
ALTASCIENCES
MOVING IN
UNISON

OUR VISION

To be the one-stop solution for outsourced early-phase drug development, whether for one study or an entire program.

OUR MISSION

To offer our clients simple, integrated, outsourcing solutions with a focus on customer service, that removes the need for multiple providers during the early stages of drug development. Whether for one study or an entire program, we are committed to helping our clients reach critical decision-making milestones sooner by improving speed and ease from lead candidate selection to clinical proof of concept, with the goal of getting better drugs to the people who need them, faster. As a partner, we continuously look for ways to build our relationships through communication and range of capabilities, offering scientific guidance and creating an environment that provides value for our clients, respect for our participants, care for our research animals, and development for our employees.

OUR EXPERTISE
AT A GLANCE

Altasciences transforms the traditional drug development outsourcing paradigm by simplifying and streamlining solutions. The result is an integrated approach to CRO and CDMO services from lead candidate selection to clinical proof of concept, and beyond, under a single, dedicated program manager and one operational structure. Altasciences combines bioanalytical assay development and validation, preclinical safety evaluation, formulation development, clinic-ready manufacturing, on-demand clinical pharmacy, and clinical testing to proof of concept.

For over 25 years, Altasciences has taken a proactive approach to partnering with sponsors. By applying robust insights at each development stage, we deliver educated, faster, and more complete early drug development decisions.

Discover our vision

9 LOCATIONS IN NORTH AMERICA

BIOANALYTICAL FACILITY AND RESEARCH SUPPORT
Laval, Canada

PRECLINICAL AND BIOANALYTICAL FACILITY
Seattle, U.S.A.

PRECLINICAL FACILITY
Scranton, U.S.A.

PRECLINICAL AND BIOANALYTICAL FACILITY
Columbia, U.S.A.

PRECLINICAL FACILITY
Sacramento, U.S.A..

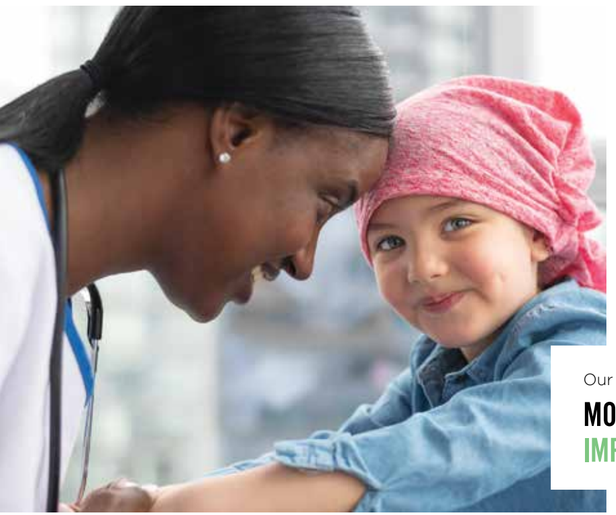
CLINICAL FACILITY
Montreal, Canada

CLINICAL FACILITY
Kansas City, U.S.A.

CLINICAL FACILITY
Los Angeles, U.S.A.

CDMO FACILITY
Philadelphia, U.S.A.

COMPREHENSIVE
FULL-SERVICE OFFERING



INTEGRATED DRUG DEVELOPMENT SOLUTIONS

Altasciences offers a simplified pathway for full drug development programs. We can support your entire program end to end, or you can partner with us for just one element — we offer you complete flexibility. Our outsourcing platform enables you to work with a single, integrated partner from lead candidate selection to proof of concept, and beyond. Our program managers are the single point of contact for a comprehensive, full-service package designed to minimize hand-offs, resulting in shorter timelines and reduced costs.

We work closely with you to design the most efficient preclinical, clinical, bioanalytical, or manufacturing program that meets all regulatory requirements. We offer a flexible and customized approach for study start-up, design, and conduct, and an industry-leading Quality Management System that is consistently applied across all services.

We are committed to ensuring timely information capture, proactive communication, and smooth transitions between phases and studies.

Our mantra is:

MOVING IN UNISON TO DELIVER BIG IMPACT WITH A PERSONAL TOUCH.

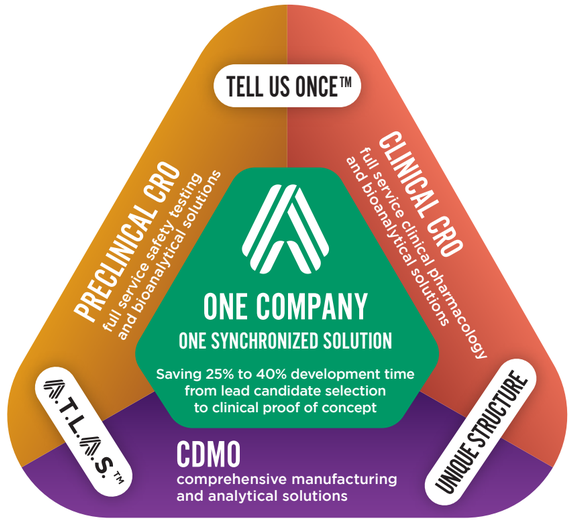
OUR UNIQUE APPROACH

At Altasciences, we provide you with clear, customized roadmaps, supported by our real-time data generation, proprietary communication platforms, central program management, and scheduling. This Proactive Drug Development approach is based on three core pillars: **Tell Us Once™**, **A.T.L.A.S.™**, and our **unique organizational structure**. Together, these pillars translate into a results-driven exchange of information, and reduced costs and drug development timelines, whether for one study or an entire program.

