Meet Your Altascientists
KEY PRECLINICAL RESEARCH PARTNERS

- Mike Broadhurst, Executive General Manager
- Ian Vanterpool, Vice President, Operations
- Francis Douville, Vice President, Technical Operations
- Dr. Norbert Makori, BVM, MSc, PhD, DABT, Vice President, Toxicology
- Dr. Wendell P. Davis, DVM, DACVP, Vice President, Pathology
- Bruce Bernacky, DVM, Chief Animal Welfare Officer
- Andy Brown, Site Director
- Dr. Jeffrey Burdick, VMD, DSP, Site Director and Attending Veterinarian
- Dr. Scott Boley, PhD, DABT, Senior Scientific Advisor
- Julie Forget, DESS Tox, DABT, Senior Director, Safety Assessment
- Dr. Alexander Walz, PhD, Director, Safety Assessment
- Catherine (Catie) Selby, MS, Director of Operations
- Isabel Tourigny, Director, In Vivo Operations

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KEY PRECLINICAL RESEARCH PARTNERS

- Dr. Megan Haney, DVM, PhD, DACLAM, Director, Veterinary Services, Attending Veterinarian
- Yafei Chen, MS, Director, Toxicology
- Dr. Simone Iwabe, DVM, PhD, DACVO, Senior Veterinary Ophthalmologist
- Emily Callahan, DVM, Staff Veterinarian
- Dr. Sandra Love, PhD, Director, Safety Pharmacology
- Dr. Adam Martin, PhD, Clinical Pathology and Test Material Department Manager
- Dr. Lisa Biegel, Senior Scientific Director, Preclinical Services
- Annette Kenser, Senior Director of Quality Assurance, Preclinical Services
- Shayna Halverson, Manager, Quality Assurance

PATHOLOGISTS

- Dr. Keven Jackson, DVM, PhD, DACVP, Principal Pathologist
- Dr. Shunji Nakatsui, PhD, DJSTP, DJCVP, Research Pathologist

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KEY PRECLINICAL RESEARCH PARTNERS

PATHOLOGISTS
- Dr. Johanna Rigas, DVM, MS, DACVP, Veterinary Clinical Pathologist
- Dr. Elaine Debien, DVM, DEC, MSc, DACVP, Principal Pathologist
- Dr. Christine Watson, DVM, MS, DACVP, Research Pathologist
- Dr. Anil Puttaswamy, DVSc, DABT, MVSc, BVSc & AH, Senior Pathologist

STUDY DIRECTORS
- Dr. Satoru Oneda, DVM, PhD, DRDT, Study Director III
- Narine Lalayeva, MS, Study Director II
- Jean-Christophe Queudot, Study Director, Principal Scientist
- Dr. Li Zhan, MD, PhD, DABT, Study Director II
- Dr. Kelsey Brooks, PhD, Scientist/Study Director, Safety Assessment
- Dr. Cassi Johnson, PhD, Study Director

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KEY PRECLINICAL RESEARCH PARTNERS

STUDY DIRECTORS

- Stefan Nechev, MD, DABT, Study Director III
- Dr. Katherine Irby, PhD, Associate Scientist, Study Director
- Monserrath Camacho Ayala, MS, Associate Scientist, Study Director
- Dr. Rosemary Cook, CVT, PhD, Scientist, Study Director
- M.L. Diane Joyal, BSc, Scientist, Study Director
- Brian Klatt, Associate Scientific Director, Safety Pharmacology
- Zurith Lopez, MSc, Laboratory Manager and Study Director, Analytical Chemistry
- Jay Pennell, MS, Principal Scientist, Study Director
- William Tuman, MS, Associate Scientific Director, PK
- John MacMaster, Associate Scientist, Study Director, Safety Assessment
- Tim Madsen, Senior Principal Study Director

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KEY PRECLINICAL RESEARCH PARTNERS

STUDY DIRECTORS

- Dr. Luke Zhang, MD, MS, Principal Study Director
- Dr. Joseph Agolory, PhD, RLATG, Senior Study Director
- Kyle Klepner, Senior Study Director
- Kalleigh McGinley, MS, RLAT, Senior Study Director
- Miri Pannu, MS, Study Director
- Ryan Therrien, Study Director
- Michelle Jewett, MS, Associate Scientist, Study Director
- Jennifer Shenise, Associate Scientist, Study Director
Mike Broadhurst joined Altasciences in 2018. As the Executive General Manager for Altasciences’ preclinical facility, 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, Massachusetts.
Ian joined Sinclair Research (now 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 joined the Altasciences team in 2018, as Vice President, Technical Operations, Seattle. 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 and up to Director of in vivo and Laboratory Sciences Operations. Francis’ career extends beyond his beginnings in Montreal, 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 that reopened an east-coast facility in Shrewsbury, Massachusetts.
Dr. Norbert 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 role and in management.

Prior to joining Altasciences, Norbert led the General Toxicology department at Charles River’s site in Ashland, Ohio, 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 PhD in Comparative Pathology.
Dr. Wendell P. Davis, DVM, DACVP  
Vice President, Pathology  
Seattle, WA

