior to joining Altasciences, Dr. Brooks completed her postdoctoral fellowship at the Oregon National Primate Research Center, outside of Portland, OR.





Dr. Stefan Nechev, MD, DABT

Senior Toxicologist, Scientific Reviewer, Seattle, WA

Dr. Nechev joined Altasciences in 2005. With 23 years of preclinical CRO experience (immunotoxicology, general toxicology, and clinical pathology), Dr. Nechev is a board-certified toxicologist with a Doctor of Medicine background.

His expertise includes general medicine, biochemistry, clinical pathology, immunotoxicology, and animal research. He has directed or assisted in the data interpretation of preclinical rodent, and non-rodent safety assessment studies.





Dr. Li Zhan, MD, PhD, DABT

Research Scientist, Study Director, Seattle, WA

Dr. Zhan joined Altasciences in 2015. With 10 years of experience as a board-certified toxicologist, Dr. Zhan has experience in toxicology and related fields (cardiovascular and genetic toxicology).

With four years of experience working as a study director on GLP preclinical safety studies at CRO West China-Frontier Pharma Tech Co., Ltd., three years of genetic toxicology, and six years of cardiovascular toxicology experience in the academia arena, Dr. Zhan served as a postdoctoral fellow at the Indiana University School of Medicine, and at the School of Medicine at the University of Louisville School of Medicine.





Dr. Katherine Irby, PhD

Scientific Program Manager Seattle, WA

Dr. Irby joined Altasciences in 2021 as a study director and quickly progressed in the role prior to becoming a scientific program manager in 2025. With prior experience designing and running clinical Phase I and II studies at a global CRO, she brings a comprehensive mindset to her preclinical projects to help the evolution towards first-in-human trials.

She brings her scientific guidance and regulatory knowledge to the program management team and clients to reach the goal of the studies while adhering to all necessary guidances. Dr. Irby received a Doctorate from Purdue University, IN, with a focus in analytical chemistry and mass spectrometry techniques, method development, and complex mixture analysis. She brings this analytical mindset to every project and has a keen eye for details.





Monserrath Camacho Ayala, MS

Scientist, Study Director Scranton, PA

Monserrath joined Altasciences in 2021. As Study Director, she works closely with clients, consultants, and internal team members to develop and execute preclinical studies involving small and large animals. Having graduated from the University of Scranton with a Bachelor of Science in Biology and a Master of Science in Biochemistry, her thesis work focused on protein purification and neuronal redox homeostasis in rodent models.

Prior to joining Altasciences, Monserrath worked at a clinical infectious disease lab where she participated in the validation of novel molecular testing procedures and related computer systems, quality assurance, and team management.





Dr. Rosemary Cook, CVT, PhD

Scientist, Study Director Scranton, PA

Dr. Cook joined Altasciences' toxicology department as a study director, directing both non-GLP and GLP studies with an expertise in running studies in both large and small animals. Dr. Cook is also a licensed veterinary technician and has experience with laboratory animals, exotic animals, large animals, and companion animal medicine.

Prior to becoming a study director, Dr. Cook chaired a veterinary technology program for over a decade. Her graduate work focused on DNA vaccine development targeting the adult stage of Schistosoma mansoni. This work implemented a novel surgical technique that allowed for implantation of adult worms into the mesenteric circulation of mice, thus bypassing the larval stages of the parasite.





Brian Klatt

Associate Scientific Director, Safety Pharmacology Scranton, PA

Brian Klatt joined Altasciences in 1987 and has a Bachelor of Science in Biology. He began as a pharmacology research technician and worked his way up to Associate Scientific Director, Safety Pharmacology. He also serves as a study director for CNS, respiratory, and cardiovascular studies, for which he is responsible for all aspects, from protocol development through to final report preparation.

In his 34 years of experience, he has conducted many of the various discovery pharmacology studies, such as anti-inflammatory, analgesia models, cardiovascular, and more.





Breanna Colley, BA

Study Coordinator III Columbia, MO

Breanna Colley joined Altasciences in 2019 as a Study Coordinator, bringing over 10 years of experience in the toxicology field. She graduated with a Bachelor of Arts in Biology from Columbia College, MO, in 2017. She assumed her current role as Study Coordinator III in 2023.

As Study Coordinator III, Breanna holds a dual role as Study Coordinator and Study Director on non-GLP pharmacokinetic studies. With her knowledge and time at Altasciences, she has become a certified trainer, providing mentoring and training to many other study coordinators over the years.

Breanna has experience with a wide variety of non-GLP/GLP studies for both rodent and non-rodent animal models. She relishes learning about the indication of new compounds, discovering each client's goals, and how Altasciences can make those goals a reality. Each day, she is motivated by seeing how the work at Altasciences makes an impact on human and animal medicine.





Jay Pennell, MS

Principal Scientist, Study Director Scranton, PA

Jay joined Altasciences as a study director in 2006 and has since directed hundreds of toxicology studies. Jay has worked with a wide variety of small and large animal species, and has experience with ocular, oral, dermal, and parenteral dose routes. At Altasciences, Jay has been primarily involved in ophthalmic products, including formulations applied topically to the surface of the eye and eyelids—and liquid, gel and solid formulations administered intravitreally.

Prior to joining Altasciences, he worked with a CRO in upstate New York, where he conducted acute toxicology. Jay has over 20 years of professional experience in nonclinical safety evaluation. As a Master's student, he conducted toxicologic experiments designed to better understand the mechanisms by which heavy metals inflict injury on the renal proximal tubule (RPT) and how those injuries, in turn, impact the transport of molecules across the RPT.





Bill Tuman, MS

Associate Scientific Director, Pharmacokinetics Scranton, PA

Bill Tuman joined Altasciences in 1982. He has extensive experience in running preclinical pharmacokinetic studies in multiple species.

In addition, Bill is Altasciences' Radiation Safety Officer at the preclinical Scranton site and oversees the Analytical Chemistry group, which provides dosing formulation analysis support for on-site toxicology and safety pharmacology studies.





John MacMaster

Scientist, Study Director, Seattle, WA

John MacMaster joined Altasciences in 2021, bringing 20 years of experience in conducting large and small molecule drug discovery studies at major biotech and pharmaceutical companies. His area of expertise is conducting small animal efficacy studies for oncology and autoimmune disease. John earned a Bachelor of Science at the University of California, Davis where he developed an interest in wine, and has spent some time as an analytical chemist and educator in the wine industry.

John is excited to be involved in the next step of the drug development process, helping sponsors advance their programs into the clinic, safely and seamlessly.





Tim Madsen

Associate Director, General Toxicology Columbia, MO

Tim Madsen joined Altasciences in 2003, and has approximately 35 years of industry experience in regulatory toxicology. Tim has served as a GLP Study Director, conducting a significant number of animal health studies (safety, dental, and diet), along with surgical device, diabetic testing, wound-healing, and general toxicology studies. In his current role, he provides leadership and oversight to the study direction team. In addition, Tim serves as the facility's unofficial historian and storyteller.

Tim graduated with a Bachelor of Arts in Biology from Central Methodist College in Fayette, MO. Prior to joining Altasciences, he spent more than 14 years in metabolism chemistry and aquatic toxicology divisions at ABC Laboratories in Columbia, MO.

When not working, you will likely find him performing a prairie restoration project, bird watching, and/or hiking in a national park somewhere around the world.





Kyle Klepner

Senior Study Director Columbia, MO

Kyle Klepner joined Altasciences more than 13 years ago, and has held a variety of operational and project management roles. Kyle is experienced in all aspects of study monitoring, test article preparation, sample handling, data collection, and management. He is driven by a passion for animal welfare, health, and science.

A graduate of the University of Missouri, MO, Kyle has participated in a wide variety of animal model development and non-GLP and GLP toxicology studies to meet IND-enabling requirements. In addition, he has an extensive background with infusions in large animal models using various infusion pumps, including stationary syringe pumps and ambulatory peristaltic pumps, as well as managing and overseeing efficacy and pharmacokinetic/pharmacodynamic studies in the diabetic minipig animal model.





Kaileigh McGinley, MS, RLAT

Senior Study Director Columbia, MO

Kaileigh McGinley joined Altasciences in 2012 as an animal technician after graduating with a Bachelor of Science in animal science from the University of Missouri. She moved into the research department in 2013, primarily working with Type I diabetic pig models in pharmacodynamic/pharmacokinetic studies.

While working as a study director, Kaileigh achieved a Master of Science in Integrative Pharmacology from Michigan State University. She currently conducts the CNS safety pharmacology studies for Altasciences. Kaileigh has experience with a wide variety of non-GLP/GLP toxicology, efficacy, and IND-enabling studies for both rodent and non-rodent animal models, and has worked with all aspects of study monitoring, test article management, and data collection and management.

Kaileigh enjoys learning about the indication and mechanism of action for each new compound she works with, and teaching others at Altasciences how their daily work makes an impact on human and animal medicine.





Miri Pannu, MS

Associate Scientific Director Columbia, MO

Miri joined Altasciences in 2017. As a research and development scientist, Miri works closely with the scientific committee to ensure the development of preclinical solutions that support new animal models and *in vivo* and *in vitro* assays.

