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# Meet Your Altasciences Team

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PRECLINICAL SERVICES EXPERTS

CLINICAL SERVICES EXPERTS

BIOANALYSIS & RESEARCH SERVICES EXPERTS

MANUFACTURING AND ANALYTICAL SERVICES EXPERTS


COMPLIANCE, REGULATORY AFFAIRS AND QUALITY ASSURANCE

# KEY PRECLINICAL RESEARCH PARTNERS

- Mike Broadhurst, General Manager
- Francis Douville, Vice President, Technical Operations
- Bruce Bernacky, DMV, Chief Animal Welfare Officer
- Joseph A. Francisco, PhD, Chief Toxicologist, Safety Assessment
- Julie Forget, DESS Tox, DABT,  Director Safety Assessment
- Isabel Tourigny, Director, *In Vivo* Operations
- Shayna Halverson, Manager, Quality Assurance

## PATHOLOGISTS

- Holly Kolenda-Roberts, DMV, PhD, Research Pathologist
- Keven Jackson, DMV, PhD, Research Pathologist
- Shunji Nakatsuji, BS, MS, PhD, Research Pathologist

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# KEY PRECLINICAL RESEARCH PARTNERS

## STUDY DIRECTORS

- Satoru Oneda, DVM, PhD, DRDT, Study Director III
- Narine Lalayeva, MS, Study Director II
- Jean-Christophe Queudot, Study Director, Principal Scientist
- Vivienne Bunker, MS, RQAP-GLP, Research Scientist, Safety Assessment
- Mark Campbell, BSc, PMP, Research Scientist, Safety Assessment
- Li Zhan, MD, PhD, DABT, Study Director II
- Anthony Celori, LAT, Associate Scientist, Study Director
- Kelsey Brooks, PhD, Associate Scientist, Study Director
- Karla Thrall, PhD, DABT, Study Director III
- Stefan Nechev, MD, DABT, Study Director III

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# Mike Broadhurst

**General Manager**
Seattle, WA

Mike Broadhurst joined Altasciences in 2018. As the General Manager for Altascience's 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.

# Francis Douville

**Vice President, Technical Operations**
Seattle, WA

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 started his career in Montreal, Canada; opened a CRO in Shanghai, China; and joined to a U.S. west coast preclinical facility. Prior to moving to Seattle, Francis was part of the team that reopened an east-coast facility in Shrewsbury, Massachusetts.

# Bruce Bernacky, DVM

**Chief Animal Welfare Officer**
Seattle, WA

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 32-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.

# Joseph A. Francisco, PhD

**Chief Toxicologist, Safety Assessment**
Seattle, WA

Dr. Francisco joined Altasciences in 2020 with over 25 years of experience in drug development in the CRO and biotech industries, and as an independent consultant. He has significant experience in the nonclinical development of small molecule drugs, protein therapeutics, and cell therapies. Dr. Francisco brings an expert understanding of the strategic and tactical aspects of successful preclinical drug development programs: program design, execution, and leadership, as well as proven leadership in coordinating, integrating, and leading multidisciplinary teams. Dr. Francisco holds a PhD in Chemical Engineering from the University of Texas, and a bachelor's degree in Chemical Engineering and Biochemistry from Rice University. He is a Member and Councilor (2017-2020) of the American College of Toxicology (ACT); Member of SOT, including serving as Councilor of the Biotechnology Specialty Section (2015-2017).

# Julie Forget, DESS Tox, DABT

**Director Safety Assessment**
Seattle, WA

Julie Forget joined Altasciences in 2018 as Director, Safety Assessment. 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.

# Isabel Tourigny

**Director, *In Vivo* Operations**
Seattle, WA

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.

# Shayna Halverson

**Manager, Quality Assurance**
Seattle, WA

Shayna Halverson joined Altasciences in 2018. 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. Prior to joining Altasciences, Shayna worked as a Technician handling NHPs.