Dr. Wendell 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 diplomat member of the American College of Veterinary Pathologists.
Dr. Bernacky, DVM, joined Altasciences in October 2014 as Site Director for the Seattle facility before becoming Chief Animal Welfare Officer in December 2016. Throughout his 34-year career, he has held positions of Chief Clinician, Researcher, Attending Veterinarian, and Animal Welfare Officer, in a myriad of environments (private practice, the federal government, academia, research, and CROs). Bruce ensures that animals utilized at Altasciences are guaranteed the highest level of care so as to achieve their maximum health potential while providing the highest level of results from their research protocols.
Andy Brown joined Altasciences in 2021 as part of Altasciences’ acquisition of Sinclair Research Center, LLC. As the site director for Altasciences’ preclinical facility in Columbia, MO, Andy works closely with the executive management team to enable the development and deployment of high-quality preclinical research services aimed to support sponsors’ small and large molecule drug development programs. Andy is focused on creating a high-performance work culture backed by a scalable operational infrastructure and emphasis on continuous process improvement. Prior to joining Altasciences, Andy spent the last 15 years of his career serving in a variety of commercial leadership roles with increasing responsibility for leading the companies’ core business operations and growth strategy. Before Altasciences, Andy was the Vice President of commercial operations at Sinclair Research, LLC (October 2018–December 2021). Prior to that, he served as the Vice President of global strategic accounts for pharmaceutical, crop protection, and chemical at Envigo, Inc. Andy earned a BA in marketing management and ecommerce from Anderson University and an MBA with concentrations in leadership and finance from Butler University.
Jeffrey Burdick joined Altasciences in 2015. As Site Director and Attending Veterinarian he 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 VMD from the University of Pennsylvania and completed an ACLAM residency program at GSK. He has over 20 years of combined biomedical research experience in academic, pharmaceutical, and CRO settings.
Dr. Scott Boley, PhD, DABT, 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. In his role as Senior Vice President of Research, Scott oversees the research, report services, and SEND groups at Sinclair Research (now Altasciences) in support of each sponsor’s preclinical safety programs.

Scott is a diplomate of the American Board of Toxicology and holds a Bachelor of Science in Biochemistry and a PhD in Biochemistry/Environmental Toxicology from Michigan State University.
Julie Forget joined Altasciences in 2018 as Director, Safety Assessment and became Senior Director in 2022. With over 15 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 Charles River Laboratories on the east coast, which contributed to her experience as manager.
Dr. Walz joined Altasciences in 2008. From initial client contacts to protocol design, from study monitoring to data interpretation, Alex 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, Alex’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. Alex earned his PhD in molecular biology at the University of Dresden/Germany in conjunction with the University of Minnesota with highest honors.
Catherine (Catie) Selby, MS
Director, Operations
Columbia, MO

Catie Selby has worked in biomedical research for 10 years in variety of operational and research roles. Catie started her career as a Research Assistant in an academia role and moved to Study Director at Sinclair Research (now Altasciences) in 2012. Since 2015, she has served as Sinclair Research’s Director of Operations. In this capacity, she oversees the in-life operational group, husbandry group, and the sample logistics group. Catie has a background in animal science, a master’s degree in Swine Reproduction, and experience in all aspects of study monitoring, study management, and staff development.
Isabel Tourigny

Isabel joined Altasciences in 2019. As Director of Operations, Isabel is responsible for husbandry, scientific services for large and small animals, necropsy, histology, and sample management. She has over 22 years of preclinical industry experience, and has worked in different environments, departments, and countries within large CROs.
Dr. Megan Haney joined Sinclair Research (now Altasciences) in 2019 and oversees the animal care program. In this capacity, Megan manages the veterinary services team and is involved in facility and operational management as well. Prior to joining Sinclair Research, she received her DVM from Kansas State University and completed a PhD and ACLAM residency program at the University of Missouri.
Yafei Chen has 18 years of experience in general toxicology, safety pharmacology, and investigative biomarkers from the CRO and pharmaceutical industries. He 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.

Yafei Chen joined Sinclair Research (now Altasciences) in 2021. Prior to Sinclair Research, he held Study Director and Study Monitor roles at both CROs and pharmaceutical developers, including AstraZeneca and Janssen.

A graduate from Peking Union Medical College, with a MS 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. Simone Iwabe, DVM, PhD, DACVO

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.

Dr. Iwabe received a Master’s degree 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).
Emily Callahan joined Sinclair Research (now Altasciences) in 2018. As a Staff Veterinarian, she has an emphasis in surgery and also assists with protocol and model development. Prior to joining Sinclair Research, she received her DVM from the University of Missouri’s College of Veterinary Medicine and worked as a clinical veterinarian in a private companion animal practice.
For more than 20 years, Dr. Sandra Love has specialized in providing safety pharmacology research services to small and large biopharmaceutical drug developers. Prior to joining Sinclair Research (now Altasciences) in 2020, Sandra was Director of Pharmacology at Charles River-Stilwell where she oversaw the safety pharmacology program, providing guidance on study designs to sponsors and supervising all functions and personnel for the pharmacology group.

A graduate of the University of Missouri, Dr. Love holds a PhD in Pharmaceutical Sciences from the University of Missouri, Kansas City.
Dr. Adam Martin, PhD, MS, has been with Sinclair Research (now Altasciences) since June, 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 Sinclair Research, and is still a contributing member of the team while overseeing the clinical pathology and test materials (pharmacy) groups within laboratory services. Dr. Martin received an MS in Applied & Environmental Biology, a PhD in Chemistry from the Missouri University of Science & Technology, and post-doctoral training at University of Missouri focusing on flow cytometry.
Lisa Biegel joined Sinclair Research (now Altasciences) in 2022. Lisa 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. She 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 VP, 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.

Lisa received a PhD in toxicology from Texas A&M University. In her current role, she will provide 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.
Annette Kenser’s key interests lie in scientific studies, research and development, quality assurance, and regulatory management. She obtained a bachelor of science degree in biology, with a minor in chemistry, from Rockhurst University.

Annette began her career as a microbiologist for upstream processing of viral antigens, and then moved on to vaccine quality control testing. After mastering her laboratory skills, she transitioned into the regulatory environment of GLP quality assurance (QA). As a scientific QA auditor, she was able to learn the global regulations, laws, and guidelines supporting scientific research in all GxP areas. As an auditor, she acquired critical thinking skills and became adept at managing ambiguity, important assets given the continual evolution of the requirements and interpretations of regulations, laws, and guidelines. Throughout her career, she has worked for CMOs, CROs, and sponsors. She received her registered quality assurance professional certification in GLPs in 2008, maintaining it through continued education. Between her education and experience, she has been fortunate to learn the multiple interfaces of product development from drug discovery through product maintenance.

