ALTASCIENCES

OPHTHALMIC

END-TO-END DRUG DEVELOPMENT SOLUTIONS

EYE-OPENING FACTS

The eye is a multi-faceted organism with many barriers to drug delivery. Formulation and delivery options must be expertly planned and developed to ensure that the maximum bioavailability is achieved without negatively impacting vision or the physical structure of the eye. Planning of preclinical studies must consider the appropriate animal species for the route of administration and therapeutic area of the investigational drug. During clinical trials, the delicate nature of the eye and the importance of subject safety are key factors to take into account. As important, the bioanalysis of trial samples necessitates the use of techniques created especially for the often uncommon and frequently fragile matrices involved. Finally, understanding the regulatory environment and related guidances, as well as proactive and appropriate discussions with relevant agencies, when warranted, are critical components of the pathway that can help ensure a seamless experience.

The specific challenges and complexities in ophthalmic drug development can be mitigated by partnering with an integrated CRO/CDMO provider with extensive regulatory knowledge and scientific expertise in the ocular space. **Altasciences can support your program from day one to market. Clients benefit from working with a single partner as the product advances through each phase of drug development—from prototype formulation through preclinical testing, to early phase clinical trials, and manufacturing. This could mean up to 40% in both time and cost savings**.

OUR SOLUTIONS, AT A GLANCE

- Prototype Development, Formulation, and Manufacturing
- Preclinical Safety Testing
- Bioanalysis
- Clinical Research
- Regulatory Expertise

PROTOTYPE DEVELOPMENT, FORMULATION, AND MANUFACTURING

Altasciences' contract development and manufacturing (CDMO) team has significant expertise in developing small molecule ocular drugs, including nanomilling, suspensions, and pre-sterilized injectables. Our CDMO capabilities provide a seamless transition from formulation development to clinical manufacturing to commercialization of your ophthalmic products. Our services include:

- Formulation development and manufacturing of all ophthalmic products, including potent compounds, controlled substances, and terminally sterilized injectables (DEA-licensed for Schedules I–V)
- Class C and D cGMP manufacturing suites for development and clinical/commercial batches
- Multiple dosage forms, including liquids, gels, injectables, or capsules
- Flexible filling options, including vials, droppers, liquid-filled capsules, and custom containers
- Scale options from small batches up to 400L
- Milling capabilities for micro- and nano-suspension products
- Analytical method development, validation, and ICH stability testing
- Finished dosage form manufacturing and packaging

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PRECLINICAL SAFETY TESTING

To ensure you get your program off on the right foot, and rapidly advance to clinical trials, Altasciences' highly skilled scientists offer a vast range of preclinical expertise, including:

- 50 years of experience with all ophthalmic therapeutic indications—no study ever rejected for reasons of design, conduct, or data integrity
- All ophthalmic routes of administration and specialized techniques
- Experience with many different types of formulations, including nanoparticles and ocular implants
- Studies ranging from single-dose acute to six- and nine-month duration
- Ocular pharmacokinetic studies in multiple species
- On-site Diplomate, American College of Veterinary Ophthalmologists (DACVO)
- Significant investment in specialized equipment like optical coherence tomography (OCT) and RetCam

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BIOANALYSIS

Altasciences' bioanalytical scientists work hand in hand with our study directors to ensure appropriate handling of samples for all your preclinical and clinical studies, supporting both small and large molecules. Our state-of-the-art instrumentation and assay platforms help us achieve low limits of quantitation for systemic exposure, and provide the ultra-low sensitivity necessary for plasma or serum TK/PK samples for ocular drug development. In addition, our in-house ocular scientists have expertise working with rare and limited matrices such as tears.

CLINICAL RESEARCH

Working with an integrated CRO/CDMO such as Altasciences is extremely beneficial to sponsors, as tight integration between the techniques and analysis used in the preclinical laboratory, the study clinic, and the ophthalmology clinic is essential for a safe and efficient study that can lead to NCE progression to a Phase II study.