# Holly Kolenda-Roberts, DVM, PhD

**Research Pathologist**
Seattle, WA

Dr. Kolenda-Roberts joined Altasciences in 2013. She has a DVM, anatomic pathology residency training, and PhD (Infectious Diseases & Immunology) from the University of Florida College of Veterinary Medicine. She has 20 years of pathology experience, with 12 years' experience in toxicological pathology, as an Immunohistochemistry Consultant with special interest in immunotoxicology.

# Keven Jackson, DVM, PhD

**Research Pathologist**
Seattle, WA

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

# Shunji Nakatsuji, BS, MS, PhD

**Research Pathologist**
Seattle, WA

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.

# **Satoru Oneda**, DVM, PhD, DRDT

**Study Director III**
Seattle, WA

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

**Study Director II**
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

**Study Director,**
**Principal Scientist**
Seattle, WA

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.

# Vivienne Bunker, MS, RQAP-GLP

**Research Scientist, Safety Assessment**
Seattle, WA

Vivienne Bunker joined Altasciences in 2018 as a Research Scientist, Safety Assessment. With over 15 years of CRO industry experience, Vivienne brings an array of knowledge to the Altasciences team. Prior to joining Altasciences, Vivienne gained extensive experience working as a Quality Assurance Auditor, a Study Director for veterinary medicine, a Laboratory Technician for radiotracer studies, and a Technician for in-life procedures. Her current role has her managing various preclinical studies, both GLP and non-GLP, including general toxicology, safety pharmacology, and toxicokinetic studies.

# Mark Campbell, BSc, PMP

**Research Scientist, Safety Assessment**
Seattle, WA

Mark Campbell joined Altasciences in 2018 as a Study Director. Mark leads studies in all species, supporting programs in both small and large molecules/biologics. With over 15 years of preclinical industry experience, and an additional seven years in clinical research, Mark brings a well-balanced skillset to the Altasciences team. Prior to joining Altasciences, Mark was Senior Project Manager in the CRO Division of a local clinical diagnostic lab, and was also a Study Director in the CNS Research Division of an international preclinical CRO, formerly based in the Seattle area.

# Li Zhan, MD, PhD, DABT

**Study Director II**
Seattle, WA

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

# Anthony Celori, LAT

**Associate Scientist, Study Director**
Seattle, WA

Anthony joined Altasciences in 2015, and has been conducting and directing GLP preclinical toxicology and related research for the past seven years. He has experience conducting GLP/Non-GLP with both small and large molecules, and in general toxicology (single and multi-dose designs), dose range finding, safety pharmacology and JET ECG, infusion (small animals and NHPs), male reproduction, and model development. Anthony has been a key player in expanding Altasciences' safety pharmacology program and other technological capabilities.

# Kelsey Brooks, PhD

**Associate Scientist, Study Director**
Seattle, WA

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.

# **Karla Thrall**, PhD, DABT

**Study Director III**
Seattle, WA

Dr. Thrall joined Altasciences in 2014. With 25 years of experience in toxicology, pharmacokinetics, and radiation biology, she has seen to the development of animal models for assessing radiological injuries, development of novel biomaterials for decorporation of radionuclides, development of non-invasive and minimally invasive methodologies for exposure assessment, and *in vivo* animal and human studies to understand the absorption, distribution, metabolism, and elimination (ADME) of compounds within the body. At Pacific Northwest National Laboratories (PNNL), Dr. Thrall was Associate Division Director for 15 years, conducting radiation experiments in rodents, NHPs, and minipigs. She also served as Principal Investigator or Program Manager on a number of research grants and contracts that were focused on developing countermeasures for acute radiation syndrome (ARS).

# Stefan Nechev, MD, DABT

**Study Director III**
Seattle, WA

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.