Tell Us Once™ is Altasciences' commitment to ensuring you never need to repeat yourself during studies or at each stage of drug development. Our proprietary database collects and shares client-specific data, preferences, drug information, and study results with our scientific teams across all departments and locations, facilitating communication and swift decision-making.

A.T.L.A.S. represents your drug development roadmap. Our A.T.L.A.S. platform anticipates program-specific roadblocks and streamlines an integrated approach to CRO and CDMO services. Your roadmap is guided by one cross-functional program manager and one operational structure that uses a centralized scheduling system for synergy across services.

Our **unique organizational structure** leverages the extensive preclinical, clinical, bioanalytical, and manufacturing backgrounds of our management team and scientists, supporting an integrated end-to-end solution. Our entire company operation is overseen by two executives, dedicated to ensuring a seamless process as you move from one milestone to the next.



You speak, we listen! Tell Us Once™ and we'll take care of the rest.

Watch a Tell Us Once™ Story

Our CEO explains Proactive Drug Development

PRECLINICAL
SERVICES

Altasciences offers a full range of *in vivo* non-GLP and GLP preclinical evaluation studies in both rodent and non-rodent species to thoroughly assess the safety of our clients' molecules. Our solution offering includes IND/NDA-enabling toxicology, safety pharmacology, and laboratory services that meet global regulatory requirements, for both small and large molecules.

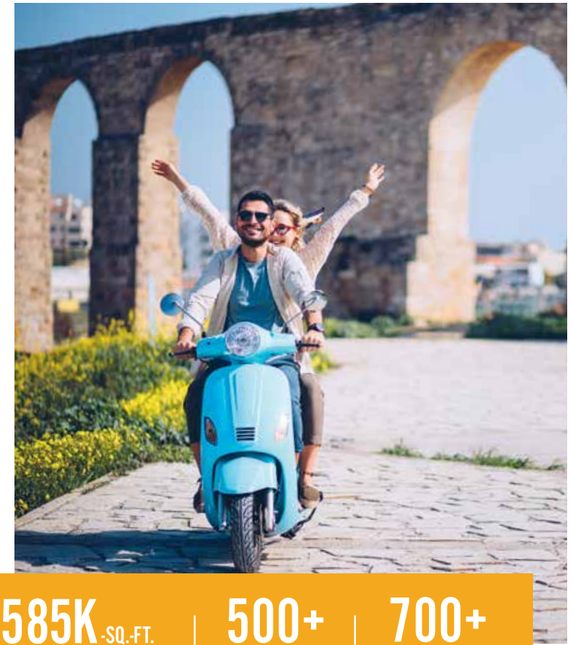
Our team of scientists and technicians has been conducting toxicology studies for decades, and is committed to working as an extension of our clients, moving in unison, and going above and beyond to meet your critical milestones.

Experience the possibilities

PRECLINICAL FACILITIES

We have AAALAC-accredited, USDA-registered, purpose-built facilities, with OLAW Assurance and BSL-2 certification, which are fully compliant with GLP requirements from the FDA and OECD.

- Management with over 450 combined years of experience in pharma, biotech, and CRO
- Expertise with both rodent and non-rodent species
- Experience in small and large molecule safety testing
- QA leadership with over 20 years' experience
- 585,000 square feet of purpose-built facilities
- 280 custom-designed animal rooms, including
  - American housing
  - European housing
  - Barrier facilities for small animals
- Archive facility and services on-site



585K -SQ.-FT.
of purpose-built facilities

500+
team members

700+
safety studies conducted annually

PRECLINICAL SERVICES

Safety Testing Services

- Lead optimization (discovery pharmacology)
- ADME
- General toxicology (acute, sub-chronic, chronic, carcinogenicity)
- Safety pharmacology (CNS, cardiovascular, respiratory)
- Immunotoxicology and immune function
- Pharmacokinetics (PK)
- Pharmacodynamics (PD)

Routes of Administration

- Oral (gavage, diet, and capsule)
- Parenteral
- Ocular
- Dermal
- Implant
- Intranasal
- Intrathecal
- Intravaginal and intrapenile
- Rectal

Species

- Rats
- Mice
- Guinea pigs
- Rabbits
- Swine
  - Specialized in miniature swine
- Dogs
- NHPs
  - Cynomolgus
    - Cambodian
    - Chinese
    - Vietnamese
    - Mauritian
  - Rhesus
    - Chinese