By partnering with our clinical team, you benefit from:

- An in-house ophthalmologist with over 20 years of experience
- Extensive expertise in FIH to Phase lla trials (more than 40 ophthalmology trials completed)
- Three North American inpatient units (from coast to coast) with over 500 beds—fully equipped inpatient and outpatient capabilities
- Robust network of ophthalmology research centers in close proximity to our clinics, including key opinion leaders and principal investigators
- Database of over 400K participants for healthy normal and patient recruitment
- Clinical pharmacology units with the latest equipment to perform various ophthalmological procedures

In addition to standard diagnostic devices, Altasciences has the following experience and tools:

- Coordination of ophthalmic testing with intensive PK and PD clinical laboratory testing
- Close coordination between ophthalmic and general medical treatments, evaluations, and testing (i.e., intravenous infusions, ERGs, radiological testing, and clinical laboratory testing)
- Clinical trial design, including genomic trials
- Best-corrected visual acuity (BCVA) using established Early Treatment of Diabetic Retinopathy Study (ETDRS) protocols
- Slit-lamp examinations and photography
- Standardized testing for dry eye or corneal toxicity
- IOP measurement
- Standardized installation of eye drops
- Gonioscopy
- Fundus photography
- Optical coherence tomography (OCT) of both the anterior and posterior segment
- Optical coherence tomography angiography (OCTA)
- Fluorescein angiography
- Multifocal electroretinography (mfERG)
- B-scan ultrasonography

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REGULATORY EXPERTISE

Altasciences provides regulatory submission expertise for products, preparations, and medical devices, such as:

- Briefing documents and support for all types of global regulatory meetings, including:

FDA

- Pre-IND gap analysis
- Pre-IND briefing package preparation and FDA meeting support
- IND preparation and submission
- Investigator's Brochure preparation

Health Canada

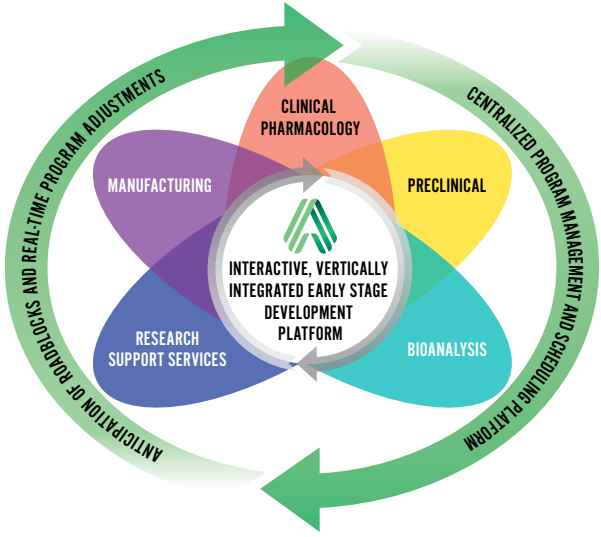
- Pre-CTA gap analysis
- Pre-CTA package preparation and Health Canada meeting support

- CTA preparation, submission, and maintenance
- Nonclinical and clinical regulatory strategy
- Toxicology consulting and strategic advice

Our experts are always fully informed about the most recent regulatory guidances, ensuring that your program stays on track.

KEY TAKEWAYS

Ophthalmic medications have a particular set of challenges that can impact their successful path to market. From prototype formulation through preclinical testing, early phase clinical, and manufacturing and development, ophthalmic drug development presents with specific and unique complexities. It is best to entrust drug development to a partner with regulatory knowledge, scientific and technical expertise, and a thorough understanding of the market in this growing therapeutic area.



For decades, Altasciences has been a leading ophthalmic drug development partner for pharmaceutical and biotech companies worldwide, providing end-to-end solutions from lead candidate selection to clinical proof of concept, and beyond. As a single, integrated CRO/CDMO, we maximize efficiency and optimize drug development—saving you up to 40% in drug development time and costs—to ultimately bring better products to market, faster.

Contact us to get started

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