ALTASCIENCES

REGULATORY EDGE: SMART SOLUTIONS FOR DRUG DEVELOPMENT

Streamlined Submissions, Strategic Impact

STRENGTHENING YOUR REGULATORY EDGE

Navigating drug development regulatory pathways alone can be one of the most complex and time-intensive aspects of drug development. Delays, fragmented oversight, and misaligned data can slow progress to first-in-human (FIH) and beyond.

We address these challenges for you through an integrated early-phase development model that connects regulatory strategy with **nonclinical**, **bioanalytical**, **clinical**, and **manufacturing** activities. This approach aligns data and reduces fragmentation to reduce handoffs, limit rework, and support faster, more informed decision-making across the program lifecycle. This is your **regulatory edge**.

Whether you are planning an Investigational New Drug (IND) submission in the U.S.A. or a Clinical Trial Application (CTA) in Canada, Europe, or other global regions, our **regulatory solutions** are designed from the very beginning to support your program at every stage—from early product development through commercialization.

TWO REGULATORY PATHWAYS, ONE PARTNER

U.S.A. IND Pathway

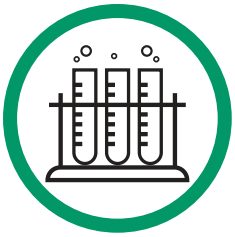
Our comprehensive IND support services encompass every step of the process, from guiding the strategy for the initial pre-IND consultations through assembly, submission, and ongoing maintenance. We closely monitor the evolving regulatory landscape to ensure your submission aligns with the latest regulatory expectations and incorporates FDA feedback into your development plan to avoid costly delays.

Canadian CTA Pathway

From initial CTA and supporting document preparation and submission, to amendments and compliance management, our team ensures regulatory hurdles don't impede your trial progress, enabling timely study initiation and data generation. Execution within an integrated framework supports alignment with study start-up timelines and clinical readiness.

A COMPREHENSIVE REGULATORY ROADMAP

Altasciences develops regulatory strategies alongside nonclinical, clinical, and CMC activities, ensuring alignment across all phases of early development and supporting coordinated oversight throughout your program lifecycle. We support continuous progression, rather than sequential delays between phases.



Drug Development and Regulatory Guidance

We provide targeted regulatory intelligence and strategy informed by integrated program data, helping you design comprehensive nonclinical and clinical development plans that meet with health authority expectations—minimizing risks and enabling clear pathways to approval.

Gap Analyses

Our team conducts thorough regulatory gap analyses to identify potential challenges well before submission, allowing your team to proactively address issues and avoid costly rework or delays.

Chemistry, Manufacturing, and Control (CMC) Support

We provide regulatory consulting and author critical CMC documents, including Module 3 (IND) and the corresponding Quality Overall Summary (QOS) for CTAs, so that your manufacturing data meets regulatory requirements appropriate to each development phase.

Target Product Profile and Clinical Development Plans

We help you craft comprehensive clinical strategies to reflect your target product profile, driving progress toward key corporate milestones while maximizing the likelihood of regulatory success, clinical proof-of-concept, and market authorization.

Investigator's Brochure (IB) Preparation

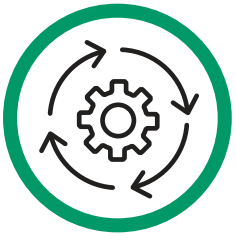
Our team develops thorough, scientifically sound IBs that meet regulatory requirements and support clinical trial safety and transparency.

Pre-IND/Pre-CTA Meeting Support

We manage every detail of meetings with regulatory agencies, including developing the upfront strategy to align questions and messaging. We prepare briefing documents, facilitate rehearsal sessions, attend meetings, and document minutes, so that your team is fully prepared and confident.

Submission Assembly and Maintenance

We coordinate document preparation and electronic submission within a unified framework, reducing fragmentation and maintaining consistency across modules. From assembly through submission, IND and CTA filings are prepared to meet regulatory requirements. Post-submission, ongoing compliance is supported through timely amendments and updates.



IND and CTA Post-Approval Maintenance

Our support continues well beyond initial approvals. As such, we manage all regulatory correspondence, safety reporting, annual updates, and lifecycle activities to keep your clinical development on track and in full compliance.

REGULATORY AFFAIRS SIMPLIFIED:

Expert Guidance at Every Phase

Our global regulatory team provides regulatory insight across your program lifecycle. With regulatory strategy developed in parallel with nonclinical, clinical, and CMC activities, we maintain alignment from the early planning stages through submission and Health Authority interactions. From initial gap assessments and regulatory roadmaps to submission execution, support remains aligned with program goals and evolving data. This helps you:

- Streamline complex objectives by aligning development plans with regulatory expectations.
- Effectively manage risk through early identification and resolution of potential hurdles.
- Enhance investor confidence by demonstrating regulatory readiness and strategic foresight.
- Accelerate time to market through optimized submission strategies and proactive agency engagement.
- Reach early value-inflection points with greater speed and predictability.

WHY CHOOSE ALTASCIENCES?

By partnering with Altasciences, you gain access to a team with deep regulatory and scientific expertise across global frameworks.

We go beyond regulatory execution to shape a clear, efficient pathway that accelerates your program's progress. Regulatory strategy is developed within an integrated operating model that connects nonclinical, clinical, bioanalytical, and manufacturing activities—reducing handoffs, aligning data, and supporting faster advancement through each phase of development.

This structure supports measurable advantages:

- Eliminate operational handoffs between vendors, reducing delays and misalignment
- Reduce rework by aligning regulatory strategy with real-time program data
- Accelerate timelines through parallel execution of regulatory and development activities
- Enable faster progression to first-in-human studies
- Maintain consistency across documentation, data, and submission strategy
- Support informed decision-making through centralized oversight

A Partner You Can Trust

Whether delivered as a standalone solution or alongside program execution, our coordinated approach supports real-time data sharing, faster decision-making, and improved operational efficiency.

Early engagement ensures regulatory strategy is in accordance with program design and health authority expectations from the outset, supporting a more efficient and consistent path from initial development, through first-in-human and beyond, without losing momentum.

NAVIGATING COMPLEX REGULATORY PATHWAYS?

Connect with our experts to discover how we can keep your program on track, and advance confidently toward your key milestones.

SPEAK WITH AN EXPERT

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altasciences.com | contact@altasciences.com