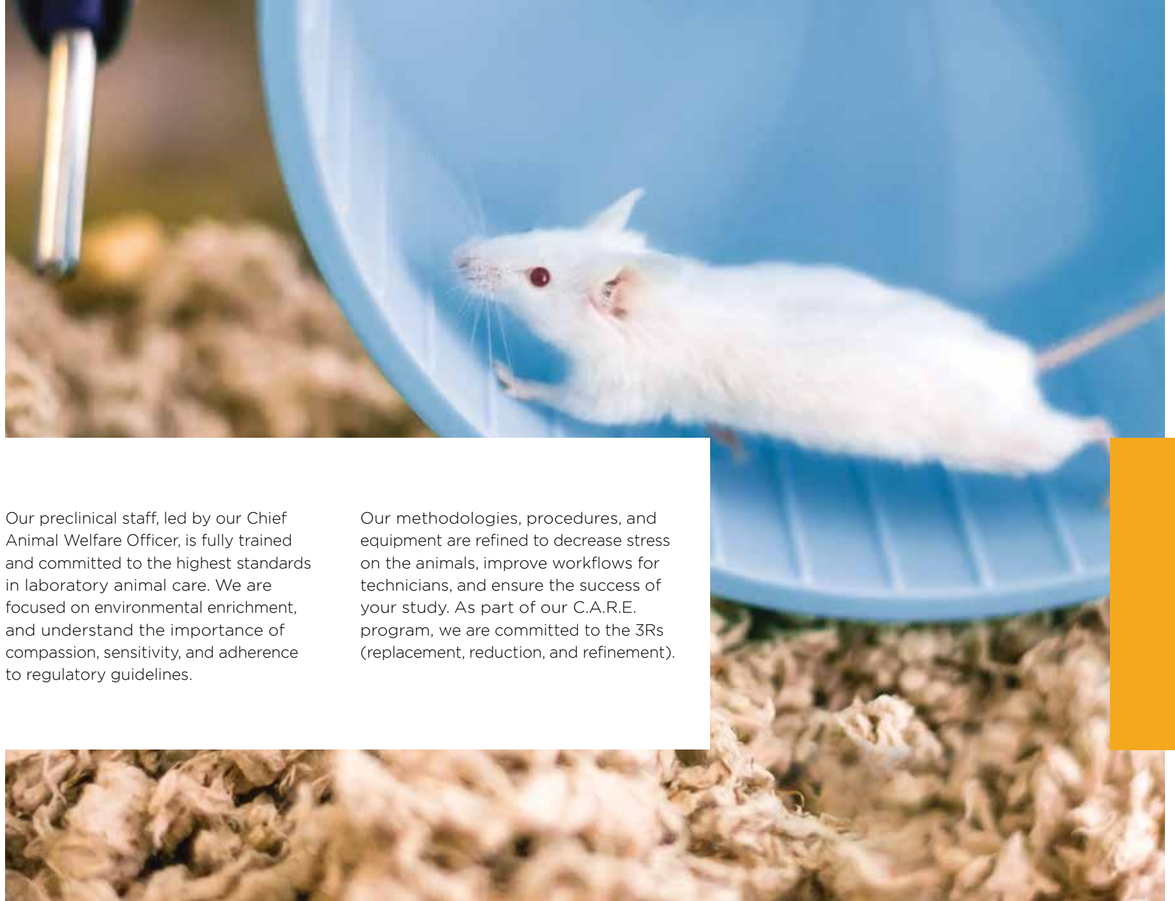
Comprehensive Full-Service Offering

- Analytical chemistry
- Analytical biology
- Immunohistochemistry
- Bioanalysis
- PK/TK data analysis
- Specialized necropsies
- Anatomic pathology
- Clinical pathology
- SEND – Standard for Exchange of Nonclinical Data
- Archiving

OUR COMMITMENT TO ANIMAL WELFARE

Our preclinical staff, led by our Chief Animal Welfare Officer, is fully trained and committed to the highest standards in laboratory animal care. We are focused on environmental enrichment, and understand the importance of compassion, sensitivity, and adherence to regulatory guidelines.

Our methodologies, procedures, and equipment are refined to decrease stress on the animals, improve workflows for technicians, and ensure the success of your study. As part of our C.A.R.E. program, we are committed to the 3Rs (replacement, reduction, and refinement).



Unique Handling, Animal Care, and Housing:

- AAALAC accreditation
- Comprehensive environmental and animal enrichment program
- Consistent healthcare, welfare, and enrichment from point of origin to final destination
- Dedicated animal enrichment staff and NHP behaviorist
- Passive-restraint NHP procedure cages
- EU-compliant group housing for NHPs
- Minipig habitat caging configured to allow for snout-to-snout interactions

C.A.R.E.

