ALTASCIENCES

REGULATORY SERVICES

At Altasciences, we make regulatory submissions seamless—so you can focus on advancing your drug product to market. Whether you're pursuing an **IND (Investigational New Drug) submission** in the U.S. or a **CTA (Clinical Trial Application)** in Canada and Europe, our integrated solutions model provides comprehensive regulatory support at every drug development stage—from early product development to commercialization.

TWO REGULATORY PATHWAYS—ONE EXPERT PARTNER

U.S. IND Pathway

We provide full support, from **pre-IND meetings** to **IND assembly, submission, and maintenance**.

CTA Pathway

We handle everything from **initial applications to ongoing compliance**, ensuring a smooth regulatory journey.

ALL-IN-ONE REGULATORY ROADMAP: FROM STRATEGY TO SUBMISSION

- **Drug Development and Regulatory Guidance**
  We provide comprehensive support, including nonclinical and clinical regulatory guidance, nonclinical drug development plans, and clinical development plans.
- **Gap Analyses**
  We identify and address regulatory risks before submission.
- **Chemistry, Manufacturing, and Control (CMC) Support**
  We conduct gap analyses and regulatory consults, and author Modules 2 and 3.
- **Target Product Profile and Clinical Development Plans**
  We provide full-scale strategic planning to maximize your success.
- **Investigator's Brochure (IB) Preparation**
- **Pre-IND and/or Pre-CTA Meeting Support**
  We manage meeting requests, briefing packages, rehearsals and attendance, and coordinate the minutes.
- **Submission Assembly and Maintenance**
  We prepare your IND/CTA documents and filings, and perform compliance updates.
- **IND and CTA Post-Approval Maintenance**
  We provide ongoing regulatory support to ensure compliance and seamless progression through clinical development, including amendments, safety updates, annual reports, regulatory correspondence, and lifecycle management for your IND or CTA.

WHY CHOOSE ALTASCIENCES?

Because we don't just check boxes—we partner with you to create a streamlined, strategic regulatory pathway that accelerates your program's success.

Let's take the complexity out of regulatory submissions.

Contact us today!

contact@altasciences.com
altasciences.com

REGULATORY AFFAIRS SIMPLIFIED: EXPERT GUIDANCE AT EVERY PHASE

Our dedicated experts provide tailored strategies and seamless support, ensuring your compound moves efficiently through each development phase.

	DISCOVERY	PRECLINICAL	CLINICAL			BEYOND
		IND/CTA-Enabling	Phase I	Phase II	Phase III	Phase IV/ Commercialization
REGULATORY SUPPORT/ SCIENTIFIC LEADERSHIP	Gap Analyses/You are Here Report					
	Target Identification and Nonclinical Development Planning	Pre-IND/Pre-CTA Meeting Planning and Conduct	IND/CTA Submission and FIH Study Initiation	Protocol Submissions for Continued Development	NDA/NDS Preparation and Filing	
	Formulation Development, CMC Development and Scale-up					
		Investigator's Brochure Preparation	IRB Submissions			
	Proof of Concept					
			Post-Submission Information Request Support and IND/CTA Maintenance			

Life Cycle Management

We offer global regulatory guidance, leadership, and insight to support you throughout your drug development journey. This includes gap assessments, regulatory roadmaps, strategies for special designations and accelerated pathways, and coaching for interactions with health authorities. With tailored solutions to fit your program's unique needs, our regulatory team will guide your product from concept to commercialization, optimize objectives, and enhance investor confidence.

A Partner You Can Trust

Altasciences' regulatory team is integrated with our preclinical, clinical, bioanalytical, and manufacturing teams. This holistic oversight allows our experts to fully understand your program and ensure all data is collected and analyzed most efficiently. Our unique structure also streamlines the transfer of information, giving you access to real-time data generated by our interdisciplinary teams.

Let us define your regulatory pathway early on, identifying the necessary steps and requirements for getting your drug candidate through the initial stages (e.g., IND filing, CTA submissions) and ensuring alignment with regulatory expectations.

CONTACT US TODAY!

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