Annette joined Altasciences in 2022, and looks forward to collaborating with colleagues to identify areas of improvement and align quality assurance activities across the organization.
Shayna Halverson joined Altasciences in 2006. As the Manager, Quality Assurance Unit, at our preclinical facility, Shayna works closely with the site’s management team to maintain a pulse on quality and compliance with FDA GLP regulations. Additionally, Shayna works with Quality Assurance management across Altasciences to ensure a consistent approach towards quality and compliance. Shayna has been in the industry for over 13 years, and previously worked as a Technician handling NHPs.
Dr. Keven Jackson, DVM, PhD, DACVP

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 PhD in Veterinary Microbiology from the Washington State University.
Dr. Shunji 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 and a master’s degree in Agricultural Sciences from Kobe University, and a PhD 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. 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. Her doctorate in veterinary medicine was earned at Oregon State University, followed by a residency in veterinary clinical pathology. Her Master's degree was in biology at 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 DVM and master’s degree in 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 member of the American College of Veterinary Pathologists.

Prior to joining Altasciences, Dr. Debien served as a senior veterinary pathologist at Charles River Laboratories, where she developed experience and interest for gene therapy, biotherapeutics, and intrathecal toxicity studies in nonhuman primates, and carcinogenicity studies in transgenic mice.
Dr. Watson joined Altasciences in 2022. She is a board-certified veterinary anatomic pathologist with extensive experience in toxicological pathology, including discovery and preclinical test article development. Dr. Watson received a master’s degree in biology (oncology focus) from Southern Connecticut State University, DVM from the University of Glasgow, and completed an anatomical pathology residency at the University of Minnesota. She has worked at a few different CROs as well as a non-profit cancer research center where she focused on immunotherapeutics and novel test article development.
Dr. Puttaswamy joined Altasciences in 2022. He is a board-certified toxicologist and veterinary anatomic pathologist with extensive experience in toxicological pathology, including discovery and preclinical development. Dr. Puttaswamy received both a bachelor’s degree in veterinary medicine and a master’s degree in veterinary pathology from the Bangalore Veterinary College in India. He then completed a doctorate of veterinary sciences (DVSc) degree with an immunology and infectious disease focus at the University of Guelph, where he also completed a residency in laboratory animal pathology. Prior to joining Altasciences, Dr. Puttaswamy worked as a discovery pathologist and toxicologist supporting anticancer drug discovery and development, and as a study pathologist at GLP-accredited CROs in India.
Dr. Oneda joined Altasciences in 2002. With 30 years of industry experience in general toxicology, developmental and reproductive toxicology (DART), and certified as a developmental and reproductive toxicologist (DRDT) with the Japanese Teratology Society, Dr. Oneda is a DVM with significant preclinical GLP CRO experience. He has targeted expertise in facilitating and managing DART studies (fertility, EFD, PPND, placental transfer, etc.) in rodents, rabbits, and NHPs, and general toxicology studies in rodents, canines and NHPs. Dr. Oneda began his career as a toxicology research associate/husbandry staff member and, for many of those early years, garnered a breadth of practical, hands-on experience with many study-related procedures, including dosing, observations/measurements, necropsies, and fetal examinations.
Narine Lalayeva, MS
Seattle, WA

Narine joined Altasciences in 2005. She has 15 years’ of experience conducting GLP/Non-GLP studies with small and large molecules, with particular expertise in the conduct and direction of GLP preclinical toxicology, and related fields such as developmental and reproductive toxicology (DART), and general toxicology. She has targeted experience in toxicity (single dose, multi dose, chronic), DART (NHP) and small animals; including enhanced ePPND studies in NHPs), JET ECG, safety pharmacology, vaccine studies (small animals), toxicology, intrathecal, dose range finding, and model development (diabetic NHP model). She has also been instrumental in the development of Altasciences’ DART background dataset.
Jean-Christophe Queudot joined Altasciences in 2019. As Principal Scientist, Jean-Christophe works closely with internal teams to ensure the development of preclinical solutions that support both small and large molecules in all standard laboratory species. As a Study Director with over 12 years of experience in safety assessment, Jean-Christophe also supports the preclinical Safety Pharmacology division for developing and maintaining industry standards in this field.
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). He has four years of experience working as a study director on GLP preclinical safety studies at CRO West China-Frontier Pharma Tech Co., Ltd., coupled with 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 School of Medicine at Indiana University and at the School of Medicine at the University of Louisville.
Dr. Kelsey Brooks joined Altasciences in 2019 with a focus on chromosome segregation abnormalities during early embryo development. Prior to joining Altasciences, Kelsey completed her postdoctoral fellowship at the Oregon National Primate Research Center, outside of Portland.
Dr. Cassi Johnson, PhD

Dr. Johnson joined Altasciences in 2020 as a Research Scientist and has two-years experience directing both non-GLP and GLP studies. Her expertise includes running studies in both large and small animals and conducting vaccine studies. Prior to becoming a Study Director, Dr. Johnson’s graduate work focused on the effect of Chronic Kidney Disease on the intestinal microbiome.
Dr. Nechev joined Altasciences in 2005. With 20 years of preclinical CRO experience (immunotoxicology, general toxicology, and clinical pathology), Dr. Nechev is a board-certified toxicologist with an MD 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. Katherine Irby, PhD

Dr. Irby joined Altasciences in 2021 as a Study Director with previous experience designing and running clinical GCP studies. Dr. Irby completed her doctoral work at Purdue University with a focus in analytical chemistry and mass spectrometry techniques, method development, and complex mixture analysis. She looks forward to working closely with each client to develop and run the best possible preclinical studies for their needs. She enjoys diving into the unknown with sponsors and her colleagues to learn more about new drug candidates and to help the evolution towards first-in-human trials.
Monserrath Camacho Ayala, MS
Associate Scientist,
Study Director
Scranton, PA

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

Prior to joining Altasciences, she 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

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.
M.L. Diane Joyal, BSc

Scientist, Study Director
Scranton, PA

Diane Joyal joined Altasciences in 1993 as a Senior Project Leader and quickly transitioned into a Study Director, where she conducts studies in small and large animals, including DART studies, acute, sub-chronic and carcinogenicity studies, and ocular toxicology studies. Diane brings over 33 years of professional experience in preclinical safety evaluation to clients’ programs.