As a study director, Miri has been running GLP studies for over five years, with a primary focus on cardiovascular and cardiopulmonary safety pharmacology studies in telemetered canines and miniature swine. Prior to joining Altasciences, Miri completed a Bachelor of Science in Biology at St. Louis University, MO, and earned a Master of Science in Biomedical Sciences, with thesis work performed in medical microbiology and immunology at A.T. Still University–Kirksville College of Osteopathic Medicine.

Miri's personal inspiration and motivation for pursing the research field stems from her enthusiasm for working with clients, and seeing how her efforts contribute to developing and achieving their preclinical goals.





Jennifer Shenise

Associate Scientist, Study Director Scranton, PA

Jennifer Shenise joined Altasciences in 2001 and holds an associate's degree in veterinary animal science. She began as a research associate in toxicology, transferred to safety pharmacology in 2005, before becoming a study director in 2021. Jennifer is responsible for planning, coordinating, and supervising interdepartmental activities during all phases of telemetered cardiovascular studies. She also plays an integral role in the surgical preparation of telemetry colony animals.





Dr. Andrew Payne, PhD

Study Director Columbia, MO

Dr. Payne joined Altasciences in 2023, having previously worked in the Vision Research Center (VRC) at the University of Missouri–Kansas City School of Medicine. With a doctorate in Neuroscience and Pharmacology, Dr. Payne has a robust medical knowledge with over 10 years of academic research experience, having worked in immunology, flow cytometry, microscopy, and cell culture.

Dr. Payne has an impressive bibliography, and has been responsible for conceiving, conducting and reporting on many projects and studies over his career. A skilled mentor, he is experienced in teaching research techniques and methodologies to medical students.

Dr. Payne is also a trained chef, and in another life worked as an associate chef for a restaurant in Fort Worth, TX.





Vanessa Plummer, BS

Study Director Columbia, MO

Vanessa Plummer joined Altasciences in 2023 as a study director, having previously worked as a quality engineer for 3M in Columbia, MO. Vanessa graduated from the University of Missouri-Columbia with a Bachelor of Science in Animal Science, minoring in Biology and Chemistry. While studying, she also worked in the university's Animal Science Research Center.

Vanessa specializes in agriculture animal science, and has accumulated more than 25 years' experience in various quality and regulatory affairs positions across the drug development field; both in GLP and GMP environments. Vanessa is proud to work for Altasciences and takes great satisfaction from her ability to contribute towards improving lives. She is always looking to the future for more rewarding and meaningful experiences.





Dr. Gabriela Campoy, DVM

Scientist, Study Director Seattle, WA

Dr. Campoy joined Altasciences in 2023. She is an accomplished researcher with expertise in conducting efficacy studies in hematology-oncology, HIV, and autoimmune disease. Dr. Campoy graduated from Veterinary School in Brazil in 2011. Over the years, she held diverse roles, including Veterinary Clinical Pathologist and Research Scientist, with a focus on bone marrow transplantation, gene therapy, and oncology.

Her passion extends beyond the laboratory; she actively engages in kitten neonatal care and feral colony management, volunteering at two animal rescues in Washington State, and caring for her cat, that has congenital hypothyroidism.





Dr. Nirmala Chinnappareddy, BVSc, PhD, DABT, ERT

Study Director Seattle, WA

Dr. Chinnappareddy joined Altasciences in 2022. She is a board-certified toxicologist with more than 15 years of experience in designing, conducting, and reporting of efficacy, mechanism of action, and preclinical toxicology studies to support early drug discovery and development. Dr. Chinnappareddy earned her a Bachelor of Science in Veterinary Medicine, and a doctoral degree in Veterinary Pharmacology and Toxicology from Bangalore Veterinary College, India—in addition to postdoctoral trainings from Ontario Veterinary College, University of Guelph, and Atlantic Veterinary College, University of Prince Edward Island, Canada.

Dr. Chinnappareddy's areas of expertise include cardiovascular pharmacology, CNS pharmacology, and regulatory toxicology. Prior to joining Altasciences, she worked as a research toxicologist, regulatory toxicology specialist, and research scientist supporting early drug discovery and regulatory submission of human and animal health products.





Dr. Petronella Magunda, BVSc, MPH, PhD

Associate Scientist, Study Director Seattle, WA

Dr. Magunda joined Altasciences in 2022 as an associate scientist. She has experience leading the technical conduct of both GLP and non-GLP studies, data interpretation, analysis, documentation, and reporting of results of nonclinical studies for the discovery and development of drugs.

Dr. Magunda has experience in veterinary practice and biomedical research, using *in vivo* laboratory animal models. She holds a doctorate in Molecular Biology, Immunology, and Infectious Diseases, with a veterinary clinical background.





Dr. Vishal Kothari, PhD

Scientist, Study Director Seattle, WA

Dr. Kothari joined Altasciences in 2022 as a study director. He has broad and extensive experience in designing and running various preclinical studies with small and large molecules. Prior to joining Altasciences, Vishal completed his postdoctoral fellowship at the University of Washington, School of Medicine.

In addition, he has 5 years of experience working as a scientist on cardiometabolic diseases, relevant preclinical studies at Eurofins Advinus, India.





Ashley Mahoney, MA, RLATG

Study Director Sacramento, CA

Ashley joined Altasciences in 2021, and became study director in 2022. As Study Director, she executes non-GLP discovery studies at the Sacramento site. Ashley is a registered Laboratory Animal Technologist, and possesses a Master of Science in Psychology from California State University, Sacramento, CA, where her thesis work focused on elucidating the function of the perirhinal cortex in learning and memory processes.

Prior to joining Altasciences, Ashley was a research associate at the University of California, Davis, where she worked with small and large animal models of spinal cord injury in a neuroengineering lab.





Dr. Elena Silva, PhD

Study Director Sacramento, CA

Dr. Silva joined Altasciences in 2023. She received a doctorate in Veterinary Medicine from São Paulo State University in Brazil, in 2003. Dr. Silva earned a doctorate in Reproductive Biology from the University of Illinois, IL, at Urbana-Champaign. During her postdoctoral training at the University of Colorado Anschutz Medical Campus, she wanted to connect biomedical research and clinical application, by studying the impact of obesity/diabetes on fetal growth.

Prior to joining Altasciences, Dr. Silva has worked for multiple startups and CRO companies supporting *in vitro* and *in vivo* discovery studies, evaluating the efficacy and pharmacokinetics of new drugs.





Larry Karnes, BS

Study Director Columbia, MO

Larry Karnes joined Altasciences in 2013 as an animal technician after graduating with a Bachelor of Science in Biology from the Central Methodist University, MO. He subsequently moved into the research department in 2014 and worked in various study types, including pharmacodynamic, pharmacokinetic, and dermal toxicology.

While working as a study director, Larry continues to expand his experience in a wide variety of non-GLP and GLP toxicology, efficacy, biologics, and IND-enabling studies, for both rodent and non-rodent animal models. Additionally, he has worked in all aspects of study monitoring, test article management, and data collection and management.

Larry is proud to be a part of Altasciences, as the work he performs improves lives. He enjoys learning about new compounds, and working with sponsors to help them meet their timelines and achieve their goals.





Shanté Jackson, BS

Scientist, Study Director Columbia, MO

Shanté Jackson joined as a study coordinator in August 2021, and quickly transitioned to her current role as study director in May 2022. As Study Director, Shanté has experience with running studies in accordance GLP standards, standard operating procedures (SOPs), and regulatory agency expectations, with a primary focus on nonclinical research in rodents, canines, and miniature swine.

Prior to joining Altasciences, Shanté completed a Bachelor of Science in Biochemistry at Kenyon College, OH, and was involved in graduate study research related to pharmaceutical sciences, pharmacology and toxicology. She began working in the industry as study director for drug metabolism, drug inhibition, and drug transport at an *in vitro* research CRO.

Shante's personal motivation for pursing the research field stems from her passion for working with clients, which ultimately allows her to contribute to the development and achievement of various nonclinical goals as a crucial steppingstone for potential, future life-changing compounds.





James Wilson

Scientist/Study Director, Safety Assessment Scranton, PA

James Wilson joined Altasciences in 2022 as Study Director, and works closely with clients, consultants, and internal team members to develop and conduct preclinical studies involving small and large animals.

James' primary focus since joining Altasciences has been ocular toxicology studies. He has worked on studies with dose routes ranging from topical ocular administration, intracameral injection, to intracameral medical devices. Prior to joining Altasciences, James earned a Doctor of Pharmacy from Ohio State University, OH, where he also developed his interest in early drug development.

During his time at Ohio State University, James worked with in an in silico drug discovery laboratory.





Dr. Nicholas Buss, PhD

Associate Scientist, Study Director, Safety Assessment Scranton, PA

Dr. Buss joined Altasciences in 2022 in the role of Study Director. In this role, he works closely with clients to successfully conduct GLP and non-GLP preclinical safety assessment studies across a variety of model species and dose routes.

Prior to joining Altasciences, Dr. Buss worked as a toxicologist, using laboratory experiments to evaluate the influence of toxicant exposure on resistance to infectious diseases in numerous species of aquatic wildlife.





Dr. Thomas Rundell, PhD

Associate Scientist, Study Director, Scranton, PA

Dr. Rundell joined Altasciences in 2023. As Study Director, he guides preclinical studies from protocol design to data interpretation in both large and small animal models. He earned a doctorate in genetics from Binghamton University, NY, studying genomic and molecular solutions to the physiological challenges posed by Type 2 diabetes.