- A contract signed by every employee to iterate their commitment to prioritizing the humane care of animals used in research

ANIMAL WELFARE COUNCIL

- Made up of veterinarians, scientists, and members from the community

VETERINARIAN COMMITTEE

- For decision-making in difficult euthanasia situations

USE OF HUMANE ENDPOINTS

- To minimize pain and discomfort

Feel the love

CLINICAL
SERVICES

Altasciences' expertise covers all the clinical pharmacology studies required for regulatory submissions across a wide range of therapeutic areas, covering small molecules, biologics, and 505(b)(2) or hybrid applications.

Our experts will guide you in clinical strategy and ensure proper conduct of your studies — working with you to leverage preclinical data in the design of clinical trials that will take your programs through to proof of concept.

With over 25 years of experience delivering clinical services, we conduct trials in state-of-the-art facilities in the U.S. and Canada, with over 500 beds and a vast participant database (healthy normal and patient populations). Regardless of participant type or length of stay, our recruitment and retention rates are excellent, with 95% on-time panels, year after year.

Experience the difference

500+ beds | **285+** clinical trials completed annually | **400K+** participants in our database

CLINICAL PHARMACOLOGY EXPERTISE

- Early phase expertise for Phase I-II, including all Phase I NDA-enabling requirements
- First in human – stand alone or integrated protocols
  - Single and multiple ascending dose (SAD/MAD)
  - Fully adaptive design capabilities
  - Integrated POC and food effect
- Proof of concept
- Special populations
- Drug-drug interaction (DDI)
- Ethnobridging studies (Asian/Non-Asian)
- Comparative bioavailability (BA) and bioequivalence (BE)
  - Food effect
  - Gender effect
  - Age effect
  - PK/PD
- 505(b)(2)
- Biologics and biosimilars

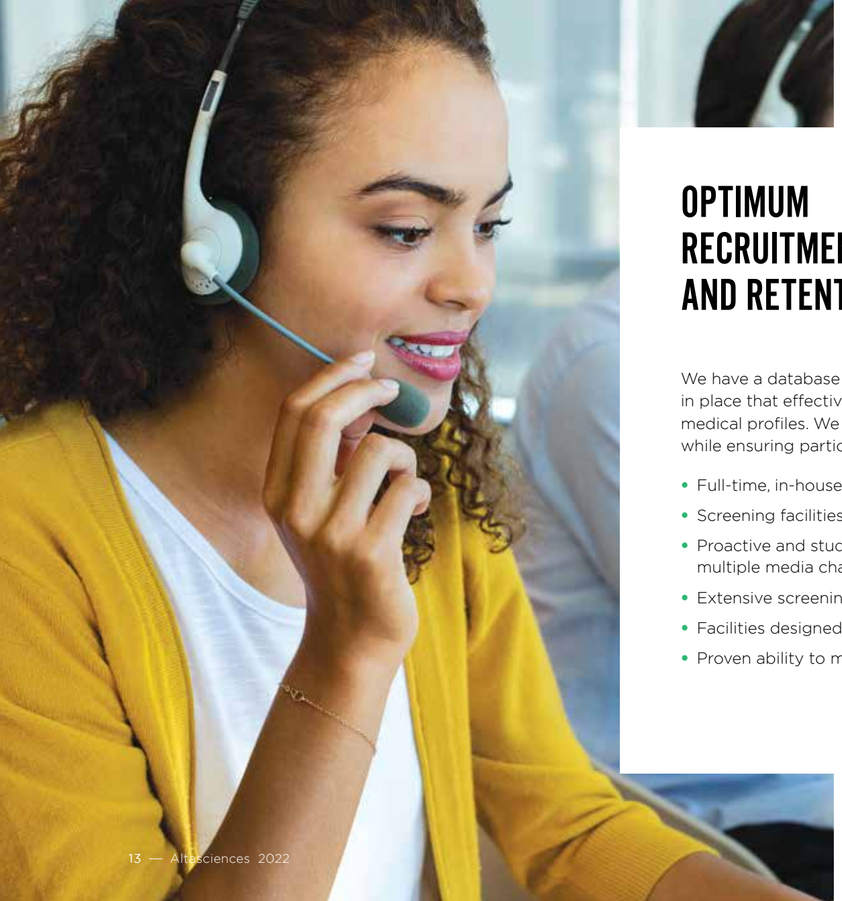
Specialty Trials and Assessments

- CNS Center of Excellence
  - Human abuse potential
  - Physical dependency
  - Factor 8 analysis
  - Driving simulation
  - Cognition
  - Pain
- Cardiac safety – early precision QT/TQT
- Renal and hepatic impairment
- Vaccines
- Metabolism and endocrinology
  - NAFLD/NASH
  - Type I and II diabetes
  - Obesity
  - Clamping
- Infectious diseases
- Ophthalmology
- Inhalation/Insufflation
- Pulmonary function tests
- Cannabis products
- Topical/Transdermal drugs
  - HRIPT
  - Adhesion/High-precision, automated assessment
  - Local tolerance, dermal irritancy
  - MUsT trials
- Imaging
- CSF collection
- PBMC collection and separation
- LPS challenge

Research Support Services

Available as stand-alone services or as part of a development package:

- Manufacturing and analytical services for small molecules
- Scientific, regulatory, and strategic guidance
- Protocol development
- Project management
- Bioanalysis (small and large molecules)
- Data management
- Biostatistics
- Reporting
- CDISC
- Archiving

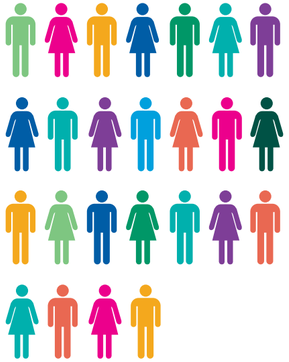


OPTIMUM RECRUITMENT AND RETENTION

We have a database of over 400,000 participants, and systems in place that effectively match study requirements to participant medical profiles. We offer rapid recruitment and study start-up while ensuring participant retention throughout the trial.

- Full-time, in-house, multilingual recruiting staff
- Screening facilities with direct access to public transportation
- Proactive and study-focused recruitment strategies using multiple media channels
- Extensive screening histories for effective recruitment
- Facilities designed for optimum recruitment and retention
- Proven ability to meet recruitment milestones

CLINICAL TRIAL POPULATIONS



Participant and Special Populations

- Healthy normal volunteers (HNVs)
- Elderly
- Asian
- Overweight and obese
- Post-menopausal women
- Substance abusers and recreational drug users

Patient Populations

- Allergy
- Asthma
- ADHD
- Atopic dermatitis
- Anxiety disorders
- Binge eating disorder
- COPD
- Constipation
- Diabetes
- Dyslipidemia
- Epilepsy
- Fibromyalgia
- GERD
- Gout
- Glaucoma
- Hepatitis
- Hypercholesterolemia
- Hypertension
- Lupus
- Major depressive disorder
- Migraine
- Osteoarthritis
- Osteopenia
- Overactive bladder
- Pain and inflammation
- Panic disorder
- Premenstrual dysphoric disorder
- Psoriasis
- Restless legs syndrome
- Sleep disorders

Others upon request

BIOANALYTICAL
SERVICES

Capacity to accommodate

60,000+ study samples per month

25+ research and development scientists

200+ highly trained regulatory bioanalysis specialists

Responsive and flexible, our team of over 200 bioanalytical subject matter experts is there for you, throughout all stages of your drug development pathway. From preclinical to Phase IV, we work scientist to scientist as a collaborative CRO/CDMO partner to deliver integrated bioanalytical solutions for your toughest assay needs.

Following clear processes, in accordance with GLP and current FDA/EMA guidelines, and supported by our unique array of platforms and large list of validated assays, our team ensures the most effective methods for your individual programs.

We have state-of-the-art, purpose-built laboratories at our locations in the U.S. and Canada, with designated containment Level 2 areas for work with Risk Group 2 pathogens. Staffed by highly skilled analysts, and shifts running 24/7 (as needed), we can process over 60,000 study samples per month.

Explore the innovation

BIOANALYTICAL SERVICES

From Discovery to Preclinical to Phase IV — Method Development, Validation, and Sample Analysis

Altasciences has experience with a wide spectrum of biological matrices in both animal species and humans, including serum, plasma, blood, urine, feces, tissues, cerebrospinal fluid, and vitreous humor.