Prior to joining Altasciences, Diane was a Project Leader and Scientist at a CRO located in Senneville, Quebec, where she conducted sub-chronic and carcinogenicity studies and basic FOB testing. Outside of the CRO industry, Diane was a Study Director in the pet food industry for two years, designing and conducting studies for palatability, digestibility and nutritional assessments, as well as dental studies (for the VOHC Seal of Approval) in dogs and cats.
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 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 at Altasciences, he has conducted many of the various discovery pharmacology studies, such as anti-inflammatory, analgesia models, cardiovascular, and so on.
Zurith Lopez joined Altasciences in 2018. As a Study Director in Analytical Chemistry and as a Laboratory Manager, she oversees the conduct of method validation and dose formulation analysis of compounds that are used in clinical and preclinical studies. She manages the workflow of the analytical department and works closely with Quality Assurance and other study directors in maintaining GLP compliance and improving processes. Zurith has over 15 years of experience in the CRO industry in Canada and the United States in different roles: Chemical Analyst, Team Leader, Validation Auditor, and Quality Assurance Auditor. She holds a BSc in Pharmacology from Universidad de las Americas and a MSc in Biotechnology from CINVESTAV-IPN, Mexico. Zurith regularly attends online seminars in quality and continuous improvement.
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/or eyelids and liquid, as well as gel and solid formulations administered intravitreally.

Prior to joining Altasciences, he worked with a CRO in upstate NY where he conducted acute toxicology studies. In total, 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

Bill Tuman joined Calvert Laboratories in 1982 before it became Altasciences in 2021. 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 also oversees the Analytical Chemistry group, which provides dosing formulation analysis support for on-site toxicology and safety pharmacology studies.
John MacMaster joined Altasciences in 2021 and brings with him 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 his bachelor’s degree 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

Senior Principal Study Director
Columbia, MO

Timothy (Tim) Madsen joined Sinclair Research (now Altasciences) in 2003 and has more than 32 years of preclinical research experience. As a part of Sinclair Research, Tim has served as a GLP study director, conducting animal health, surgical device, diabetic testing, wound-healing, and general toxicology studies. 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, and spent more than 14 years in the Metabolism Chemistry and Aquatic Toxicology divisions at ABC Laboratories in Columbia, MO.
Dr. Luke Zhang joined Sinclair Research (now Altasciences) in 2007 and has more than 25 years of toxicity assessment and drug development experience. In the role as Principal Study Director, Luke is responsible for study management including multiple aspects such as toxicology, efficacy, wound healing and medical device testing, specific program training, new model development, and client support for nonclinical needs.

Luke has extensive expertise in drug development as well as the regulatory expectations for a variety of study types, including those related to wound healing.

Luke graduated from a medical school with a clinical medicine degree (MD) in China and holds a MS in molecular pathology. In addition, Zhang has more than a decade of experience in human pathology and has extensive research experience in anticancer drug development.
Dr. Joseph Agolory joined Sinclair Research (now Altasciences) as in 2021. His responsibilities include running both non-GLP and GLP studies, developing IACUC and study protocols, overseeing wide variety of studies (including toxicology, pharmacokinetic, and pharmacodynamic studies), data interpretation, report writing, and communication with all key stakeholders. He is experienced in all aspects of study monitoring, test article management, sample handling, and data collection, and management.

Joseph has worked in biomedical research for over 17 years. He received his DVM from Moscow State Academy for Veterinary Medicine and Biotechnology in 1997, and earned his PhD in Veterinary Medicine from the same institution in 2001. He has been a certified Laboratory Animal Technologist since May 2005.

Prior to joining Sinclair Research, Joseph was a Senior Study Director, Custom at WuXi AppTec. His past work experience also includes holding a variety of roles such as Associated Director, Principal Scientist, and Study Director at other research companies.

For Joseph, a day spent at work is one step closer to saving human lives.
Kyle Klepner joined Sinclair Research (now Altasciences) more than 11 years ago and has held a variety of operational and project management roles. Kyle is experienced in all aspects of study monitoring, test article management, 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, Kyle 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 joined Sinclair Research (now Altasciences) in 2012 as an animal technician after graduating with a Bachelor of Science degree in animal science from the University of Missouri. She moved into the research department in 2013, primarily working with Sinclair Research’s type I diabetic pig model in pharmacodynamic/pharmacokinetic studies.

While working as a study director, Kaileigh achieved a Master of Science degree in integrative pharmacology from Michigan State University. She currently conducts the CNS safety pharmacology studies for Sinclair Research. 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 joined Sinclair Research (now 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 Sinclair Research, Miri completed her bachelor’s degree in biology at St. Louis University, and earned an M.S. 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 pursuing the research field stems from her enthusiasm for working with clients, and seeing how her efforts contribute to developing and achieving their preclinical goals.
Since joining Sinclair Research (now Altasciences) in 2019, Ryan has conducted a wide array of preclinical toxicology and animal health studies, as well as pharmacokinetic/pharmacodynamic and animal model research utilizing diabetic minipigs. Prior to joining Sinclair Research, Ryan worked in an academic setting, helping develop an automated way to classify hematoxylin- and eosin-stained slides.
Michelle joined Altasciences in 2022 with an extensive background in cardiovascular and cardiopulmonary health and public health administration.

As a study director, she works closely with clients, consultants, and internal team members to develop and execute GLP and non-GLP preclinical studies involving small and large animals.

Her thesis work focused on utilizing positive pressure ventilation to decrease preload (end diastolic filling) and afterload (average arterial pressure) in heart failure stage C and D patients, thereby reducing hospital admission days and facility readmission.