# KEY CLINICAL RESEARCH EXPERTS

- Ingrid Holmes, Vice President, Global Clinical Operations
- Beatrice Setnik, PhD, Chief Scientific Officer
- Amy Denvir, General Manager
- Lisa Moore, BS, CPM, Associate Director, Project Management, Phase I Clinical Development
- Beth Williams, Associate Director, Scientific Project Management, Phase I Clinical Development
- Lauren Szczurowski, Senior Director, Project Management
- Matthew Logan, Senior Director Clinical Operations, Clinic
- Dr. Martin Kankam, M.D., PhD, MPH, Co-Medical Director, Phase I
- Dr. Debra Kelsh, MD, Principal Investigator
- Dr. Gaetano Morelli, MD, Chief Medical Officer
- Dr. Eric Sicard, MD, Clinical Principal Investigator
- Dr. Benoit Deschamps, MD, Clinical Principal Investigator

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# Ingrid Holmes

## Vice President, Global Clinical Operations

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.

# Beatrice Setnik, PhD

**Chief Scientific Officer**

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.

# Amy Denvir

**General Manager**
Kansas, KS

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. This is what is used in ALL marketing documentation.

# Lisa Moore, BS, CPM

**Associate Director, Project Management, Phase I Clinical Development**

Lisa Moore joined Altasciences in 2017 with two decades of experience in drug development. Lisa's drug development career started with experience in preclinical, specifically IND-enabling programs and drug-candidate portfolio management. During this period, Lisa managed more than 30 IND-enabling programs in various species, including mouse, rat, minipig, canine, and primate. She supported bioanalytical and test article validation/analysis, toxicology, genetic toxicology, *in vitro/in vivo* DMPK, safety pharmacology, reproductive toxicology, and carcinogenicity studies. In addition to IND-enabling programs, Lisa managed preclinical portfolios and post-IND projects to support NDA and BLA filings. Following Lisa's eight-year preclinical tenure, she spent two years managing and developing a regulatory writing team, where she wrote and reviewed preclinical sections of IND and NDA applications. To round out her cross-functional drug development experience, Lisa has spent the last eight years as a leader in Phase I clinical project management. Lisa has developed in-depth experience with management and oversight of data packages (data management, SAS programming, biostatistics, pharmacokinetics, and medical writing) as well as serving as a Project Manager for dozens of full-service Phase I clinical trials, all while leading dynamic project management organizations.

# Beth Williams

**Associate Director, Scientific Project Management, Phase I Clinical Development**
Kansas, KS

Beth Williams joined Altasciences in 2017, bringing six years of clinical research project management experience to her position. Beth previously worked at a large CRO, a central laboratory and a GMP manufacturing facility, and she is well versed in all of the GxPs. Within her current role, Beth is responsible for managing a diverse portfolio of clinical research studies, including SAD, MAD, PK, HAP, renal impairment, hepatic impairment, NASH, nicotine, and cannabis. Beth is also responsible for management of the Project Coordinator team within the Project Management department.

# Lauren Szczurowski

**Senior Director, Project Management**
Kansas, KS

Lauren Szczurowski joined Altasciences in 2017 and has more than 15 years of clinical trial management experience, including eight 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 Senior Director of Project Management at Altasciences, Lauren is responsible for leading, developing, and effectively managing the Project Management department.

# Matthew Logan

**Senior Director Clinical Operations**
Montreal, QC

Matthew Logan joined Altasciences in 2011, and currently holds the role of Senior Director, 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. Martin Kankam, M.D., PhD, MPH

**Co-Medical Director, Phase I**
Kansas, KS

Dr. Kankam joined Altasciences in 2008 as Clinical PI and was promoted to Co-Director of Altasciences' Kansas City site in 2017. He has over 20 years' medical experience and over 10 years' clinical research background. Prior to joining Altasciences, Dr. Kankam was active in medical practice and academic positions in the U.S.A., Africa, and India.

# Dr. Debra Kelsh, MD

**Principal Investigator**
Kansas, KS

Dr. Kelsh has been with Altasciences' Kansas City facility since its founding in 2001. She joined Altasciences after almost 10 years as the Assistant Clinical Professor at KU Medical Center in the Department of Psychiatry and Behavioral Sciences. She is a member of the American Psychiatric Association with over 18 years of clinical research experience. Dr. Kelsh is a graduate of the University of Kansas School of Medicine.

