ALTASCIENCES

CENTRAL NERVOUS SYSTEM (CNS)

FROM LEAD CANDIDATE SELECTION TO CLINICAL PROOF OF CONCEPT, AND BEYOND

Altasciences' CNS Center of Excellence is renowned for offering expert, fully integrated, comprehensive early phase drug development solutions. Our streamlined solutions and processes help you advance from milestone to milestone, delivering up to **40% time savings** through the early phases of your drug development.

NONCLINICAL SAFETY TESTING

- Decades of expertise in IND-enabling studies for CNS indications
- Dedicated CNS-focused facility with expertise in cell and gene studies in NHPs
- Vast experience with cognitive measures, functional observational batteries (FOBs), EEG-implanted telemetry equipment, MRI scanning, and other imaging modalities

MANUFACTURING AND ANALYTICAL SERVICES

- Seamless transition from protoype formulations to clinical manufacturing
- High potency manufacturing, including controlled substances
- DEA manufacturing and analytical license (Schedule I-V)
- State-of-the-art Grade C and D cleanrooms
- Various dosage forms, including liquid-filled capsules, and wet media milling capabilities for micro- and nanosuspension products
- Analytical support for method development, validation, and ICH stability testing
- Commercial batch manufacturing

REGULATORY AND SCIENTIFIC AFFAIRS

CLINICAL TRIALS

- Three state-of-the-art clinical research campuses:
  - designed for multifaceted safety monitoring assessments of CNS studies
  - staffed 24/7 by paramedics, safety officers, and nurses trained in Advanced Cardiac Life Support
- Pharmacists with extensive, direct experience in preparing and dosing substance abuse, CNS, and HAP studies via oral, sublingual, intranasal, and parenteral routes
- Clinical expertise in the evaluation of benzodiazepines, gabapentin, and opioids, including transdermal and extended-release pain formulations

BIOANALYTICAL SERVICES

- Proven scientific expertise in the development and validation of bioanalytical assays supporting CNS indications
- State-of the-art instrumentation to achieve low limits of quantitation in plasma samples
- Expertise working with rare and limited matrices such as cerebrospinal fluid (CSF)
- LC-MS/MS, LBA or hybrid LBA/LC-MS/MS assay platforms

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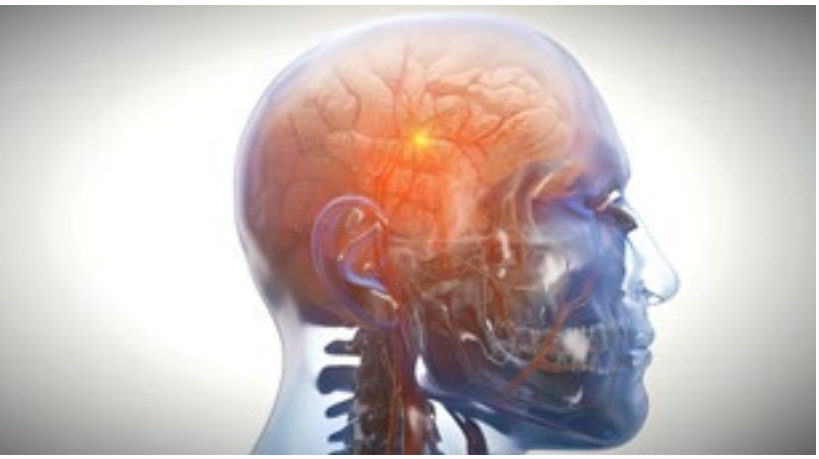
REGULATORY PROCESS EXPERTISE AND SUPPORT

- Briefing documents and support for all types of global regulatory meetings and consultancy, including:
  - Health Canada
    - Pre-CTA gap analysis
    - Pre-CTA package preparation and Health Canada meeting support
    - CTA preparation, submission, and maintenance
    - QOS (Quality Overall Summary) writing and preparation
  - FDA
    - Pre-IND gap analysis
    - Pre-IND briefing package preparation and FDA meeting support
    - IND preparation and submission
- Investigator's Brochure preparation
- IND preparation and submission
- Nonclinical and clinical regulatory strategy
- Toxicology consulting and strategic advice



BIOANALYTICAL CAPABILITIES

- Leading-edge technology and capabilities for preclinical and clinical CNS studies
- Equipment and assay platforms that provide the ultra-low sensitivity necessary for CSF, plasma, or serum samples

NONCLINICAL SAFETY TESTING

- Experience with small and large molecule CNS programs, including a full range of study types and animal models of disease, in all species
- Purpose-built facility in Sacramento has particular expertise in non-GLP exploratory CNS research, focused on cell and gene therapies and oligonucleotides, among others
- Robust understanding of the CNS safety protocols in the **ICH S7A** regulatory guideline ensures that your drug development program rapidly advances to clinical trials

ADAPTIVE CLINICAL PHARMACOLOGY UNITS

Available for:

- Clinical trials involving controlled substances, including psychedelics, cannabinoids, and opioids
- Healthy normal volunteers or patients
- Medical and clinical teams with extensive experience administering CNS drugs at high doses
- Capability to manage psychiatric adverse events in our customized facilities
- Pharmacodynamic expertise, specialized assessments in:
  - Driving
  - Cognition
  - Pain scales
- State-of-the-art pharmacies with multiple security features and multilayered controlled access

MANUFACTURING AND ANALYTICAL SERVICES

Our CDMO capabilities support your development program, from formulation to market, with state-of-the-art manufacturing, analysis, and packaging.

Dosage Forms	Processes
Liquid-filled, hard-shell capsules	Formulation development to commercialization
Powder-filled capsules	Particle size reduction (wet milling/ nanomilling)
Gels and creams	Powder blending
Solutions and suspensions	Analytical method development, validation as well as ICH stability testing
Terminally sterilized injectables	Clinical packaging (bottles and blisters)

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