Prior to joining Altasciences, Michelle worked as a registered respiratory therapist, emergency medical technician and polysomnographer. She has a Bachelor of Science degree in health studies from Pennsylvania College of Technology, Williamsport, Pennsylvania, and a Master of Science degree in healthcare administration from the Kings College, Wilkes-Barre, Pennsylvania. She is also certified Six Sigma Black Belt.
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, and became a study director in 2021. Jennifer is responsible for planning, coordinating, and supervising interdepartmental and intradepartmental activities during all phases of telemetered cardiovascular studies. She also plays an integral role in the surgical preparation of telemetry colony animals.
KEY CLINICAL RESEARCH EXPERTS

- **Ingrid Holmes**, Vice President, Global Clinical Operations
- **Beatrice Setnik**, PhD, Chief Scientific Officer
- **Mel Affrine**, PharmD, President and Chief Scientific Officer
- **Amy Denvir**, General Manager
- **Matthew Logan**, General Manager, Clinical Operations
- **Dr. David Nguyen**, MD, MBA, General Manager and Medical Director
- **Dr. Martin Kankam**, MD, PhD, MPH, Medical Director
- **Dr. Gaetano Morelli**, MD, Chief Medical Officer
- **Dr. Debra Kelsch**, MD, Senior Principal Investigator
- **Dr. Éric Sicard**, MD, Senior Principal Investigator

MORE CLINICAL SPECIALISTS on next page
KEY CLINICAL RESEARCH EXPERTS

- Lester Galan, Executive Director, Clinical Trial Management
- Dr. William Foster, PhD, MD, Principal Investigator
- Dr. David Y. Kim, MD, Principal Investigator
- Dr. Javid Ghandehari, MD, Principal Investigator
- Dr. Kanwal Chaudry, MD, Principal Investigator
- Dr. Colleen Harrison, MD, Principal Investigator
- Dr. Brett Smith, MD, MPH, MBE, Principal Investigator
- Susan Stieben, Senior Director, Clinical Operations
- Kevin Noble, Senior Director, Laboratory Operations
- Brandon O’Reilly, Director, Quality Assurance and Risk Management
- Dr. Kevin Kirkcaldy, BPharm, MBA, PharmD, Director, Pharmacy Operations
- Dr. Andy Pham, PharmD, Director, Pharmacy
Ingrid Holmes joined Altasciences in 2011 as Vice President of Clinical Operations for Altasciences’ Montreal site. Now, as Vice President, Global Clinical Operations, Ingrid's responsibilities include oversight of all Altasciences’ clinical pharmacology units, with 400 early phase beds, a dedicated driving simulator unit with 10 simulators on-site, and purpose-built inhalation facilities. 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, Ingrid 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. Setnik joined Altasciences in August 2019. Dr. Setnik has been working in the area of clinical drug development and abuse potential assessment since 2005. She is an Adjunct Professor at the University of Toronto (Department of Pharmacology and Toxicology), and she earned her doctorate degree in Pharmacology and the Collaborative Program in Neuroscience from the University of Toronto. In her former role as Vice President of Scientific & Medical Affairs at INC Research/inVentiv Health (Early Phase), she was responsible for scientific input on early phase clinical trials and in strategic initiatives in business growth and development. In her previous role as Senior Director, Clinical Sciences (King Pharmaceuticals and Pfizer, Inc), Dr. Setnik led the clinical development, regulatory filing, and lifecycle management, including abuse potential evaluation, of several pain compounds, including abuse-deterrent opioid formulations. In her previous role as a Research Scientist (formerly Ventana/Decisionline Clinical Research, Toronto, Canada), Dr. Setnik 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 has presented at over 200 scientific meetings and conferences. In addition, she is the Managing Director and Clinical Subgroup Lead for the Cross Company Abuse Liability Council and chair of the Clinical Pharmacology Community of the Drug Information Association (DIA). Dr. Setnik is also an active member and participant in several congresses, including the College on Problems of Drug Dependence. She has also been actively engaged in many aspects of abuse potential assessment, including development of patient reported outcome instruments and contributing to post-marketing surveillance studies.
Mel Affrime, PharmD

Mel Affrime has an extensive background in Global Clinical R&D. 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 WCCT Global in 2011 as the Senior Vice President of Translational Medicine, Mel managed the medical staff at ICON Development Solutions’ three CPUs, the Population PK software business, and the R&D department from 2006 to 2011. His experience also includes heading Global Profiling Clinical Pharmacology 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 joined Altasciences in 2018 as Director, Integration and Deployment. Now General Manager of Altasciences’ clinical pharmacology unit in Kansas City, KS, Amy is responsible for the harmonization of clinical processes across Altasciences’ sites, including system implementation. Amy started her clinical research career in 1991 at Harris Laboratories (now Celerion). Prior to joining Altasciences, she 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 to eSource and Training platforms.
Matthew Logan joined Altasciences in 2011, and currently holds the role of General Manager, Clinical Operations, at Altasciences’ purpose-built, state-of-the-art clinical pharmacology unit in Montreal, Quebec. 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 Montreal-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

Dr. David 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. Kankam is an Internal Medicine physician with more than 25 years of academic and industry experience. Prior to joining Altasciences in 2008, Dr. Kankam spent 10 years in clinical practice with faculty positions in the U.S.A. Dr. Kankam was a Research Scientist, Epidemiologist and a scientific reviewer at the U.S. 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 Directorship position in 2020. Dr. Kankam is an expert in early phase drug development with broad experience including clinical development and operations across many therapeutic disciplines. He has published over 20 manuscripts in peer reviewed journals.