# Dr. Gaetano Morelli, MD

**Chief Medical Officer**

Dr. Morelli is Altasciences' Chief Medical Officer. He is a member of the Collège des Médecins du Québec, with over 30 years' medical experience and almost 15 years' clinical research background. He joined Altasciences in 2017, first as Medical Advisor then as Clinical PI. Prior to joining Altasciences, he was a practicing gastroenterologist at the McGill University Health Center (2012 - 2017). Prior to that, Dr. Morelli was the Global Medical Director at MDS Pharma for 10 years, overseeing five clinical sites in Canada, the U.S.A., and Ireland.

# Dr. Eric Sicard, MD

**Clinical Principal Investigator**
Montreal, QC

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.

# Dr. Benoît Deschamps, MD

**Clinical Principal Investigator**
Montreal, QC

Dr. Deschamps is a member of the Collège des médecins du Québec with over 20 years' medical experience and 15 year's clinical research experience. Dr. Deschamps' background includes palliative and emergency care, as well as academic and oversight responsibilities for various medical associations and foundations in Quebec.

# KEY BIOANALYTICAL SPECIALISTS

- Lynne LeSauteur, PhD, Vice President, Immunochemistry and Immunology
- Anahita Keyhani, PhD, Senior Director, Scientific Operations, Mass Spectrometry
- Danielle Salha, PhD, Senior Director, Immunochemistry & Immunology, Ligand Binding Assays
- Christian Gauthier, PhD, Associate Director, 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, Bioanalytical Sciences
- Yasuhiro Yamashita, Senior Manager, Bioanalysis
- Andrea Wong, PhD, Scientist, Analytical Biology


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# Lynne LeSauteur, PhD

**Vice President, Immunochemistry and Immunology**

Dr. LeSauteur joined Altasciences in September 2019, and leads a team of 60 scientists involved in bioanalysis, immunogenicity, biomarkers, and immunotoxicity assessments for large 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.

# Anahita Keyhani, PhD

**Senior Director, Scientific Operations, Mass Spectrometry**
Laval, QC

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.

# Danielle Salha, PhD

**Senior Director, Immunochemistry & Immunology, Ligand Binding Assays**
Laval, QC

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. Dr. Salha leads a team of 45 Scientists, QCs and Analysts dedicated to method development, assay validation, and sample analysis to support clinical and preclinical PK, PD, and immunogenicity studies. Prior to joining Altasciences, Dr. Salha worked in the bioanalytical group at Charles River Laboratories, where she was a Study Director supporting preclinical and clinical immunogenicity studies. Previously, she worked at Sanofi Pasteur for over 14 years, supporting different functions and departments across the spectrum of product development, from discovery to Phase II clinical development, holding different positions of increasing responsibility. In her last position at Sanofi Pasteur, Dr. Salha led the Bioanalytical Department to develop and validate *in vitro* potency assays to support clinical Phase I and II product release, including vaccines and monoclonal antibodies.Dr. Salha has authored or co-authored over 10 peer-reviewed publications, and is an inventor, with four patent applications to her credit. She has presented numerous posters and presentations in the bioanalytical and R&D domains at several international conferences. Dr. Salha received her Bachelor of Science at the University of Montreal and her PhD at McGill University from the Department of Immunology and Microbiology