Dr. Neha Chitre, PhD

Research Scientist, Study Director, Seattle, WA

Dr. Chitre joined Altasciences in 2024, bringing previous experience as a general toxicology study director within preclinical safety assessment. Her educational training is in Pharmaceutical Sciences, with her doctoral research focus being on Neuropharmacology and Neurotoxicology.

Dr. Chitre has a strong desire to contribute to advancing therapeutics and enjoys working with clients to review the details of their *in vivo* programs to ensure they are full set up for success. Dr. Chitre is passionate about animal welfare, both personally and professionally, and strives to combine animal welfare with experimental rigor.









Ingrid Holmes

Vice President, Global Clinical Operations Montréal, QC

Ingrid Holmes joined Altasciences in 2011 as Vice President of Clinical Operations for the Montréal site. Now, as Vice President, Global Clinical Operations, Ingrid's responsibilities include oversight of all our clinical pharmacology units. Additionally, Ingrid is responsible for the harmonization of clinical processes across Altasciences' sites, and acts as Global Compliance Lead within the Quality Management System.

Ingrid started her career in clinical research in 1995 at LAB Pharmacological Research. Over the years, she has held various management roles in early-stage clinical operations, progressing to become Director of Business Operations and Continuous Improvement; overseeing the financial and quality performance of five international clinical sites.

In her various roles, she has gained extensive experience in the conduct of early-phase trials, international regulatory requirements, business operations, quality management systems, and Lean Six Sigma. Prior to joining Altasciences, Ingrid provided consulting services for early-stage CROs, and has successfully implemented company-wide management systems, including financial, client services, and operational KPIs in a number of organizations.





Dr. Beatrice Setnik, PhD

Chief Scientific Officer Raleigh, NC

Dr. Setnik joined Altasciences in 2019, and has been working in clinical drug development and abuse potential assessment since 2005. She earned a doctorate in Pharmacology and the Collaborative Program in Neuroscience from the University of Toronto—where she currently works as an Adjunct Professor. In her former role as Vice President of Scientific & Medical Affairs at INC Research/inVentiv Health, she was responsible for scientific input on early-phase clinical trials, and in strategic initiatives in business growth and development.

In her previous role, Dr. Setnik led the clinical development, regulatory filing, and lifecycle management, including abuse potential evaluation of several pain compounds, including abuse-deterrent opioid formulations. Prior to which, she worked as a research scientist in Toronto, Canada, and was responsible for providing scientific input on various specialty Phase I/II clinical trials—including abuse potential studies for CNS drugs. Dr. Setnik has published numerous research articles in internationally recognized peer-reviewed journals, and is a peer-reviewer for manuscripts submitted to Pain Medicine and Drug and Alcohol Dependence.

An active member and participant in several congresses, including the College on Problems of Drug Dependence, Dr. Setnik has also been engaged in many aspects of abuse potential assessment, including development of patient reported outcome instruments, and contributing to post-marketing surveillance studies.

In 2024, Dr. Setnik was recognized as a PharmaVoice 100 winner, and named one of the 30 Most Influential People in the Pharma Industry by The Medicine Maker.





Dr. Mel Affrime, PharmD

President and Chief Scientific Officer Los Angeles, CA

Dr. Affrime has an extensive background in global clinical research and development. Following completion of PharmD training at PCP&S in Philadelphia, he completed a Clinical Pharmacology Fellowship with Marcus Reidenberg, MD, at Temple University College of Medicine. He then co-founded the clinical pharmacology research unit at Hahnemann Hospital, Philadelphia, PA, with David Lowenthal, MD, PhD, in 1976. He remained on the faculty at Hahnemann until 1982, when he joined Hoechst-Roussel Pharmaceuticals as Associate Director, Clinical Pharmacology.

Prior to joining Altasciences in 2011 as Senior Vice President of Translational Medicine, Dr. Affrime managed the medical staff at ICON Development Solutions' three CPUs, the Population PK software business, and the Research and Development department from 2006 to 2011. His experience also includes heading the Global Profiling Clinical Pharmacology department at Novartis Pharmaceuticals, and 16 years at Schering-Plough Research Institute where he managed the early development programs for the entire Schering pipeline.





Amy Denvir

Senior Director, Deployment and Integration Kansas City, KS

Amy Denvir joined Altasciences in 2018 as Director, Integration and Deployment. Having started her clinical research career in 1991 at Harris Laboratories (now Celerion), Amy held various management roles in early-and late-stage clinical operations, including Senior Director, Clinical Operations, overseeing the financial and quality performance of multiple research sites.

She has extensive experience in conducting early- and late-phase trials in healthy normal and patient populations, as well as in business operations, quality management systems, and systems designs and implementation, including eSource and training platforms.





Melanie Barth, BA

Director, Scientific Project Management

With over 25 years of experience in early-phase clinical research, Melanie Barth joined Altasciences in 2014. She is renowned for her deep understanding of sponsor needs, working closely with the project management team to consistently exceed expectations.

Melanie's career highlights include significant contributions to clinical operations, project management training programs, and risk management strategies. She has provided meticulous oversight of trial master files (TMFs) and has led project managers, project coordinators, and TMF specialists to ensure seamless execution and compliance throughout clinical trials. Melanie champions a collaborative and proactive approach to project management, emphasizing continuous improvement and client satisfaction. Her dedication to advancing early-phase clinical research methodologies is unwavering, and she remains committed to fostering a culture of excellence and innovation within her team.



Jeremy Mussallem, BS

Associate Director, Scientific Project Management

Jeremy Mussallem joined Altasciences in January 2013, and plays a pivotal role in overseeing clinical and CDMO projects as Associate Director of Scientific Project Management. With over 11 years of expertise in strategic project and program leadership encompassing early-stage drug development, CDMO manufacturing, and clinical operations, Jeremy oversees the CDMO project management group and supervises several clinical project managers.

Jeremy has a wealth of experience in managing diverse projects and demonstrating exceptional problemsolving abilities to resolve complex issues and ensure seamless project execution. He holds a Bachelor of Science from Bloomsburg University, PA.



Aditya Martowirogo, BASc Senior Scientific Project Manager

Aditya Martowirogo joined Altasciences in 2020. Prior to that, he was a project manager at an oncology-focused biotech startup and developed and implemented quality improvement and patient safety projects in several hospitals across Toronto, Canada. Aditya obtained his Bachelor of Applied Science in Engineering Science, and a Master of Health Science in Clinical Engineering from the University of Toronto, Canada.

In his current role, Aditya leads various clinical project teams, manages key internal and external relationships, and drives intra- and inter-departmental quality improvement initiatives.





Daniel Bustillo, MBA, BA

Senior Director, Scientific Project Management

Daniel Bustillo joined Altasciences in 2023 and has over twenty years' experience as a leader in project management, primarily at clinical CROs. Prior to joining Altasciences, Daniel served as the director of U.S. project management for a global early-phase CRO. Prior to that, he led teams through all phases of research and managed project teams at two technology companies.

Daniel is a graduate of Georgetown University, DC, and holds a Master of Business Administration from the University of Miami, FL.





Matthew Logan

General Manager, Clinical Operations Montréal, QC

Matthew Logan joined Altasciences in 2011, and currently holds the role of General Manager, Clinical Operations, of Altasciences' clinical pharmacology unit in Montréal, QC. In partnership with Altasciences' quality assurance team, he has successfully hosted multiple regulatory audits, year after year. Matthew started his career in the Microbiology department of the Royal Victoria Hospital, before joining a large Montréal-based CRO. Over the course of 15 years, Matthew held various positions of increasing responsibility, culminating in his leading and collaborating with cross-functional project teams as Clinic Operations Manager.

With close to 25 years of experience in clinical research, Matthew understands the needs of sponsors, and works closely with them to meet (and exceed) expectations, regulatory requirements, and overall business objectives.





Dr. David Nguyen, MD, MBA

General Manager and Medical Director Los Angeles, CA

Dr. Nguyen is an anesthesiology-trained general manager and medical director, with experience in all major inpatient surgical specialties, including neurosurgery, cardiothoracic, and obstetrics, as well as outpatient procedures and GI services. He is intimately familiar with transfusion medicine, fluid management, infusion reactions, and emergency anaphylactic airway response.

While treating chronic pain patients, Dr. Nguyen received a first-hand account of both the opioid crisis, as well as the frustrations and poor quality of life for a patient suffering from chronic pain, which was the impetus that drove him to become a patient advocate for responsible medical cannabis use. At Altasciences, his goal is to push forward high-quality pharmaceutical therapies for patients, and to ensure subject safety on all trials.

Prior to joining Altasciences in 2017, he expanded his clinical knowledge to include dermatology and regenerative medicine, prompting the launch of his medical aesthetic practice, Dr. Dave's Dermal Institute, where he functioned as both medical director and primary practitioner. He brings the same customer-focused approach from this practice to volunteers in clinical trials, ensuring subject satisfaction at all levels.



Dr. Martin Kankam, MD, PhD, MPH

Medical Director Kansas City, KS

Dr. Kankam is an internal medicine physician with more than 25 years of academic and industry experience. Prior to joining Altasciences in 2008, he spent 10 years in clinical practices with faculty positions in the U.S.A.

