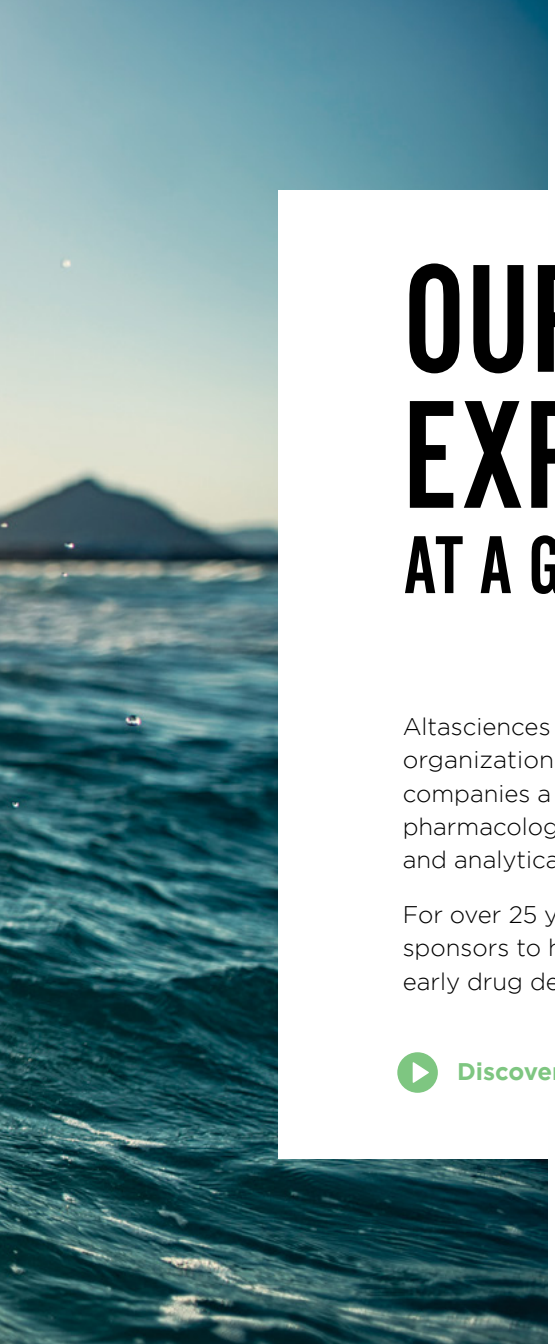

ALTASCIENCES
MOVING IN
UNISON



OUR EXPERTISE
AT A GLANCE

Altasciences is a forward-thinking, mid-size contract research organization offering pharmaceutical and biotechnology companies a proven, flexible approach to preclinical and clinical pharmacology studies, including formulation, manufacturing, and analytical services.

For over 25 years, Altasciences has been partnering with sponsors to help support educated, faster, and more complete early drug development decisions.

Discover our vision

5 LOCATIONS IN NORTH AMERICA

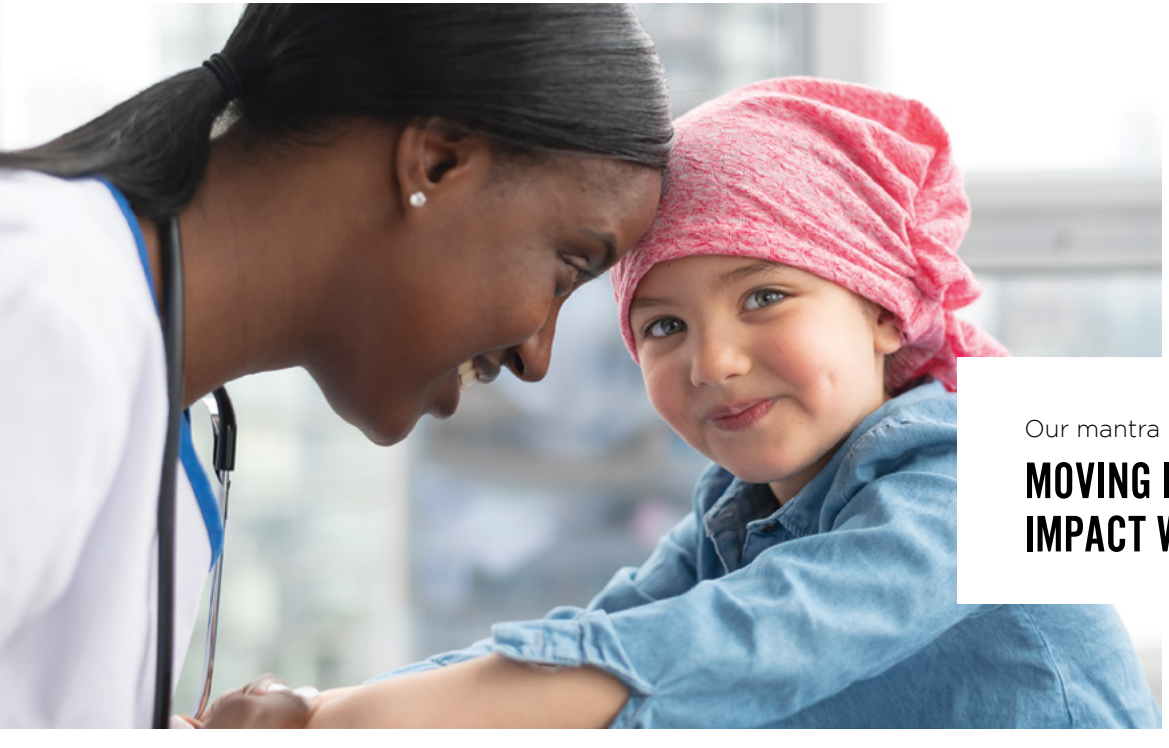
PRECLINICAL AND BIOANALYTICAL FACILITY
Seattle, U.S.A.