Dr. Kankam received his medical degree from Creighton University School of Medicine and completed his post-graduate training in Medicine at the University of Kansas School of Medicine. He holds a PhD in Epidemiology from University of Oklahoma and an MPH from Tulane University. He is a member of the American Medical Association and a Fellow at the Academy of Physicians in Clinical Research.
Dr. Gaetano Morelli, MD

Dr. Morelli joined Altasciences in 2017 as a Medical Advisor/Consultant for complex studies. He quickly transitioned to Clinical Principal Investigator before becoming a 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, involved in medical training of students, residents, and specialty fellows. Previously, Dr. Morelli was the 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 an 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, Dr. Kelsh 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. Sicard has been with Altasciences since 2002 in positions of increasing responsibility, now as 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 has been with Altasciences for over 20 years and brings 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; this 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 1 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 1 Unit and is responsible for the Screening, the Clinical Operations, the Clinical Trial Management, and the Clinical Data Processing departments.
Dr. William 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, and UCLA, he has held faculty positions at a number of research universities. As a bioengineer, he enjoys interdisciplinary collaboration.
Dr. David Kim is a urology-trained principal investigator with a background in oncology research. He received his bachelor's in public health from the University of Pennsylvania and his MD 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 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, Dr. Kim 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. Javid Ghandehari brings his extensive experience as a clinical researcher, anesthesiologist, and interventional pain management physician to his current role as Principal Investigator at Altasciences. He has worked at leading pain research centers like Memorial Sloan Kettering Cancer Center, MD Anderson Cancer Center, Mount Sinai Hospital, and INSERM U161. Dr. Ghandehari completed his anesthesiology residency at Maimonides Medical Center, and his fellowship training in interventional pain medicine at University of Washington, home to the world’s first multidisciplinary pain medicine clinic. His background includes translational research in opioid and adjunct therapies for acute and chronic cancer, orthopedic, and post-operative pain, and he is passionate about furthering the study of pain, upholding high ethical standards, and creating policies to ensure patient safety. Dr. Ghandehari received his bachelors in physics from the University of California, Berkeley, and his MD from UT Health San Antonio.
Dr. Kanwal Chaudry joined Altasciences in July 2022 as Principal Investigator following a 12-year career as an outpatient general pediatrician. She served 11 of those years as a civilian pediatrician at Munson Army Health Center, Fort Leavenworth, taking care of children from active military families. She also performed ER duties at Children's Mercy Hospital immediately after graduating from a pediatric residency at Kansas University Medical Center.

Dr. Chaudry’s favorite period along the path to medicine was serving as a clinical research coordinator. Her resume boasts of saving a Phase III clinical research study from premature closure due to insufficient subject enrollment. Dr. Chaudry took on the study, and not only saved it from closure, but became the highest enrollment coordinator in the United States, thereby successfully completing the study. Her passion, for utilizing innovative techniques and procedures following evidence-based medicine, along with her aptitude for conducting clinical studies, is enabling her to look forward to new horizons involving pharmaceuticals and biotech in her current role.
Dr. Colleen Harrison joined Altasciences in 2019, as a clinical sub-Investigator, becoming a Principal Investigator in January, 2022.

Dr. Harrison received her medical degree from Harvard Medical School in 2009. Since then, she has been practicing family medicine in various clinic and hospital settings in the USA and Canada.
Dr. Brett 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’s degree in genetics from Rutgers University, a MD from the UMDNJ-Robert Wood Johnson Medical School, a Master of Bioethics from the University of Pennsylvania, and a Master of Public Health with a focus on epidemiology from the University of California, Berkeley.
Susan Stieben
Senior Director, Clinical Operations
Kansas City, KS

Susan joined Altasciences in 2021. Her responsibilities include oversight of the Clinical Operations group to assure regulatory compliance of all research activities, to support the consistent delivery of quality research outcomes, and to mentor staff to reach their full potential.

Susan began her career in clinical research in 1995 as a Project Manager for a global central laboratory provider. Her career led her to clinical site management, having previously held various leadership roles in the regulatory and compliance sector.

Susan has always been interested in research and experienced first-hand how advances in medicine can improve health outcomes. Her professional life has been dedicated to working toward better treatments for patients suffering from a life-threatening disease. The reward has been seeing new treatments come to market that improve the quality and longevity of life.
Kevin Noble

Senior Director, Laboratory Operations
Los Angeles, CA

Kevin joined Altasciences in 2013, and worked as a Lab Coordinator, Laboratory Supervisor, Research Laboratory Manager, before taking on the role of Senior Director. Kevin is not only in charge of assuring the integrity of the sample collection and preparation in the pharmacokinetic laboratory, he also developed and currently oversees our Clinical Safety Laboratory and Cell Isolation (PBMC) Laboratory in Los Angeles.

Kevin has a strong background in laboratory management, operations efficiency, vendor contract negotiation, has hosted 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 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. Brandon used this experience to transition into Quality Assurance and has now been with Altasciences for over ten years.

Brandon has hosted regulatory inspections for both the FDA and PMDA on more than a dozen studies. His role as Director of Quality Assurance and Risk Management 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. In this role, Brandon also oversees the Clinical Monitoring Group to better align quality and monitoring initiatives.
Dr. Kevin Kirkcaldy joined Altasciences in 2019, and brings 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, controlled substance management, and the like. 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.

He has a bachelor’s degree and a Pharm.D. degree in Pharmacy, a MBA in pharmaceutical management, and a graduate degree in Pharmaceutical Product Development.
Dr. Andy Pham has over 20 years of pharmacy experience, including a decade in clinical research and investigational drugs. Dr. Pham is a proven professional who utilizes his strong educational background and experience in study drug management to ensure Altasciences’ adherence to Good Clinical Practice (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 by pharmacy and clinical staff alike. He is skilled at training staff on new investigational drugs, and proper procedures for storage, administration, and the recording of data. Dr. Pham 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.
KEY BIOANALYTICAL AND RESEARCH SUPPORT SPECIALISTS