OUR BIOANALYTICAL SERVICE OFFERING

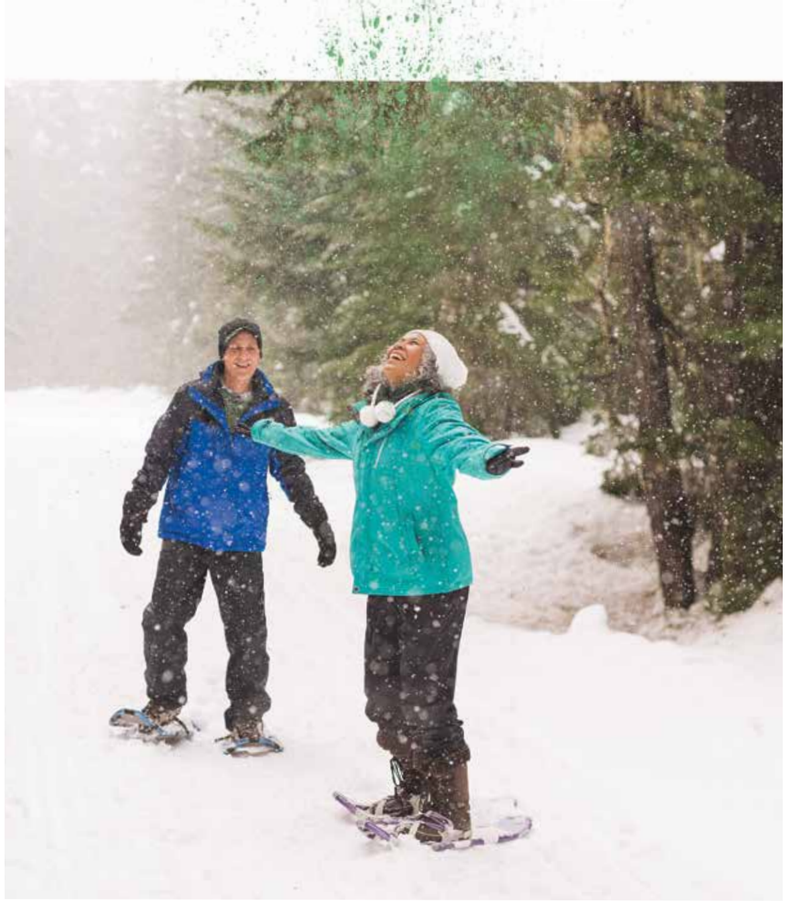
Small and Large Molecule Capabilities

Small Molecules

- Extensive, in-house database of over 680 assays covering 615 molecules
- Customized, unique solutions in derivatization, chiral separation, drug stabilization, and multiple metabolite quantitation
- State-of-the-art instrumentation to achieve low quantitation with limited sample volume
- Certain small molecules are suitable for our cutting-edge ligand binding platforms

Large Molecules

- We evaluate each request and provide customized workflows to allow accurate platform selection by hybrid LC-MS or ligand binding
- Our experienced and dedicated research and development scientists develop validation-ready assays, customized to your needs, using advanced instrumentation



LC-MS/MS

Instrumentation:

- Over 34 LC-MS/MS instruments, including Sciex 5000, 5500, 6500+, and Selexion with Nexera UHPLCs
- HRMS, including the Sciex 6600 and ThermoFisher Q Exactive™
- Micro-flow and nano-flow capabilities for the front end of our HRMS systems

Ligand Binding

Instrumentation:

- Mesoscale S600 electrochemiluminescence sector imager
- BioTek Synergy™ H4 multimode plate reader using absorbance, fluorescence, or luminescence
- Luminex® 200™ system
- Simoa HD-1 analyzer
- BioTek EL406 microplate washer/dispenser
- SpeedVac for tissue extraction
- Percellys® Evolution homogenizer
- Droplet Digital PCR and qPCR analysis

Flow Cytometry Instrumentation:

- BD Biosciences FACSCanto™ II cytometer
- BD LSRFortessa™ with FACSDiva™ 9 (two units)
- BD LSR™ II with FACSDiva™ 9

Quantitative Analysis Using LC-MS/MS

- Experience with monoclonal antibodies, antibody-drug conjugates, and proteins (intact and peptide quantification)
- Automated immunoaffinity sample preparation producing high-throughput assays with impressive sensitivity
- Biomarkers and endogenous analytes
- Labile metabolite quantitation
- Industry experts supporting microsampling (Mitra® VAMS™ and dried blood spots) for preclinical and clinical programs

Our ligand binding assay types:

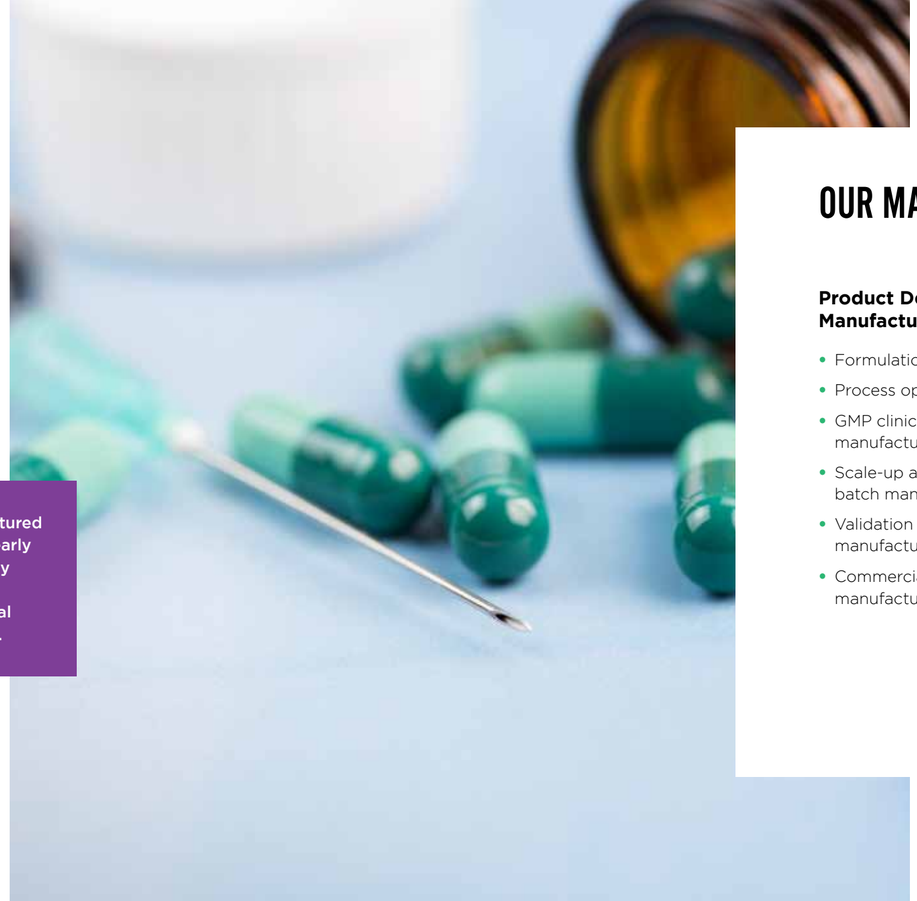
- Immunogenicity
  - ADA (screening, confirmatory, titration)
  - NAb by non-cell-based and cell-based assays
- Quantification methods using various platforms
- Hybridization ELISA/ECLIA of various types (ligation, dual hybridization)
- Functional cell-based assays
- Antibody response (TDAR)
- Biomarkers
- Cell lineage and functional immunophenotyping by flow cytometry
- PCR analysis