Dr. Kankam worked as a research scientist, epidemiologist, and a scientific reviewer at the U.S.A. Food and Drug Administration, Center for Devices and Radiological Health. In 2017 he was promoted to Co-Medical Director of Altasciences' Kansas City site, and ascended to the Medical Director position in 2020.

An expert in early-phase drug development with broad experience in clinical development and operations across many therapeutic disciplines, he has published over 20 manuscripts in peer-reviewed journals. He received his Doctor of Medicine from Creighton University School of Medicine, NE, and completed his postgraduate training in Medicine at the University of Kansas School of Medicine. He holds a doctorate in Epidemiology from University of Oklahoma, and a Master of Public Health from Tulane University, LA.

Dr. Kankam is a member of the American Medical Association, and a Fellow at the Academy of Physicians in Clinical Research.





Dr. Gaetano Morelli, MD

Executive Vice President Medical Affairs, Chief Medical Officer Montréal, QC

Dr. Morelli joined Altasciences in 2017 as a medical advisor/consultant for complex studies. He quickly transitioned to Clinical Principal Investigator before becoming Chief Medical Officer in 2020.

He is a member of the Collège des Médecins du Québec, a Fellow of the Royal College of Physicians of Canada, certified in Internal Medicine and Gastroenterology, and a Fellow of the American College of Gastroenterology.

Dr. Morelli has over 30 years of medical-clinical experience, and 25 years of experience in clinical research. He is a clinical academic gastroenterologist at the McGill University Health Network, and an associate professor of medicine at McGill University, QC—involved in medical training of students, residents, and specialty fellows. Previously, Dr. Morelli was Director of Global Medical Affairs (CMO) at MDS Pharma for 10 years, overseeing five clinical sites in Canada, the United States, and Ireland.





Dr. Debra Kelsh, MD

Senior Principal Investigator Kansas City, KS

Dr. Kelsh has been with Altasciences' Kansas City facility since its founding in 2001. She worked concurrently as Assistant Clinical Professor in the Department of Psychiatry and Behavioral Sciences at the University of Kansas Medical Center for 11 years from 1996 until 2007. In 2007, she joined Altasciences' team full time. She has been board certified by the American Board of Psychiatry and Neurology since 1998.

Dr. Kelsh is a graduate of the University of Kansas School of Medicine and is a member the Alpha Omega Alpha Honor Medical Society.





Dr. Éric Sicard, MD

Clinical Principal Investigator Montréal, QC

Dr. Sicard has been with Altasciences since 2002 in positions of increasing responsibility, and currently holds the position of Clinical Principal Investigator. He is a member of the Collège des médecins du Québec, with 30 years' experience in the medical field.

His well-rounded background includes academics, emergency medicine, geriatric and palliative care, and family medicine.





Lester Galan

Executive Director, Clinical Trial Management Los Angeles, CA

Lester Galan has been with Altasciences for over 20 years, bringing hands-on operational experience through his time as a Clinical Research Coordinator, in both early and late phase clinical trials. Lester is a certified clinical research coordinator through the ACRP, which allows him to stay abreast on all the latest industry trends and guidance, while instilling his vast knowledge to those he manages and interacts with daily at the Phase I Unit.

Throughout his career, Lester has overseen multiple departments with an "on the floor" perspective, which has been paramount to Altasciences' success. Lester currently leads the Phase I Unit, and is responsible for the screening, clinical operations, clinical trial management, and the clinical data processing departments.





Dr. William Foster, PhD, MD

Principal Investigator Montréal, QC

Dr. Foster joined Altasciences in 2018. He has extensive experience in both preclinical and clinical research with an emphasis in ophthalmology, including nanotechnology research.

A physician-scientist and practicing vitreoretinal surgeon, he actively leads clinical research studies and consults with clients about how to best achieve their desired milestones. A graduate of Caltech, Harvard, and Duke with training at Harvard Medical School, Washington University in St. Louis, MO, and UCLA, CA, he has held faculty positions at a number of research universities. As a bioengineer, he enjoys interdisciplinary collaboration.





Dr. David Kim, MD

Principal Investigator Los Angeles, CA

Dr. Kim is a urology-trained principal investigator with a background in oncology research. He received a Bachelor of Science in Public Health from the University of Pennsylvania, and a Doctor of Medicine with honors distinction from George Washington School of Medicine. He has provided care for patients with core and advanced genitourinary conditions, including prostate cancer, bladder cancer, kidney cancer, complex urinary stones, infectious diseases, sexual dysfunction in men, urinary incontinence, voiding dysfunction, and enlarged prostate.

He is proficient in performing routine urologic surgical procedures, cystoscopy, prostate biopsy, and ureteral stent placement. Dr. Kim has worked at the National Institute of Health Cancer Institute, QC, and has been involved in the publication and presentation of multiple early clinical trials for oncology research.

At the Children's Research Institute Center for Neuroscience, he conducted extensive translational clinical research primarily focused on neural stem cells. He has also participated in sleep disorder research at the University of Pennsylvania Center for Sleep. Dr. Kim joined Altasciences in 2020 to integrate his diverse clinical and research experience to continue the advancement of impactful pharmaceutical therapies, by integrating his diverse experience in clinical and research with his passion for patient care.





Dr. Colleen Harrison, MD

Principal Investigator Kansas City, KS

Dr. Harrison joined Altasciences in 2019, as Clinical Sub-Investigator, becoming Principal Investigator in January 2022. She received her Doctor of Medicine from Harvard Medical School in 2009. Since then, she has been practicing family medicine in various clinic and hospital settings in the U.S.A. and Canada.





Dr. Brett Smith, MD, MPH, MBe

Principal Investigator Los Angeles, CA

Dr. Smith is an internal medicine and preventive medicine-trained physician clinical investigator with extensive experience in adult primary care, outpatient medicine, epidemiology, and bioethics. He is well-versed in a broad range of therapeutic agents and disease states, including cardiology, gastroenterology, pulmonary, infectious disease, allergy, dermatology, endocrinology, and preventive care. Dr. Smith joined Altasciences in 2021 to make an impact at scale in pharmaceutical therapies. He brings clinical rigor with a dedication to patient safety and ethics to studies.

Dr. Smith earned a Bachelor of Science in Genetics from Rutgers University, a Doctor of Medicine from the UMDNJ-Robert Wood Johnson Medical School, Master of Bioethics from the University of Pennsylvania, PA, and a Master of Public Health, with a focus on epidemiology, from the University of California, Berkeley.





Kevin Noble

Senior Director, Laboratory Operations Los Angeles, CA

Kevin joined Altasciences in 2013 as Laboratory Coordinator, Laboratory Supervisor, and Research Laboratory Manager, before taking on the role of Senior Director. Kevin is responsible for the integrity of the sample collection and preparation in the pharmacokinetic laboratory, and currently oversees the Clinical Safety Laboratory and Cell Isolation (PBMC) Laboratory in Los Angeles.

Kevin has a strong background in laboratory management, operations efficiency, and vendor contract negotiation, in addition to hosting several CAP, CLIA, and COLA audits. He has worked on clinical research studies covering a wide range of therapeutic areas including allergy/asthma, cardiology, dermatology, device studies, endocrinology, gastroenterology, healthy patient studies, hematology, infectious diseases, neurology, obstetrics/gynecology, ophthalmology, otolaryngology, pain management, pharmacology, toxicology, pulmonary/respiratory, and rheumatology.





Brandon O'Reilly

Director, Quality Assurance and Risk Management Los Angeles, CA

Brandon O'Reilly brings over ten years of clinical research experience to his role as Director of Quality Assurance and Risk Management. Brandon began his career as a regulatory coordinator for a small oncology practice in 2010, and used this experience to transition into quality assurance.

Brandon has hosted regulatory inspections for both the FDA and PMDA on more than a dozen studies. His current role provides him with an esoteric overview of all operations, and keeps him closely involved with the decisions of the company—while allowing him to influence decisions that ensure compliance and quality. Brandon also oversees the clinical monitoring group to better align quality and monitoring initiatives.





Dr. Kevin Kirkcaldy, BPharm, MBA, PharmD

Director, Pharmacy Operations Montréal, QC

Dr. Kirkcaldy joined Altasciences in 2019, bringing with him over 18 years of experience as a licensed pharmacist in retail pharmacy, business management, and clinical research. As head of the pharmacy department, he oversees all activities related to IMP management, including quality control, compounding, aseptic technique, and controlled substance management. By working closely with clients, he and his team ensure optimal and timely pharmacy services that are adapted and personalized for different study designs and needs.

Dr. Kirkcaldy has a Bachelor of Science and a PharmD in Pharmacy, a Master of Business Administration in Pharmaceutical Management, and a graduate degree in Pharmaceutical Product Development.





Dr. Andy Pham, PharmD

Dr. Pham has over 20 years of pharmacy experience, including a decade in clinical research and investigational drugs. He utilizes his strong educational background and experience in study drug management to ensure Altasciences' adherence to GCP, and all applicable laws and regulations. Dr. Pham is a hands-on and knowledgeable team leader, who is well-respected for his dedication and professionalism.

Skilled at training staff on new investigational drugs, and proper procedures for storage, administration, and the recording of data, he also provides essential expertise in communications with clients and regulatory committees, as well excellent support to study investigators and nurses to ensure patient safety and the integrity of our studies.