CLINICAL FACILITIES
Montréal, Canada
Kansas City, U.S.A.

BIOANALYSIS & RESEARCH SERVICES
Laval, Canada

MANUFACTURING & ANALYTICAL SERVICES
Harleysville, Pennsylvania

COMPREHENSIVE
FULL-SERVICE OFFERING



INTEGRATED 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.

Our mantra is:

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

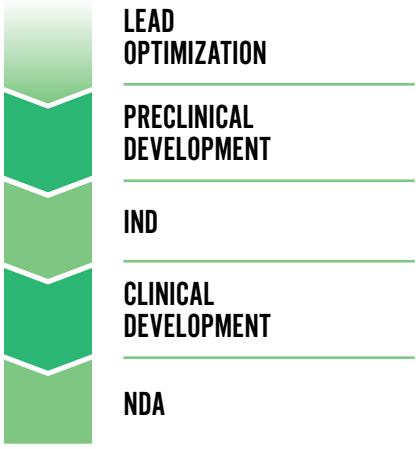
OUR APPROACH

We streamline processes and integrate into our clients' teams and their projects; we help them make educated, fast, and more comprehensive early drug research decisions. Whether a single study or complete program, our goal is to simplify your drug development process with speed and ease.

We work closely with you to design the most efficient preclinical or clinical studies that meet 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.

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



Team led by two executives for a streamlined experience:

- **Operations**
  preclinical to clinical research
- **Research Services**
  program management, manufacturing and analytical services, bioanalysis, biostatistics, data management, regulatory, medical writing, etc.

PRECLINICAL
SERVICES

PRECLINICAL DRUG DEVELOPMENT

Altasciences' solution offering includes IND/NDA-enabling toxicology, safety pharmacology, and laboratory services. Our team of scientists and technicians have been conducting toxicology studies for decades, and is committed to working as an extension of our clients, moving in unison, going above and beyond to meet your critical milestones.

We have an AAALAC-accredited, USDA-registered, purpose-built facility, with OLAW Assurance and BSL-2 certification, which is fully compliant with FDA, OECD, and GLP requirements.

With Altasciences as your partner, you can plan for Phase I/II studies at the outset, ensuring a smooth transition from preclinical to first-in-human (FIH) studies.

Experience the possibilities

OVERVIEW OF OUR PRECLINICAL FACILITY

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

Experience and Facilities:

- Management with over 300 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
- ~210,000-sq.-ft., purpose-built facility
- 140 custom-designed animal rooms, including European housing
- Barrier facilities for small animals
- Archive facility and services on site

210K -SQ.-FT.
purpose-built facility

250+
team members

2,400+
safety studies completed to date

OUR PRECLINICAL SERVICE OFFERING

Altasciences' team of scientists and technicians have been conducting toxicology studies for over 25 years, and are committed to working as an extension of our clients, going above and beyond to meet critical milestones.