MANUFACTURING AND ANALYTICAL SERVICES

We provide proof of concept, R&D, and clinical and commercial manufacturing that includes liquid-filled capsules, band/sealing technologies, powder and over-encapsulated capsules, topical formulations, and clinical and blister packaging, which are manufactured in our purpose-built facility.

All operations are on a single campus with analytical, manufacturing, and cGMP warehouse capacity.

We have manufactured and/or tested nearly every currently available pharmaceutical dosage form.



OUR MANUFACTURING SERVICE OFFERING

Product Development and Manufacturing Capabilities

- Formulation and development
- Process optimization
- GMP clinical supply manufacturing (Phases I-IV)
- Scale-up and engineering batch manufacturing
- Validation batch manufacturing
- Commercial batch manufacturing

Dosage Type and Process Capabilities

- Liquid-filled, hard-shell capsules
- Capsule banding
- Particle size reduction (wet milling/nanomilling)
- Powder blending
- Powder-filled capsules
- Over-encapsulation
- Injectable vial filling (pre-sterilized)
- Solutions and suspensions
- Gels and creams
- Clinical packaging (bottles and blisters)
- Potent product handling

Controlled Substance Manufacturing Capabilities

- DEA Manufacturing License (Schedules I-V)

Additional Client Support Services

- Facility expansion capabilities, including dedicated space and equipment, as required to meet project demands
  - Man-in-plant
  - Perform supplier audits

SIMPLIFYING
Contract Services

OUR ANALYTICAL SERVICE OFFERING

Development and Validation of Critical Methodologies

- Cleaning methods for the detection of API on manufacturing equipment
- API methods for assay/related substance
- Finished dosage products (assay/degradation, dissolution)

Stability Testing

- ICH environment stability chambers

Controlled Substance Testing

- DEA Analytical License (Schedules I-V)

Drug Product Release Testing

- High-performance liquid chromatography (HPLC) and ultra performance liquid chromatography (UPLC)
- Dissolution and disintegration
- Moisture analysis (Gravimetric and Karl Fischer [KF] titration)
- Spectroscopy (Ultraviolet/Visible [UV/VIS] and Infrared [FTIR])
- Total Organic Carbon (TOC)
- Viscosity
- Particle Size Analysis
  - Malvern
  - Horiba
  - AccuSizer (USP<788>)

FOCUSED ON QUALITY

All studies are conducted with the highest level of safety and compliance. In addition to sponsor audits, we regularly host successful regulatory inspections from agencies, such as the FDA, Health Canada, ANVISA, ANSM, MHRA, AGES, AEMPS, and SCC.

We provide:

- QA leadership with over 20 years of experience
- RQAP-GLP Registered Auditors Team actively involved in the U.S. and Canadian regulatory QA community (SQA, PRCSQA, CCSQA)
- Harmonized QA approach
- In-house QA teams to ensure trials are conducted per protocol and within ICH/GCP/CFR guidelines
- Comprehensive SOPs and employee training records

Our QA team oversees:

- SOP management
- Regulatory audits
- Sponsor audits
- GCP/GLP data audits
- On-site inspections
- Supplier audits
- GLP accreditation
- On-site GLP-compliant archiving

OUR COMMITMENT TO SAFETY

- Full-time, dedicated research physicians overseeing all aspects of clinical trials
- Daily participant assessment by an Investigator
- Staff certified in Advanced Cardiac Life Support (ACLS) on-site 24/7
- All clinical staff certified in Basic Cardiac Life Support
- Crash carts available on-site
- Scenario-based response training
- Telemetry with pulse oximetry
- Strategically placed panic buttons
- 24/7 video surveillance/controlled access throughout the facility
- Close proximity to major hospitals

WHY ALTASCIENCES?

TRUST

You can trust the quality of our data, the expertise of our staff, and the strength of our commitments.

TELL US ONCE™

Is our proactive sharing of your preferences, product information, and study results across all of Altasciences' teams. You should never have to waste time repeating yourself.