James Brazeal

General Manager, Clinical Operations Kansas City, KS

James joined Altasciences in 2023, having previously worked as Vice President of Research at Akron Children's Hospital, and most recently as Vice President of Research Operations for Circuit Clinical—an integrated research organization bringing clinical trials to local communities. With a Bachelor of Science in Biology from Kansas State University, KS, and close to a decade of experience in the healthcare and pharmaceutical sectors, James uses his robust knowledge of clinical research to oversee the day-to-day management of clinical operations at Altasciences' Kansas site.

In another life, James graduated from the University of Missouri-Kansas City School of Law, with a Doctor of Law degree (JD), and is a licensed attorney in the state of Missouri—as well as being a registered U.S. Patent Attorney. James has a personal drive to improve outcomes, experience, and quality for patients, along with a deep passion for research.







Dr. Nadine Mokhallati, MD

Dr. Mokhallati joined Altasciences in 2024 as Co-Medical Director of the Kansas site. Prior to this, she worked as a Pediatric Pulmonologist at Children's Mercy Hospital in Kansas City, MO, where she also served as medical director of the Pulmonary Function Lab, and Medical Director of their School Based Asthma Telemedicine program. Dr. Mokhallati also held the role of Assistant Professor of Pediatrics at the University of Missouri Kansas City and University of Kansas.

Dr. Mokhallati obtained her Doctor of Medicine in 2009 from the American University of Beirut. After moving to the U.S. in 2009, she completed a postdoctoral program at Cedars Sinai Medical Center in Los Angeles, her residency through the University of Arizona, and a fellowship at Cincinnati Children's Hospital Medical Center. She has also obtained certification in Clinical and Translational Research from the University of Cincinnati.

Dr. Mokhallati has received numerous research grants and contracts and served as both principal investigator and sub-investigator for research projects sponsored by the NIH, the National Heart, Lung, and Blood Institute, charitable foundations, and pharmaceutical sponsors.



KEY BIOANALYTICAL EXPERTS

- <u>Dr. Lynne Le Sauteur</u>, PhD, Vice President, Laboratory Sciences
- <u>Dr. Anahita Keyhani</u>, PhD, Senior Director, Scientific Operations, Mass Spectrometry
- <u>Dr. Danielle Salha</u>, PhD, Senior Director, Senior Director Global Immunology
- <u>Kevork Mekhssian</u>, MSc, Senior Scientific Director
- Milton Furtado, Scientific Director, Method Development
- <u>Jeff Plomley</u>, MSc, Scientific Director, Method Development
- <u>Dr. Susan Ohorodnik</u>, PhD, Senior Director, Operations
- <u>Jean-Nicholas Mess</u>, MSc, Principal Scientist, Method Development
- <u>Dr. Mano Sahoo</u>, MS, PhD, Director, Bioassay
- <u>Dr. Olga Malykhina</u>, Principal Research Scientist, Laboratory Sciences
- <u>Ted (Theodore) Brus</u>, Principal Scientist, Laboratory Sciences
- <u>Dr. Mingluan Chen</u>, PhD, Principal Research Scientist, Method Development
- James Hnilo, Principal Research Scientist
- <u>Dr. Adam Martin</u>, PhD, Principal Scientist, Laboratory Sciences
- <u>Dr. Martin Turcotte</u>, PhD, Scientific Director, Flow Cytometry





Dr. Lynne Le Sauteur, PhD

Vice President, Laboratory Sciences

Dr. Le Sauteur joined Altasciences in September 2019, and leads a team of over 260 specialists involved in bioanalysis, immunogenicity, biomarkers, and immunotoxicity assessments for large and small molecules, oligonucleotides and gene therapy. She received a doctorate in Pharmacology and Therapeutics from McGill University and has over 20 years' experience in biologic drug development.

Prior to joining Altasciences, she was Director of Downstream Processing and Analytics, as well as Program Leader, Biologics and Biomanufacturing, for the Human Health Therapeutics Research Center at the National Research Council of Canada (NRC). Here she led numerous teams and initiatives to discover, biomanufacturer, and characterize novel biologics for unmet needs in collaboration with different biopharmaceutical companies.

Prior to the NRC, Dr. Le Sauteur worked at Charles River Laboratories, where she established the Immunology Department, and led the scientific and strategic growth of that group from one to over 80 employees, effectively delivering expertise to sponsors in advancing numerous biologics through the drug development value chain.





Dr. Anahita Keyhani, PhD

Senior Director, Scientific Operations, Mass Spectrometry Laval, QC

Dr. Keyhani joined Altasciences in 2015, and leads a team of over 30 scientists dedicated to method development and innovator regulated bioanalysis, clinical and preclinical. In addition to her role as a scientific and client relationship manager, she actively trains, coaches, and mentors scientists from cross-functional departments throughout Altasciences.

Dr. Keyhani has over 20 years of CRO experience in regulated bioanalysis for preclinical and clinical development. Prior to joining Altasciences, her professional career was spent mainly within the bioanalytical group at Charles River Laboratories. She has also worked at Merck in Montréal as a senior scientist in pharmaceutical research and development and, during the pursuit of a Master of Science, participated in research and development projects for pediatric and adult nutritional products at Abbott Laboratories' Ross Product Division. Dr. Keyhani has authored or co-authored over 15 peer-reviewed publications. She has presented numerous posters and presentations in the bioanalytical domain, and actively participates in the Global CRO Council, a forum for CRO leaders to openly discuss bioanalysis and the regulatory challenges unique to the outsourcing industry.

Dr. Keyhani received her Bachelor of Science and Master of Science degrees from Ohio State University, with a doctorate from McGill University.





Dr. Danielle Salha, PhD

Senior Director, Global Immunology, Laval, QC

Dr. Salha joined Altasciences in September 2017 as Director of the Ligand Binding Assay Department and was promoted to Senior Director, Global Immunology in 2024. She leads a team of 45 scientists, QCs, and analysts dedicated to method development, validation, and sample analysis to support preclinical and clinical PK, PD, and immunogenicity studies.

Dr. Salha has over 20 years pharmaceutical and CRO experience in bioanalysis supporting drug development from preclinical to Phase I and II clinical studies, including vaccines, monoclonal antibodies, ADCs, and Oligonucleotides. Dr. Salha has authored and co-authored several peer-reviewed publications and is an inventor, with four patent applications to her credit. She received a Bachelor of Science from the University of Montréal, and a doctorate at McGill University from the Department of Immunology and Microbiology.





Kevork Mekhssian, MSc

Senior Scientific Director, Laval, QC

Kevork Mekhssian joined Altasciences in 2013. He has over 15 years of pharmaceutical and CRO experience in mass spectrometry-based characterization and quantitation of biotherapeutic proteins using LC-MS and hybrid LBA-LC-MS workflows.

He has actively participated in setting up high-throughput biotherapeutic quantitation methods and has greatly contributed to establishing Altasciences as an industry leader in this field. Kevork has authored and co-authored several peer-reviewed publications and presented at numerous bioanalytical and mass spectrometry international meetings. Kevork completed a Master of Science in Biochemistry at Concordia University in Montréal, Canada.





Milton Furtado

Scientific Director, Method Development Laval, QC

Milton Furtado joined Altasciences in 2007. He has over 25 years of experience in bioanalysis in the pharmaceutical industry. Milton has worked in the preclinical and clinical environments and has developed over 300 LC-MS/MS assays. Over the years, Milton has been a key asset in overcoming bioanalytical challenges and providing scientific direction in the CRO industry.

Milton has published over 25 journal articles, and peer-reviewed multiple scientific papers. He received his Bachelor of Science in Chemistry from Concordia University in Montréal, Canada.





Jeff Plomley, MSc

Scientific Director, Method Development Laval, QC

Jeff Plomley began his research career in the Gas Phase Ion Chemistry Laboratory of Prof. Raymond E. March as a research scientist designing novel ion trap scan functions to support applications development. He then joined Thermo Instruments Canada as an Applications Marketing Chemist, then SCIEX as a Senior Scientist in Product Definition and Core Research. Jeff has worked in both the preclinical and clinical CRO environment since 2001, developing over 250 de novo LC-MS/MS assays.

He has contributed to the publication of over 25 peer-reviewed papers, 70 scientific posters and technical publications, holds patents on MS instrumentation, and frequently blogs and presents on microsampling workflows and advanced MS techniques. Jeff's current research interests include applications development involving ion-mobility spectrometry, and the implementation of microsampling technology into patient-centric medical devices. Jeff holds a Master of Science in Chemistry from Queens University in Kingston, Ontario, Canada.





Dr. Susan Ohorodnik, PhD

Senior Director, Operations Seattle, WA

Dr. Ohorodnik joined Altasciences in July 2022. She leads the U.S.-based Laboratory Sciences departments, overseeing more than 45 scientific staff involved in the bioanalytical and immunological testing of small and large molecules, in support of preclinical and clinical programs. Dr. Ohorodnik has over 22 years of experience in bioanalysis with CROs and small biotech companies. Prior to joining Altasciences, she worked at Labcorp (previously Covance and Envigo), where she was the site lead for small and large molecule analysis, and was promoted to the global lead for LCMS scientists.

Dr. Ohorodnik received a Bachelor of Science and Master of Science degrees in chemistry from Old Dominion University, Norfolk, VA, and a doctorate in Analytical Chemistry from the University of Florida, Gainesville, FL. Dr. Ohorodnik's emphasis is on quality, adaptability, and continual process improvement to keep abreast of the scientific and regulatory challenges encountered in the drug development process.