Toxicology Services

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

Routes of Administration

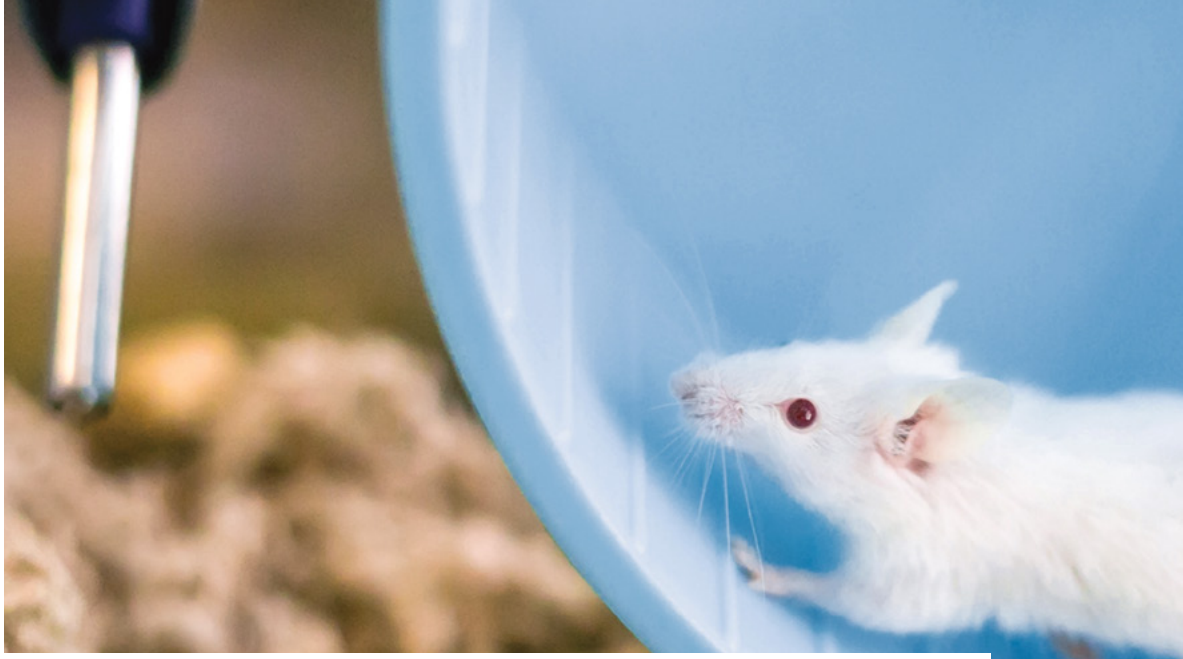
- Oral (gavage, capsule, diet)
- Parenteral (intravenous bolus, subcutaneous, intramuscular, intraperitoneal, intrathecal, intra-articular)
- Infusion
- Ocular
- Intranasal
- Intradermal, topical
- Rectal
- Intravaginal

Species

- Rats
- Mice
- Guinea pigs
- Rabbits
- Minipigs
- 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

is 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

For your early phase clinical studies, our experts in the design and conduct of clinical pharmacology and early efficacy studies ensure the data generated meets your objectives — working with you to leverage preclinical data in the design of the studies that take your programs through to proof of concept. Our 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.

With 25+ years of experience delivering clinical services, we conduct trials in state-of-the-art facilities in the U.S. and Canada, with 400 beds and a database of more than 345,000 participants (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

400 beds

250+ clinical trials completed annually

345K+ participants in our database

Our clinical services include expertise in:

- First in human
  - Single ascending dose (SAD)
  - Multiple ascending dose (MAD)
- Proof of concept
- PK in special populations
- Drug-drug interaction (DDI)
- Bridging studies
- Comparative bioavailability and PK studies
- Bioavailability (BA) and bioequivalence (BE)
  - Food effect
  - Age effect
  - Gender effect
  - PK/PD
- 505(b)(2)

Specialties include, but are not limited to:

- Biologics and biosimilars
- Infectious diseases
- Human abuse potential (HAP) with new chemical entities and abuse-deterrent formulations (ADF)
- Substance use disorders
- Metabolism and endocrinology
  - NAFLD/NASH
  - Type I and II diabetes
  - Obesity
- Renal and hepatic impairment
- Pain models and inflammation
- Topical vasoconstrictor and irritation-sensitization
- Cognitive testing
- Driving simulation
- Imaging
- QT assessment
- Smoking and vaping
- Cannabis