A.T.L.A.S.™

We develop a personalized roadmap for your program, anticipating potential roadblocks and synchronizing related activities. A dedicated, cross-functional project manager keeps you on track to meet your milestones, using our proprietary central scheduling system to ensure real-time responses and flexibility to adapt as your program evolve.

SIZE AND SPEND DON'T MATTER

Every client matters. Whether you place one study or multiple programs, we ensure that each client feels equally important, and knows that we are committed to making their project a success.

WE HAVE YOUR BACK

We believe in transparency, responsiveness, and the importance of being dependable and honest. We treat our clients like colleagues and their projects as our own.

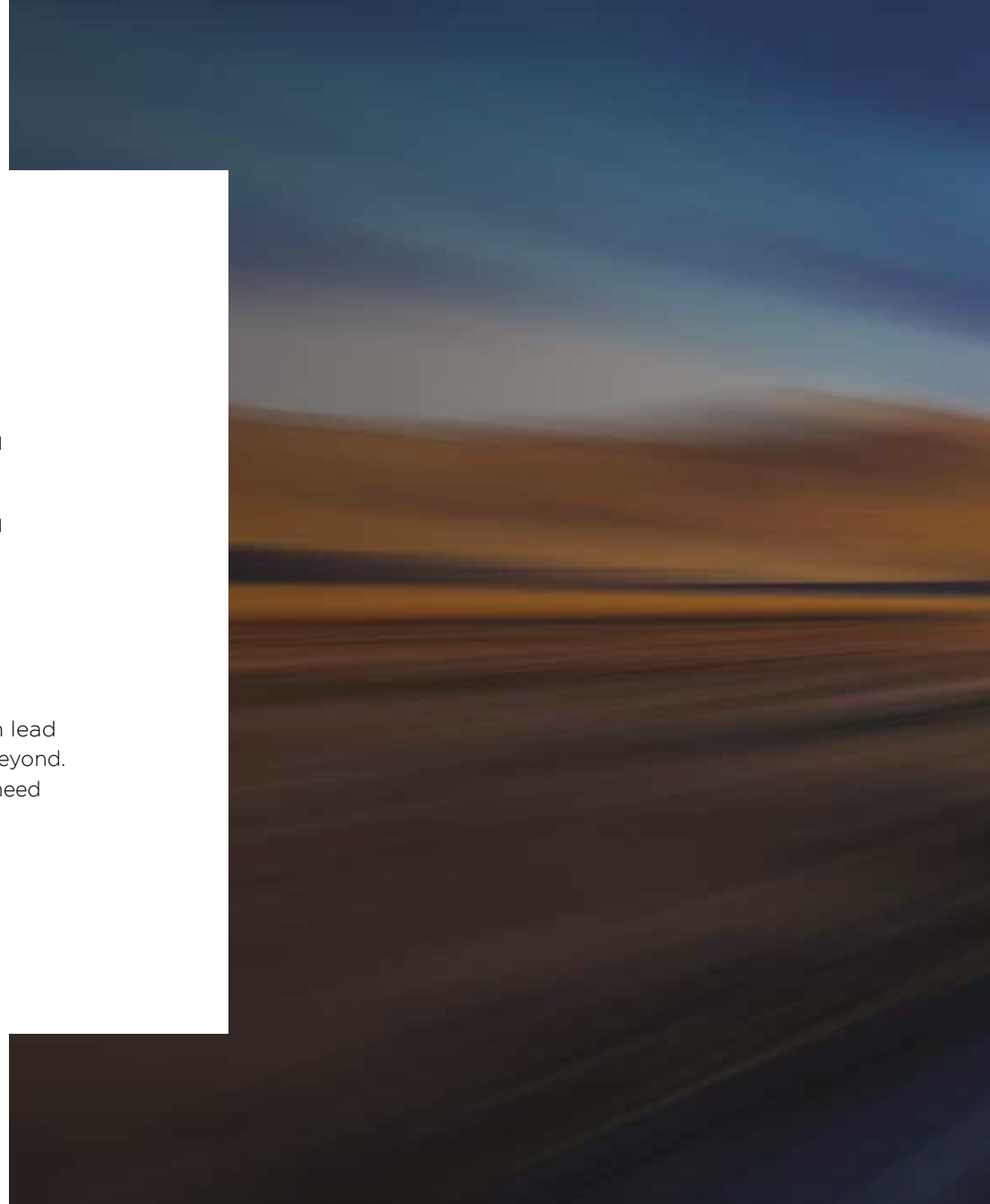
SCIENTIFIC AND OPERATIONAL EXPERTISE

We apply our scientific and operational expertise to ensuring that we deliver the highest quality, customized services in the most efficient manner, for each individual program. We have what it takes to move your molecule from preclinical to clinical proof of concept in one integrated process.

Imagine a different kind of CRO

ALTASCIENCES, A MID-SIZE, FULL-SERVICE CRO/CDMO

that delivers big impact with a personal touch, from lead candidate selection to clinical proof of concept, and beyond. Helping sponsors get better drugs to the people who need them, faster.



ALTASCIENCES

contact@altasciences.com
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