Jean-Nicholas Mess, MSc

Principal Scientist, Method Development Laval, QC

Jean-Nicholas joined Altasciences as Method Development Scientist in 2004, after obtaining a Master of Science in Biochemistry from the University of Montréal. Over the years, Jean-Nicholas has shown a growing interest in biotherapeutic protein quantitation using LC-MS and hybrid LBA-LC-MS approaches, and has authored several publications and posters on the subject.

With a strong background in bioanalytical method development and troubleshooting, Jean-Nicholas has actively participated in devising biotherapeutic quantitation workflows, and has been a key contributor in the establishment of Altasciences as an industry leader in this field. In his current role as Principal Scientist, Jean-Nicholas is responsible for providing scientific support, technical leadership, and guidance throughout assay development, validation, and sample analysis.





Dr. Mano Sahoo, MS, PhD

Director, Bioassay Columbia, MO

Dr. Sahoo joined Altasciences in November 2021. He oversees the overall scientific, regulatory, and operational needs of the bioassay department at our preclinical site in Columbia, MO. Dr. Sahoo is an immunologist with more than 17 years of experience in both academic and GLP-regulated CRO environments involving studies related to preclinical drug development, immuno-oncology, and host-pathogen interactions.

Prior to joining Altasciences, Dr. Sahoo worked as a Senior Scientist at Envigo/Covance and was later promoted to Site Scientist Lead/Manager to lead the Immunology and Immunotoxicology group.

Dr. Sahoo received a Bachelor of Science and Master of Science in India, obtained his doctorate in Microbiology (Immunology) from the University of Mississippi Medical Center, and completed postdoctoral training from Chicago Medical School, IL.





Dr. Olga Malykhina, PhD

Principal Research Scientist, Laboratory Sciences

Dr. Malykhina is a biomedical scientist with six years of regulatory bioanalysis and immunogenicity experience and over 15 years of total research experience. Dr. Malykhina works closely with sponsors to develop and optimize bioanalytical and immunogenicity assays for use on either GLP or non-GLP studies. In addition, to developing methods, Dr. Malykhina serves either as a responsible scientist or contributing scientist overseeing method validations and sample analysis studies.

Dr. Malykhina graduated from Ohio State University with a doctorate in biomedical sciences, and completed a postdoctoral training at Northwestern University. Dr. Malykhina's doctorate research focused on developing and characterizing a gene therapy vector, while her postdoctoral research included characterization of HIV mucin trapping.





Ted (Theodore) Brus

Principal Scientist, Laboratory Sciences

Ted Brus joined Altasciences in 2022 as Principal Scientist for the LC-MS group. Ted has 24 years of experience with small molecule regulated bioanalysis using LC-MS in the CRO industry. Prior to Altasciences, Ted was at Labcorp (formerly Covance) for 22 years, including 16 years as a method development scientist where he developed approximately 300 LC-MS assays, clinical and preclinical, and performed over 100 validations.

Ted enjoys training and mentoring method developers and validation chemists, and giving expert technical LC-MS and scientific guidance to internal scientific and sponsor study teams.





Dr. Mingluan Chen, PhD

Principal Research Scientist, Method Development

Dr. Chen joined Altasciences in 2014, and is a principal scientist in the LC-MS method development group. He received a doctorate in Analytical Chemistry from Wuhan University, China, focusing on the characterization of phytohormones using microscale LC-MS. Dr. Chen has developed over 100 de novo bioanalytical assays by LC-MS, for both small and large molecules.

He has authored more than 20 peer-reviewed articles and has contributed to numerous scientific posters and presentations. More recently, one of his key objectives has been the establishment of novel LC-MS-based strategies and workflows for the quantitative bioanalysis of oligonucleotide therapeutics.





James Hnilo, BS

Principal Research Scientist Seattle, WA

James Hnilo joined Altasciences in 2023. He has a Bachelor of Science in Biochemistry from Washington State University, and over two decades of experience in all phases of drug discovery research and project management. With a wealth of technical knowledge, including assay development, data analysis, and molecular biology, James also holds a Green Belt Certification in Lean and SixSigma statistical and project management tools.

Over the course of his extensive career, James' work has been presented in multiple scientific publications and featured at many scientific meetings across the United States.





Dr. Adam Martin, PhD, MS

Principle Scientist, Laboratory Sciences, Columbia, MO

Dr. Martin has been with Altasciences since 2019. He has brought with him over a decade of experience managing an academic production and research lab for DNA cloning and cell-based assays.

Dr. Martin established the initial bioassay capabilities at Altasciences, and is still a contributing member of the team while overseeing the clinical pathology and test materials (pharmacy) groups within laboratory services.

He received a Master of Science in Applied & Environmental Biology, a doctorate in Chemistry from the Missouri University of Science & Technology, and postdoctoral training at University of Missouri, focusing on flow cytometry.





Dr. Martin Turcotte, PhD

Scientific Director, Flow Cytometry Laval, QC

Dr. Turcotte joined Altasciences in 2023. Bringing with him more than 13 years of scientific experience and a keen interest in health sciences, Dr. Turcotte's initial role was Scientific Liaison, before transitioning to his current position as Scientific Director, Flow Cytometry. Following the completion of a Doctor of Philosophy in Pharmaceutical Sciences from the Université de Montréal, and several years in the CRO industry, he has developed extensive expertise in flow cytometry technologies.

Dr. Turcotte is always enthusiastic to share his knowledge, and help Altasciences' partners improve the quality of their drug development programs.



KEY CRO SERVICES EXPERTS

- <u>Dr. Nicole Maciolek</u>, PhD, Vice President, Research Services, Medical Writing and Scientific Affairs
- Kristen Fitzpatrick, Executive Director, Data Analysis and Reporting
- Cynthia Marie Fazio, Associate Director, Medical Writing
- <u>Catherine Dussault</u>, Senior Director, Scientific and Regulatory Affairs
- <u>Dr. Sophie Boudriau</u>, PhD, Senior Principal Scientist, Scientific Affairs
- <u>Dr. Denise Milovan</u>, PhD, MA, CPsych, Senior Neuroscientist, Neuropsychologist
- <u>Dr. Laura McIntosh</u>, PhD, Senior Director, Program Management and Regulatory Affairs
- <u>Scott Ward</u>, Senior Director, Biostatistics and Programming
- Roland Jbeily, Manager, Regulatory Affairs
- <u>Eryn Corriveau</u>, Senior Director, Drug Development & Regulatory Strategy







Dr. Nicole Maciolek, PhD

Vice President, Research Services, Medical Writing and Scientific Affairs

Dr. Maciolek joined Altasciences in June 2018, and oversees data management, biostatistics, programming, medical writing, and pharmacology operations. She started her career in clinical research in 2007 and has held various roles in early clinical research across project management, data management, biostatistics, pharmacokinetics, and medical writing including overseeing operations, process, and quality for all aspects of data and reporting services.

Before joining Altasciences, Dr. Maciolek was a director on the early clinical research team at DaVita Clinical Research, a niche contract research organization that specialized in patients with renal or hepatic impairment, where she gained a keen understanding of the effective design, clinical conduct, and reporting of studies in these specialty populations. She has a doctorate in Molecular Genetics from the Medical College of Wisconsin.





Kristen Fitzpatrick

Executive Director, Data Analysis and Reporting

Kristen Fitzpatrick joined Altasciences in 2019, as Director of Medical Writing, bringing more than 13 years of CRO experience, and over seven years of leadership experience to the position. In 2021, she expanded her role to oversee the pharmacology department, helping to build a high-performing team and increasing support for preclinical studies. In 2023, her role grew again to include management of the data services organization, comprised of data management, biostatistics, and SAS Programming.

Kristen received her Master of Science degree in Molecular and Environmental Toxicology and began her career in preclinical study management, taking on roles of increasing responsibility before transitioning to early phase clinical project management and leadership.





Cynthia Marie Fazio

Associate Director, Medical Writing

Cynthia Marie Fazio started her career as a research scientist at McGill University, where she received a Master of Science in Developmental Biology. She has over 15 years of CRO experience, having worked previously as a study director in preclinical services and joining Altasciences' clinical operations team in 2006 as an assistant study manager. She later worked as a Clinical Research Scientist in the Scientific Affairs department for several years, managing various aspects of clinical trials and providing scientific support. In her current role as Manager of Medical Writing, she is responsible for overseeing and supporting the medical writing team in the preparation of high-quality study documents used in the context of sponsors' research programs.

In addition to her management role, Cynthia is also Lean Six Sigma Green Belt-certified and is actively involved in cross-functional improvement initiatives and quality management.





Catherine Dussault, BSC

Senior Director, Scientific and Regulatory Affairs

Catherine Dussault joined Altasciences in 2004. She has a Bachelor of Science in Biochemistry, and a post-graduate diploma in drug development. In her current role as Senior Director, Scientific Affairs, Catherine provides scientific leadership and a deep knowledge in regulatory work for various drug development clinical research programs.

Catherine has overseen over 2,000 clinical trials including single ascending dose (SAD), multiple ascending doses (MAD), food effect (FE), bioequivalence (BE), 505(b)2, drug-drug interactions, proof-of-concept (POC), and special patient population (renal and hepatic impairment, recreational drug users) studies. Catherine is enthusiastic and highly engaged with strong critical and scientific thinking skills. She promotes interdisciplinary work and collaboration between teams.