Comprehensive Full-Service Offering

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

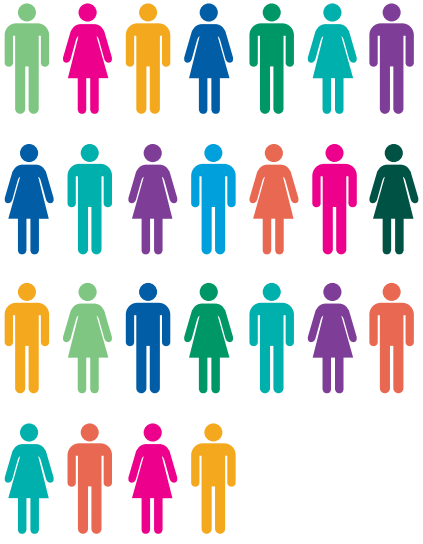
- Manufacturing and analytical services for small molecules
- Scientific, regulatory, and strategic guidance
- Protocol development
- Project management
- Bioanalysis (small and large molecules)
- Data management
- Biostatistics
- Reporting
- CDISC
- Archiving

PARTICIPANT RELATIONSHIP MANAGEMENT

We have a database of over 345,000 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 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
- Overweight and obese
- Pediatric and adolescent
- Post-menopausal women
- Substance abusers and recreational drug users
- Smokers

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

BIOANALYTICAL LABORATORY SERVICES

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.

Responsive and flexible, our team of over 200 bioanalytical subject matter experts is there for you, throughout all stages of your drug development pathway.

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.

OUR BIOANALYTICAL SERVICE OFFERING

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

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 (CONT'D)

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
- BD Biosciences FACSCanto™ II cytometer
- SpeedVac for tissue extraction
- Percellys® Evolution homogenizer
- Droplet Digital PCR and qPCR analysis

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

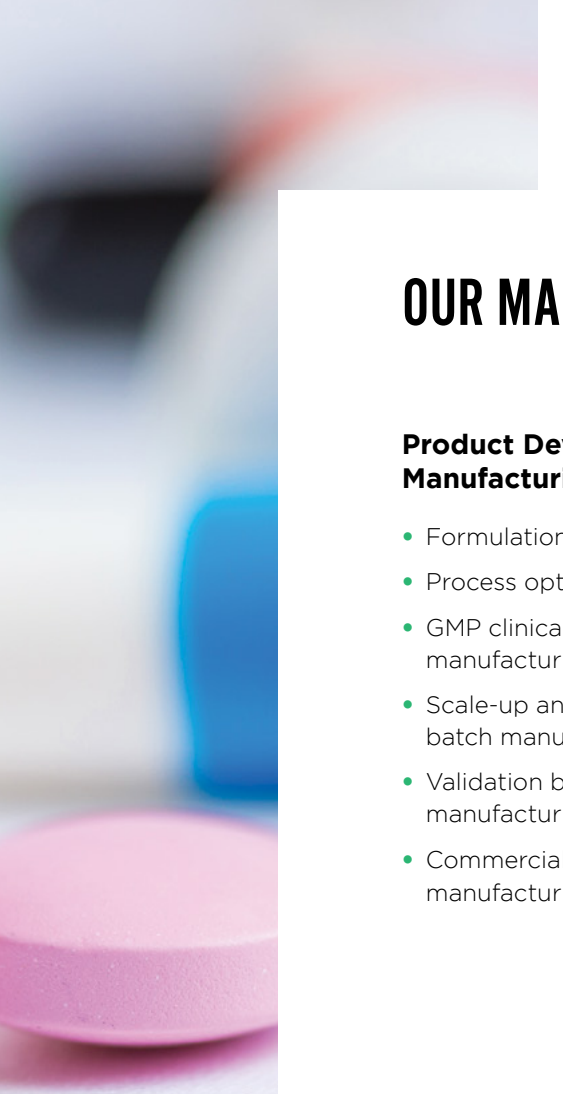
We provide proof of concept, R&D, clinical and commercial manufacturing that includes liquid-filled capsules, band/sealing technologies, powder and over-encapsulated capsules, topical formulations, and clinical and blister packaging which are manufactured in our purpose-built facility.

30,000-sq.-ft. facility

- 9,500-sq.-ft. warehouse
- 3,300-sq.-ft. manufacturing area
- 2,500-sq.-ft. segregated ISO7/8 manufacturing area (capable of handling potent compounds)
- 1,500-sq.-ft. R&D formulations lab
- 3,000-sq.-ft. analytical lab

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

100
years of combined experience



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/nano-milling)
- 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 SERVICES 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 oversee 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 are 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 Altasciences' teams. You should never have to waste time repeating yourself.

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 proof of concept in one integrated process.

Imagine a different kind of CRO

ALTASCIENCES, A MID-SIZE, FULL-SERVICE CRO

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

ALTASCIENCES

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STAY CONNECTED

Updated October 2020