- **Dr. Lynne Le Sauteur**, PhD, Vice President, Laboratory Sciences
- **Dr. Anahita Keyhani**, PhD, Senior Director, Scientific Operations, Mass Spectrometry
- **Dr. Danielle Salha**, PhD, Senior Director, Immunochemistry & Immunology, Ligand Binding Assays
- **Kevork Mekhssian**, MSc, Scientific Director, Method Development
- **Milton Furtado**, Scientific Director, Method Development
- **Jeff Plomley**, MSc, Scientific Director, Method Development
- **Jean-Nicholas Mess**, MSc, Principal Scientist, Method Development
- **Martin Poirier**, Senior Director, Laboratory Sciences
- **Dr. Mano Sahoo**, MS, PhD, Director, Bioassay
- **Olga Malykhina**, Principal Research Scientist, Laboratory Sciences
- **Ted (Theodore) Brus**, Principal Scientist, Laboratory Sciences

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KEY BIOANALYTICAL AND RESEARCH SUPPORT SPECIALISTS

- **Nicole Maciolek**, PhD, Executive Director, Data Services, Medical Writing and Scientific Affairs
- **Kristen Fitzpatrick**, Director, Medical Writing
- **Cynthia Marie Fazio**, Manager, Medical Writing
- **Catherine Dussault**, Director, Scientific Affairs
- **Sophie Boudriau**, PhD, Principal Scientist, Scientific Affairs
- **Brad Lindner**, Senior Director, Data Services
- **Catherine Mills**, Associate Director, Biostatistics
- **Lauren Szczurowski**, Vice President, Scientific Project Management
- **Carmela Parente**, Director, Program Management, Scientific Project Management
- **Denise Milovan**, PhD, MA, CPsych, Senior Neuroscientist, Neuropsychologist
- **Dr. Mingluan Chen**, PhD, Principal Research Scientist, Method Development

BIOANALYTICAL SPECIALISTS on previous page
Lynne Le Sauteur, PhD

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 her PhD 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), where she led numerous teams and initiatives to discover, biomanufacture, and characterize novel biologics for unmet needs, in collaboration with different biopharmaceutical companies. Prior to the NRC, Lynne 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. Keyhani joined Altasciences in May 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 Montreal as a Senior Scientist in Pharmaceutical Research and Development and, during the pursuit of her master's degree, 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 PhD from McGill University.
Dr. Salha joined Altasciences in September 2017 as Director of the Ligand Binding Assay Department and was promoted to Senior Director, Immunochemistry & Immunology, Ligand Binding Assays in March 2020. 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.

Danielle 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 her Bachelor of Science at the University of Montreal and her PhD at McGill University from the Department of Immunology and Microbiology.
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 in 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 his Master of Science in Biochemistry at Concordia University in Montreal, Canada.
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 Montreal, Canada.
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’s degree in Chemistry from Queens University in Kingston, Ontario, Canada.
Jean-Nicholas Mess, MSc

Jean-Nicholas joined Altasciences as Method Development Scientist in 2004, after obtaining his Master of Science in Biochemistry from the University of Montreal. 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 this topic. 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.
Martin Poirier joined Altasciences in 2019 as Senior Director of Bioanalytical Sciences. Martin oversees the various scientific disciplines in the laboratories, and ensures the quality of their operation. Martin brings 20 years of industry experience. He has contributed to the startup and/or expansion of laboratory services in many CROs worldwide. Martin’s previous position was Scientific Director of Laboratory Sciences at Charles River Laboratories, where he contributed to increasing the business on both the preclinical and clinical fronts.
Dr. Mano Sahoo joined Sinclair Research (now 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 Sinclair Research, 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 his BS and MS in India, obtained his PhD in Microbiology (Immunology) from the University of Mississippi Medical Center, and completed his post-doctoral training from Chicago Medical School.
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 The 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 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 Covance (LabCorp) 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. 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 PhD in molecular genetics from the Medical College of Wisconsin.
Kristen Fitzpatrick joined Altasciences in 2019 as Director of Medical Writing, bringing more than 13 years of CRO experience, including over 7 years of leadership experience, to her position. She received her Master of Science degree in Molecular and Environmental Toxicology and began her career in preclinical taking on roles of increasing responsibility at Covance, before transitioning into early phase clinical project management and leadership at DaVita and Parexel. In her current role, Kristen is responsible for overall oversight and guidance of the Medical Writing department, ensuring the team has appropriate resources, tools, and support to prepare high-quality deliverables. She is also responsible for the operational and financial performance and strategy of the department.
Cynthia Marie Fazio started her career as a research scientist at McGill University, where she also received her 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 the Altasciences Clinical Operations team in 2006 as an Assistant Study Manager. She later worked as a Clinical Research Scientist in the Scientific Affairs division 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 joined Altasciences in March 2004 and has a B.Sc in Biochemistry. In her current role as Director, Scientific Affairs, Catherine provides senior 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 Phase I and II, FIH, bioequivalence, 505(b)2, drug-drug interactions, QTc, POC, and special patient populations. She has extensive experience in multiple therapeutic areas including nervous system, GI tract and metabolism, cardiovascular, genito-urinary system and sex hormones, antineoplastic and immunomodulating, and anti-infective agents.
Dr. Boudriau joined Altasciences in 2013 as a 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 2016, Sophie was promoted to Principal Scientist. In this leadership position, Sophie 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. Sophie 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.

Sophie routinely reviews the evolving regulatory landscape for a wide range of regulatory agencies (FDA, TPD, and EMA, to name a few) and provides internal guidance to Medical Writers and Pharmacokinetic Scientists as well as Clients in support of their regulatory applications.
Brad Lindner  
Senior Director, Data Services  
Kansas, KS

Brad has been with Altasciences since 2017, and is responsible for Data Services (Data Management, Biostatistics and Statistical Programming). Brad has over 15 years of CRO experience with two of the larger CROs in North America, leading and working within Biostatistics, Data Management and Project Management teams, with a focus on improving client satisfaction and quality of deliverables. Under Brad’s leadership the Altasciences team has increased in both size and expertise, creating a mid-sized team that offers competitive timelines with a high level of quality, starting with the initial database build to the final TLF and CDISC delivery.