Dr. Sophie Boudriau, PhD

Senior Principal Scientist, Scientific Affairs

Dr. Boudriau joined Altasciences in 2013 as Senior Clinical Research Scientist, and has been in the CRO industry for more than 20 years. Her depth of knowledge was quickly recognized and she transitioned within the department to the research and development team (SRA R&D). In her current position, Dr. Boudriau continues to expand her expertise and adapt her specialized capabilities to trial design development and optimization, as well as becoming highly proficient in conducting PK/PD non-compartmental analysis. Dr. Boudriau has extensive capabilities in the specialized areas of protocol development, data analysis, and regulatory documentation. She has applied her knowledge to writing a number of abstracts and presenting posters/publications at international conferences.

Dr. Boudriau routinely reviews the evolving regulatory landscape for a wide range of regulatory agencies, such as the FDA, TPD, and EMA, and provides internal guidance to medical writers and pharmacokinetic scientists, as well as clients in support of their regulatory applications.





Dr. Denise Milovan, PhD

Senior Neuroscientist, Neuropsychologist

Dr. Milovan joined Altasciences in 2020. In former roles at Syneos Health and DecisionLine Clinical Research, she provided expertise and oversight of Neurocognitive early-phase programs dedicated to the assessment of the pharmacodynamic effects of CNS drugs. She has a strong interest in the adaptation and refinement of traditional neurocognitive as well as behavioural measures for computerized administration tailored to the specific requirements of early-phase clinical trials. Dr. Milovan practices clinical neuropsychology in a variety of settings, including hospitals (neurology, traumatic brain injury), non-profit organizations, and private practice.

She holds a doctorate and a Master of Science in Clinical Neuropsychology, and has also completed the requirements for a Master of Science in Clinical Pharmacology. As a member of the Council of the College of Psychologists of Ontario from 2015 to 2021, Dr. Milovan held various roles, including that of Vice President.





Dr. Laura McIntosh, PhD

Senior Director, Program Management and Regulatory Affairs

Dr. McIntosh joined Altasciences in 2022 and leads the program management team. She graduated from the University of Manitoba with a doctorate in Cell Biology, before undertaking postdoctoral studies in early diagnostic tools for skin cancer. Dr. McIntosh's robust scientific knowledge is combined with extensive experience in leadership and product development—having previously tenured as a venture partner, and led R&D in multiple biotech startups to develop innovative biological products and services.

Dr. McIntosh is driven by a passion for understanding clients' long-term strategies, finding inspiration in customizing programs with a comprehensive solution. Her commitment to understanding the bigger picture, and anticipating all stages of the sponsor's drug development strategy, is foundational to efficiently leading each program.





Scott Ward

Senior Director, Biostatistics and Programming

Scott Ward joined Altasciences in 2022, bringing with him 24 years of experience leading teams of biostatisticians and programmers in the pharmaceutical and CRO industry. Scott holds a degree in Business Management and Administration and embarked on his pharmaceutical career as a SAS programmer at Eli Lilly. During his time there, he gained valuable insights into the various stages of the clinical trial development process and honed his skills in leading studies from end-to-end.

Transitioning into the CRO industry, Scott focused on enhancing his technical expertise, particularly in latephase oncology trials. His career progression led him into management, where he spent seven years at the forefront, spearheading a team of 300 in the strategic implementation of global resource management.

In his current role at Altasciences, Scott oversees the biostatistics and programming departments. His driving motivation is the desire to assist sponsors in discovering groundbreaking and vital new therapies. Scott emphasizes a value-added approach to the representation of robust statistical data analysis, ensuring high-quality outputs that meet regulatory agency requirements





Roland Jbeily

Manager, Regulatory Affairs

Roland joined Altasciences in 2020, bringing more than seven years of experience in regulatory affairs and compliance for global authorities, such as the FDA, EMA, and TGA, with an in-depth expertise in Health Canada's drugs and cannabis regulations. As Manager, Roland oversees clinical trial applications to Health Canada for small drug molecules, biologics, natural and cannabis health products, and combo drug-medical devices.

He provides sponsors with strategic guidance on regulatory strategies, gap analysis, consultancy support, and liaison support with Health Canada. He has experience in chemistry, manufacturing and control (CMC), and pharmaceutical manufacturing.

Roland began his career working in the Québec Lab at Pharmascience as a chemistry analyst. From there, he held positions at Accord Healthcare as a regulatory affairs specialist, and Canopy Growth Corporation as a CMC manager for cannabis research products.

He is a member of the Ordre des chimistes du Québec (Order of Québec Chemists) and a member of the DIA (Drug Information Association). He earned a Master of Science in Biochemistry from Université de Montréal and a D.E.S.S. in Biomedical Engineering from Polytechnique de Montréal. He has a certificate in Leadership from edX (Harvard University), and a certificate in good clinical practices (GCP).





Eryn Corriveau, MSc, BSc

Senior Director, Drug Development and Regulatory Strategy

Eryn Corriveau joined Altasciences in 2023, bringing with her a wealth of expertise in diverse therapeutic areas. With a Master of Science in Human Physiology, and a Bachelor of Science in Biology, Eryn is currently working towards a doctorate at Quantum University; her research focuses on the impact of supramental awareness on disease prevention, healing, and health.

In her current role, Eryn guides regulatory strategies during early drug development, conducting gap analyses and leading interactions with regulatory agencies. Eryn's past positions and extensive background in regulatory affairs from companies such as Cencora, KYE Pharmaceuticals, and Verity Pharmaceuticals, showcases her commitment to advancing pharmaceutical development.





Dr. Hazel Clay, PhD, BSc

Scientific Advisor, Drug Development

Dr. Clay joined the Altasciences team in 2022 with over 30 years of experience supporting the development of innovator pharmaceutical assets.

Prior to that, she held a variety of different positions at Labcorp, from toxicology study director to head of study direction, where responsibilities included independent toxicology review for their UK clinic and ethics committee. She was a founder member of the program management service to accelerate clients through to first-in-human studies. Latterly she was Executive Director, Science and Strategy, for early-phase development solutions, leading a global team of drug development specialists. During this time, she was the industry lead for the nonclinical module at Leeds University Master's Course in Biopharmaceutical Development.

Dr. Clay is passionate about providing bespoke solutions for biotech companies and supporting their goals through nonclinical development and transitioning to first-in-human studies through to clinical proof of concept. She has extensive experience in navigating the challenges of drug development.



Peter Varney

Pharma Development and Strategy Advisor

Peter Varney joined Altasciences in 2021 as Pharma Development and Strategy Advisor. Peter brings 40 years of experience in commercial development, strategic alliances, and relationship management from his previous roles at Covance (now Labcorp). His previous roles included Vice President, Strategic Partnering, and Vice President, Sales and Marketing. Initially trained as a toxicologist, his experience grew to encompass all areas of nonclinical, clinical pharmacology, and Phase II to IV clinical development.

In all roles, the objective was to create strategic value to all clients, ranging from emerging companies through to top 20 pharma. Peter is based in the UK and provides guidance to the strategic direction of Altasciences in Europe, through the provision of industry-leading programmatic approaches to drug development.





Dr. Pete Gaskin, PhD, BSc (Hons) Scientific Advisor, Drug Development

Dr. Gaskin joined the Altasciences team in 2024, bringing over 30 years of experience in supporting the development of innovative biopharmaceuticals. Before joining Altasciences, he was the senior director and head of the global scientific advisory services team at Charles River Laboratories. He also served as a Principal at Aptuit Consulting and PPD, where he advised clients and the company on biopharmaceutical development strategy and due diligence. At Quintiles he led a team of experts managing complex global drug development projects from clinical proof of concept to market.

Prior to this, he held various positions in the life sciences and CRO industry, ranging from toxicology study director to senior toxicologist. Dr. Gaskin has presented at many international meetings and lectured on drug development at the Universities of Edinburgh, Napier, QMUL, and Porto.

Dr. Gaskin is passionate about providing tailored development strategies for innovative biological products and advanced therapies, supporting biotech companies' goals from nonclinical development to clinical proof of concept.





Jason Boehme

Associate Director, Program Management

Jason Boehme joined Altasciences in 2018 as a Project Manager. He is an experienced Project Manager and has over 20 years experience working in preclinical and clinical research. Prior to joining Altasciences Jason spent over 17 years in the CRO industry, including 10 years in preclinical research, and over seven years in clinical research.

Working in clinical research, Jason managed a variety of studies ranging from Phase I, II, and III, SAD/MAD, DDI, TQT, dermatology, renal and hepatic impairment, CNS, and endocrine in both healthy normal volunteers and patients.

Since joining Altasciences, Jason has gained additional experience working in a variety of studies, drawing on his vast experience to problem-solve and implement projects quickly and within budget. His experience includes internal and external site management, oversight of data services (data management, biostatistics, programming, clinical monitoring, and medical writing) and working with various preclinical and clinical vendors.





Jennifer Chown

Director, Strategic Programs

Jennifer Chown joined Altasciences in 2024 as Director of Strategic programs, bringing 24 years of experience in preclinical research and a passion for novel medications for new indications, data science enhancements, and regulatory strategies.