# Christian Gauthier, PhD

**Associate Director,**
**Ligand Binding Assays**
Laval, QC

Dr. Gauthier joined Altasciences in January 2020 as Associate Director within the Ligand Binding Assay Department. Dr. Gauthier oversees the operational aspect of this team of more than 45 Scientists, Quality Check Auditors, and Analysts dedicated to method development, assay validation, and sample analysis, supporting both clinical and preclinical studies, to generate PK, PD, and immunogenicity data. Prior to joining Altasciences, Dr. Gauthier accumulated 13 years' experience in contract research. Immediately following his graduate studies, Dr. Gauthier worked for four years as R&D Project Manager at CIRION BioPharma Research Inc., responsible for the development and validation of ligand binding assays and various molecular and microbiology assays used to analyze clinical and non-clinical samples. For the next nine years, Dr. Gauthier worked at ITR Laboratories Canada Inc., where he contributed to the creation of the Immunology Department, setting up this new service for large molecule assays. At ITR, Dr. Gauthier was promoted to Director, overseeing immunoassays and flow cytometry, cell-based assays, and the genetic toxicology services. Dr. Gauthier has authored two peer-reviewed publications and presented numerous posters and oral presentations at several national and international conferences, in the fields of microbiology, toxicology, and molecular biology. Dr. Gauthier received his Bachelor of Science from the University of Montreal, a master's degree in Applied Microbiology from the INRS-Armand-Frappier Institute, his PhD in Molecular Biology from the Montreal Clinical Research Institute (IRCM, U. of Montreal).

# Kevork Mekhssian, MSc

**Scientific Director,**
**Method Development**
Laval, QC

Kevork Mekhssian joined Altasciences in 2013. He has over 15 years of pharmaceutical and CRO experience in mass spectrometry-based characterization and quantitation of biotherapeutic proteins using LC-MS and hybrid LBA-LC-MS workflows. He has actively participated in setting up high-throughput biotherapeutic quantitation methods, and has greatly contributed 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

**Scientific Director, Method Development**
Laval, QC

Milton Furtado joined Altasciences in 2007. He has over 25 years of experience in bioanalysis in the pharmaceutical industry. Milton has worked in the preclinical and clinical environments and has developed over 300 LC-MS/MS assays. Over the years, Milton has been a key asset in overcoming bioanalytical challenges and providing scientific direction in the CRO industry. Milton has published over 25 journal articles, and peer-reviewed multiple scientific papers. He received his Bachelor of Science in Chemistry from Concordia University in Montreal, Canada.

# Jeff Plomley, MSc

**Scientific Director, Method Development**
Laval, QC

Jeff Plomley began his research career in the Gas Phase Ion Chemistry Laboratory of Prof. Raymond E. March as a Research Scientist designing novel ion trap scan functions to support applications development. He then joined Thermo Instruments Canada as an Applications Marketing Chemist, then SCIEX as a Senior Scientist in Product Definition and Core Research. Jeff has worked in both the preclinical and clinical CRO environment since 2001, developing over 250 *de novo* LC-MS/MS assays. He has contributed to the publication of over 25 peer-reviewed papers, 70 scientific posters and technical publications, holds patents on MS instrumentation, and frequently blogs and presents on microsampling workflows and advanced MS techniques. Jeff's current research interests include applications development involving ion-mobility spectrometry, and the implementation of microsampling technology into patient-centric medical devices. Jeff holds a master's degree in Chemistry from Queens University in Kingston, Ontario, Canada.

# Jean-Nicholas Mess, MSc

**Principal Scientist, Method Development**
Laval, QC

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

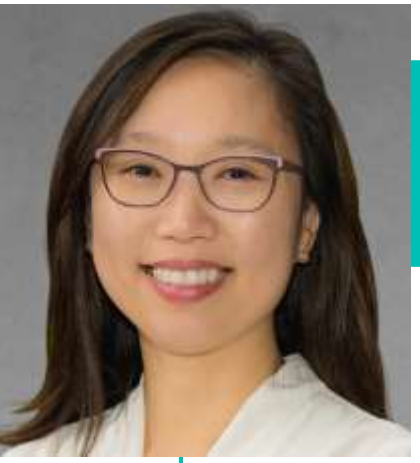
**Senior Director of Bioanalytical Sciences**
Seattle, WA

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.