Prior to joining the CRO industry Brad worked in Finance for two Fortune 500 companies and was responsible for corporate international financial planning. Brad has a bachelor’s degree from University of Iowa and an MBA from Missouri State University.
Catherine joined Altasciences in 2019 as Associate Director, Biostatistics. Catherine is focused on creating a team of experts to support all Early Phase trials. She has been working in clinical research organizations for the past 20 years. Catherine began her career working in Phase I - IV studies in many different therapeutic areas. She has extensive experience managing, leading and mentoring biostatisticians, statistical programmers and data managers.

Her previous experience includes Syneos Health (formerly Kendle/INC Research/InVentiv Health) from 2008 until the Toronto unit closed in 2019. While at Syneos Health, her focus was on the analysis of ADF and HAP studies. During this time, she collaborated with the FDA regarding new analysis methods in the updated guidances, and also presented statistical issues from many different ADF and HAP studies at various conferences and meetings. She continues to focus on studies that include pharmacodynamic measures, with her specialty being the analysis and statistical issues in ADF and HAP studies. Catherine has an Honours B.A. in Psychology, a B.Sc. in Statistics and a M.Sc. in Biostatistics, all from the University of Western Ontario.
Lauren Szczurowski joined Altasciences in 2017 and has approximately 20 years of clinical trial management experience, including 10 years in departmental leadership and strategic growth. She began her career in early development managing Phase I/IIb, multi-center studies in healthy volunteers and patient populations with a focus on CNS and infectious disease. Prior to joining Altasciences, she was responsible for a team of 18 Clinical Trial Managers, overseeing more than 30 multi-center global oncology trials ranging from Phase I to Phase III. As Vice President of Scientific Project Management at Altasciences, Lauren is a strategic and tactical leader, accountable for team and system integrations, as well as successful collaboration across Altasciences to drive the organization’s growth.
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. In her most recent role 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 of the preclinical site, lead of process improvement initiatives, and portfolio manager for key sponsors. In her current role, she will provide leadership to, and oversight of, the preclinical program management team, as well as supporting sponsors through complete preclinical services support with subsequent clinical support. She is passionate about helping our clients get critical medicines to patients quickly by providing excellent client service with a personalized approach.
Dr. Milovan joined Altasciences in 2020. In former Neuroscientist 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 PhD and a Master’s degree in clinical neuropsychology, and has also completed the requirements for a master’s degree 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. Mingluan Chen joined Altasciences in 2014, and is a principal scientist in the LC-MS method development group. He received his PhD in analytical chemistry from Wuhan University, China, focusing on the characterization of phytohormones using microscale LC-MS. Mingluan 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.
KEY MANUFACTURING AND ANALYTICAL SERVICES PARTNERS

- [Benjamin W. Reed](#), BS, General Manager, CDMO Services
Benjamin W. Reed, BS

Ben has more than 15 years of experience in the pharmaceutical industry. He has had management roles in all areas of analytical chemistry, including raw material release, stability and method development. He was the EMS/EHS Manager responsible for ISO14001 certification of a 130,000-square-foot CDMO facility. He has extensive background in manufacturing various dosage forms, from formulation development through clinical manufacturing, and process validation for commercial manufacturing. Additionally, Ben is well experienced in sourcing, purchasing and qualifying new manufacturing equipment, and the design and operation of cGMP manufacturing suites. He also has experience as a process engineer focusing on process transfer and process improvement while at PMRS and TEVA. He is a graduate of Cedarville University (BS).
KEY COMPLIANCE, REGULATORY AFFAIRS, STRATEGIC SUPPORT, AND QUALITY ASSURANCE PARTNERS

- [David Grégoire](#), Chief Quality and Compliance Officer
- [Peter Varney](#), Pharma Development and Strategy Advisor
- [Hazel Clay](#), Drug Development Advisor
- [Paul Sidney](#), Vice President, GLP Quality Assurance
- [Natasha Savoie](#), Director, Quality Assurance
- [Roland Jbeily](#), MSc, D.E.S.S., Manager, Regulatory Affairs
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 holds a Bachelor of Science in Biology from McGill University. Prior to joining Altasciences, 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. Also in 2003, he moved on to Pharmascience Inc. As the Manager of Clinical Quality Services, he implemented GLPs in a newly developed bioanalytical laboratory, and designed a quality system for their 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.
Pete Varney joined Altascences in 2021 as Pharma Development and Strategy Advisor. Pete brings 40 years of experience in commercial development, strategic alliances, and relationship management from his previous roles at Covance (now LabCorp Drug Development). 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. Pete 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.
Hazel 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 & 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 Masters Course in biopharmaceutical development.

Hazel 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.
Paul Sidney
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 and also as a quality systems and regulatory lead supporting the corporate mergers and acquisitions team. The latter role required that quality system 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 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 Natasha to a Compliance role and then to Quality Assurance 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 the QA Director position overseeing QA for the Canadian clinical and bioanalytical facilities and research services. In her 25 years of experience, Natasha actively participates in the Society of Quality Assurance, where she is the past co-chair of the Bioanalytical Specialty Section and is currently honoured to be part of the 2020 class of Distinguished Speakers recognized by the SQA Learning Foundation. 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 very proud of Altasciences’ excellent quality and inspection history, and actively works with operations in order to ensure our customers’ expectations are exceeded.
Roland Jbeily, MSc, D.E.S.S.

Roland joined Altasciences in 2020, and brings with him more than five years of experience in Regulatory Affairs and Compliance for global authorities, such as the FDA, EMA, and TGA, with an expertise in Health Canada’s drugs and cannabis regulations. As Manager, Roland oversees Clinical Trial Applications to Health Canada for small molecules, biologics, and natural health products. He provides sponsors with strategic guidance on regulatory strategies, gap analysis, consultancy support, and liaison support between them and Health Canada.

Roland began his career working in the QC Lab at Pharmascience. 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 Quebec Chemists) and a member of the DIA (Drug Information Association). He earned a master’s degree in Biochemistry from Université de Montréal and a D.E.S.S. in Biomedical Engineering from Polytechnique de Montréal.
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