Prior to joining Altasciences, Jennifer worked as Associate Director of Alliance Management at Charles River Laboratories, with oversight of the global program management team. In this position, she developed experience and interest in working with customers to optimize their drug development process through strategic partnering and effective collaboration.

Jennifer has extensive experience in leadership, regulatory, process improvement, and quality risk management, as well as program and alliance management. She received a Bachelor of Science in Microbiology and Immunology from McGill University, QC.





Dr. Laurianne Bessiere, PhD

Process Improvement Manager

Dr. Bessiere joined Altasciences in 2016 as an associate scientist in the scientific affairs team. In this role, she progressed within the team, working on increasingly complex studies and providing study design synopses for bioequivalence and Phase I studies, along with scientific guidance and support to both sponsors and internal teams.

In 2024, she transitioned to the role of Process Improvement Manager, focusing on enhancements to Compass, Altasciences' study management system. Her work aims to streamline processes and facilitate collaboration between Altasciences and its Sponsors.

Dr. Bessiere earned a Doctorate in Biology from Université Sorbonne-Paris-Cité, France, in 2015, where she studied the genetic mechanisms of a rare juvenile ovarian cancer. She is driven by a strong interest in improving the management of diseases with unmet medical needs and highlighting women's health challenges in clinical research.



KEY MANUFACTURING AND ANALYTICAL SERVICES EXPERTS

- Dennis DiBiagio, BS, Vice President, Scientific Advisor
- Andrew Buis, BSc, MSc, Senior Formulation Scientist
- Scott Myslinski, BS, Director, Manufacturing
- Nasir Egal, General Manager, CDMO Services





Dennis DiBiagio, BS

Vice President, Scientific Advisor, Harleysville, PA

Dennis joined Altasciences in 2016, and is a registered pharmacist with more than 42 years of experience in the pharmaceutical industry. With an extensive background in pharmaceutical contract manufacturing, he has been responsible for manufacturing services, and all aspects and activities associated with the operation of a GMP pharmaceutical manufacturing facility.

Dennis has successfully worked as a member of multidisciplinary teams alongside clients, to develop multiple dosage forms required in support of all phases of product development, from pre-IND clinical supply manufacturing, through commercial scale manufacturing. In his current position as Vice President, Scientific Advisor, Dennis interfaces with the business development and proposal teams in the preparation of client proposals.

Dennis was a founding partner, and Director of Manufacturing Services, of Pharmaceutical Manufacturing Research Services, Inc., where he was responsible for product development, clinical supply manufacturing, and commercial manufacturing. In addition, Dennis has held various support and leadership positions in product development, manufacturing services, and facility management while working at Greenwich Pharmaceuticals and William H. Rorer.

Dennis is a graduate of Duquesne University School of Pharmacy, PA.





Andrew Buis, BSc, MSc

Senior Formulation Scientist, Harleysville, PA

Andrew Buis joined Altasciences in 2021, bringing over eight years of experience in designing and developing drug formulations from bench top to clinical trials. With previous experience at Lubrizol Life Sciences' CDMO Division and DSM Nutritional, Andrew is well-versed in a broad range of dosage forms, scaling up and optimizing processes for GMP production, and supporting GMP manufacturing.

Andrew began his professional career at Pennsylvania State University, Eberly College of Science, where he earned a Bachelor of Science in Biochemistry. He later received a Master of Science in Biotechnology from the University of South Florida, Morsani College of Medicine, in 2016.





Scott Myslinski, Bs

Director, Manufacturing, Harleysville, PA

Scott Myslinski joined the CDMO team in 2014 as a Manufacturing Associate. Throughout his early years at the CDMO site, Scott was able to apply his experience and skills to quickly grow within the company and was promoted to Manufacturing Manager in 2015.

After successfully managing the manufacturing group for several years Scott was eventually promoted to his current role as Director of Manufacturing in 2022. Scott has over 10 years of industry experience in manufacturing. Prior to joining Altasciences, he worked with another pharmaceutical manufacturing CDMO where he gained extensive experience and knowledge in his role.



Nasir Egal, PhD

General Manager, CDMO Services Harleysville, PA

A senior executive with over 20 years of extensive experience in the pharmaceutical industry, Nasir Egal joined Altasciences in 2024. Bringing with him a deep understanding of pharmaceutical regulations, Nasir has held various senior roles at prominent organizations, including Quotient Sciences, Sanofi, Novartis, and Merck. He also spent several years as a research scientist at the U.S. FDA.

Nasir holds a doctorate in Chemistry from the American University in Washington, D.C., as well as executive management certificates from IMD Business School in Lausanne, Switzerland, and Franklin W. Olin Graduate School of Business at Babson College in Massachusetts.



KEY COMPLIANCE AND QUALITY ASSURANCE EXPERTS

- <u>David Grégoire</u>, Chief Quality and Compliance Officer
- Paul Sidney, Vice President, GLP Quality Assurance
- <u>Natasha Savoie</u>, Senior Director Quality, Clinical and Research Services
- <u>Stephen Rogenthien</u>, Senior Director Quality, CDMO





David Grégoire

Chief Quality and Compliance Officer

David joined Altasciences as Director, Quality Assurance, in 2012. In 2014, he was appointed Vice President, Quality Systems, with overall responsibility for the QA groups and the implementation of quality systems across the organization. In 2018, he became Vice President of Compliance and Regulatory Affairs. In 2021, he was appointed Chief Quality and Compliance Officer, his current role.

David started his career as a Quality Assurance Inspector at CTBR Bio-Research (now Charles River Laboratories) in 2000, where he progressed to QA Specialist in 2003. Prior to Altasciences, he worked at Pharmascience Inc.

As Manager of Clinical Quality Services, he implemented GLPs in a newly developed bioanalytical laboratory, and designed a quality system for Altasciences' clinical outsourcing operations. David has been actively involved in the Canadian QA research community as a member of the Board of Directors of the Canadian Chapter of the Society of Quality Assurance (CCSQA), for which he also served as Vice President in 2013, and President in 2014. David holds a Bachelor of Science in Biology from McGill University.





Paul Sidney, BS

Vice President, GLP Quality Assurance

Paul joined Altasciences as Senior Director, Compliance and Regulatory Affairs, in 2020, with over 35 years' experience in regulatory affairs and compliance. He has held senior management roles developing and directing multi-site GLP and GCP regulatory programs. He started his career with Sandoz Pharmaceuticals in the Medical Affairs department, in a team preparing and submitting new drug submissions to Health Canada.

He subsequently joined BioResearch Laboratories (now Charles River Laboratories) initially managing a team of auditors assuring compliance for regulated nonclinical toxicology studies and clinical research in a Phase I clinical research unit. His regulatory and compliance responsibilities grew within Charles River Laboratories to provide multi-site global oversight both in GLP/GCP regulated research, as well as a quality systems and regulatory lead supporting the corporate mergers and acquisitions team.

The latter role required that quality systems and compliance programs be developed and implemented in European and North American sites. Paul has maintained an active role in many regulatory, quality and compliance societies (RAPS, SQA, RQA, ASQ, and CCSQA). He was the founding president of the CCSQA, and has presented on regulatory and compliance topics at society conferences and academic institutions in Europe, North America, Japan and China. Paul holds a Bachelor of Science from McGill University.





Natasha Savoie

Senior Director Quality, Clinical and Research Services, Laval, QC

Natasha Savoie joined Altasciences in 1999 as a team manager in the bioanalytical laboratory. She participated in turning the laboratory into a regulated environment from a research facility, as well as helping to obtain our OECD GLP recognition. Her extensive bioanalytical background led to a compliance role and then to the Quality Assurance department, by way of corporate training, where she helped to create Altasciences' corporate training program. In her bioanalytical and QA roles, Natasha has hosted hundreds of sponsor audits and well over 40 successful international regulatory inspections.

Natasha has been with the QA department since 2013, increasing her responsibilities to oversee QA for the Altasciences' clinical and bioanalytical facilities. Natasha actively participates in the Society of Quality Assurance, where she is the past co-chair of the Bioanalytical Specialty Section. She is also part of the teams that organizes the annual "Workshop on Recent Issues in Bioanalysis", and the annual Global CRO Council Forums, participating in the authorship of over 30 articles and white papers. Natasha is proud of Altasciences' excellent quality and inspection history, and actively works with operations in order to ensure our customers' expectations are exceeded.





Stephen Rogenthien

Senior Director Quality, CMDO Seattle, WA

Stephen Rogenthien has over 25 years of experience in GLP and GMP compliance operations, and has been responsible for leading compliance programs and initiatives within several CROs. He has managed site-wide quality system operations and administration, including those operations that were required to be compliant with FDA and EPA Good Laboratory Practices (GLP) and quality standards of other regulatory bodies (ICH, OECD, JMAFF, MHLW, etc.).

As Senior Director at Frontage Labs, he managed the quality assurance program for compliance with FDA and EPA GLP and international GLP regulatory standards, as well as developed and monitored short- and long-term site-wide compliance objectives.

Stephen has maintained a leadership role in the industry, having held the role of Vice President, President, and Past President (2018-2020) of U.S. SQA. He has also served as chair on specialty sections in the SQA (notably bioanalytical).

A respected professional in the industry, Stephen has demonstrated strong leadership in building effective compliance programs in nonclinical research and GMP support laboratories.





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