# Yasuhiro Yamashita, PhD

**Senior Manager, Bioanalysis**
Seattle, WA

Yasuhiro (Jim) Yamashita joined Altasciences in 2018. Jim manages all regulated and non-regulated bioanalysis (PK/TK and ADA assays) using LC-MS/MS, ligand binding, and molecular biology assays (e.g., qPCR, RT qPCR, ddPCR). Jim also acts as a Principal Scientist on bioanalytical projects. His main area of scientific contribution is bioanalysis using LC-MS/MS to quantitate small molecules, peptides, and oligonucleotides. Jim started his career in 2002 at the leading bioanalytical CRO in Japan. He has dedicated his career to contributing to the advancement of bioanalysis in the CRO industry. His strong passion has pushed him to accepting many challenges, which resulted in him moving to the United States. Prior to his time at Altasciences, Jim worked as Research Director at JCL Bioassay Corporation in Illinois.



# Andrea Wong, PhD

**Scientist, Analytical Biology**
Seattle, WA

Dr. Wong joined Altasciences in 2018 as the Contributing Scientist for flow cytometry. Dr. Wong works closely with sponsors and prospective clients in the early phase of study design to ensure that panels are tailored to meet the sponsor's specific needs. With over 15 years' experience in flow cytometry spanning multiple species and tissues, Andrea specializes in establishing and customizing flow cytometry assays as well as receptor occupancy analyses for clients. Dr. Wong graduated from the University of Toronto with a doctorate in Immunology, and completed postdoctoral training at BloodWorks Northwest in Seattle. In both positions, Dr. Wong worked on establishing rodent models to study autoimmune diseases, such as type 1 diabetes and autoimmune hemolytic anemia.

# KEY MANUFACTURING AND ANALYTICAL SERVICES PARTNERS

- Steve Schweibenz, BS, MBA, President
- Benjamin W. Reed, BS, Vice President
- Shawn J. Connaghan, BS, Vice President, Quality Assurance

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# Steve Schweibenz, BS, MBA

**President**
Harleysville, PA

Steve has more than 30 years of experience in the pharmaceutical industry. He was a founder of Pharmaceutical Manufacturing Research Services Inc., in Horsham, PA, a company specializing in the development, manufacture, and laboratory analysis of various pharmaceutical dosage forms, including solid, semi-solid and liquid formulations. In his capacity as Director, Analytical Services, Steve developed a world-class laboratory providing cGMP-compliant component testing, API method development and validation, finished product method development and validation, and stability method development and validation. Additionally, Steve has served in laboratory operations and business development roles at E.I. DuPont, Whitehall Laboratories, Greenwich Pharmaceuticals, and Lexin Pharmaceuticals. Steve is a graduate of West Chester University (BS) and Temple University (MBA).

# Benjamin W. Reed, BS

**Vice President, Manufacturing**
Harleysville, PA

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).

# Shawn J. Connaghan, BS

**Vice President, Quality Assurance**
Harleysville, PA

Shawn has more than 20 years of experience in the pharmaceutical industry, serving in increasing quality control and quality assurance roles at PMRS and Élan. He offers extensive laboratory and compliance knowledge in all aspects of bringing materials from development through commercialization. Shawn has served as the lead liaison on various FDA and EMEA inspections, and executed numerous compliance audits both domestically and internationally. His other accomplishments include holding the roles of Project Lead and Senior Manager for the qualification, validation and ongoing operation of various pharmaceutical facilities and equipment trains. Shawn is a graduate of Penn State University (BS).

# KEY COMPLIANCE, REGULATORY AFFAIRS AND QUALITY ASSURANCE PARTNERS

- David Grégoire, Vice President, Compliance and Regulatory Affairs
- Paul Sidney, Senior Director Regulatory Affairs
- Nathasha Savoie, Director, Quality Assurance


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# David Grégoire

## Vice President, Compliance and Regulatory Affairs

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 was appointed Vice President of Compliance and Regulatory Affairs, 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.

# Paul Sidney

Senior Director, Compliance and Regulatory Affairs,
Scientific & Regulatory Affairs

TBC

# Natasha Savoie

Director, Quality Assurance
Laval, QC

Natasha Savoie joined Altasciences in 1999 as a Team Manager in the Bioanalytical Laboratory. She participated in turning the laboratory into a regulated environment from a research facility, as well as helping to obtain our OECD GLP recognition. Her extensive bioanalytical background led 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.

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