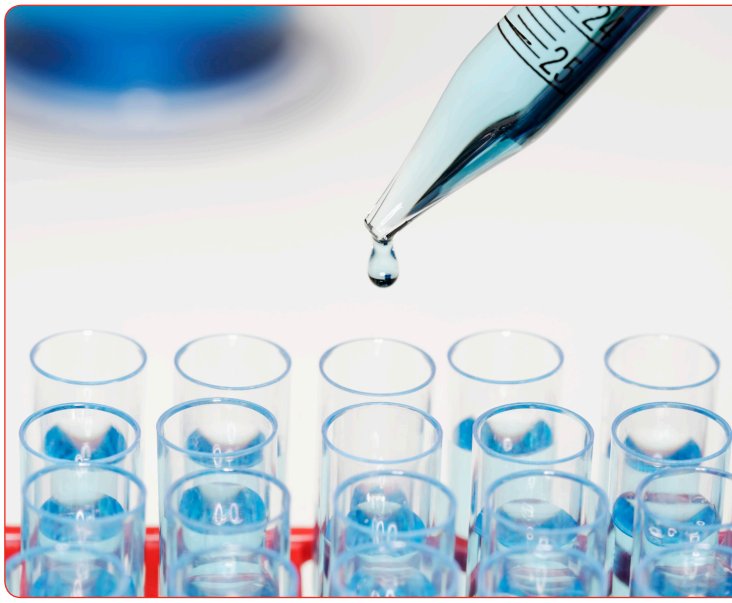
Ora

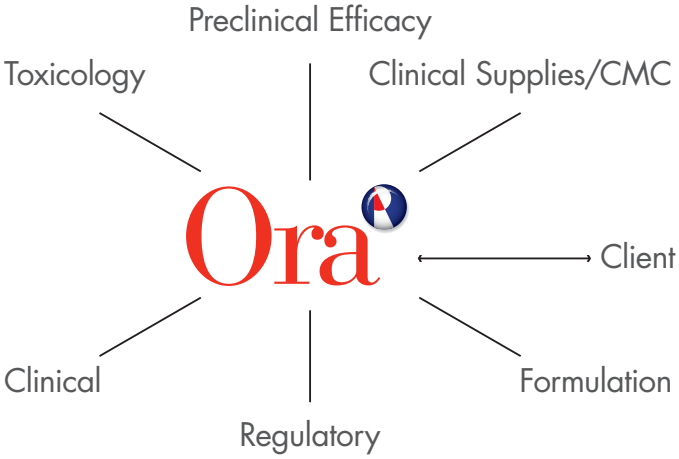
Formulation/CMC

The chemistry, manufacturing, and controls (CMC) aspects of drug development are highly complex, and development of ophthalmic products in particular is highly specialized due to the unique requirements and challenges involved. Many drug development companies do not have the necessary internal CMC expertise or require additional bandwidth. Ora can provide the critical expertise and experience needed, whether the need is turnkey clinical trials supply management or CMC consulting and regulatory writing. The Ora CMC team also can perform initial ophthalmic formulation screening of drug candidates and prepare supplies for non-GLP preclinical studies. Ora CMC is a trusted partner in helping advance drug candidates to the next stage and ultimately to NDA approval. We also add a high level of integration across clinical-regulatory strategy formulations, clinical supplies, and regulatory submissions.



CMC Services

- Clinical Trial Scale-Up and Supply Management
- Product Development Plans
  (Integration of CMC, Clinical, and Pharm/Tox)
- Formulation Evaluation/Test Article Preparation for Non-GLP Studies
- CMC Consulting Services
- CMC Regulatory Submissions



Ora CMC Advantages

- PMP-certified project management and ophthalmic product expertise for on-time/on-budget delivery of clinical supplies and test articles
- Ophthalmic formulation screening in close collaboration with Ora pharmacology/toxicology and clinical regulatory teams
- Integrated, world-class product development strategy with early engagement of Ora's top clinical and preclinical teams
- Strategic partnerships with GMP contract manufacturers, laboratories, and consultants
- Experienced CMC regulatory writing and consulting
  (pre-IND, IND, EOP2, CTD, NDA)
- Creative solutions to address clinical supply management

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Our team has been directly involved with the chemistry and manufacturing of many approved ophthalmic drugs and can provide assistance from early-stage formulation design and preservative selection to sterile process development and commercial manufacturing scale-up.

Case: Phase III Process Scale-Up of Viscous Solution

Case Details	Key Highlights
Phase III turnkey development to manage commercial manufacturing process for a virtual company First engineering batch, produced as part of process transfer/scale-up to commercial manufacturing site, did not meet product quality attributes	Process optimized to reach product quality attributes within aggressive program timelines Previous technical experience with viscous solutions allowed for root causes to be rapidly identified Daily project coordination/reinforcement and strong relationships with vendors minimized timeline impact

Case: Pre-formulation Development to Improve Ocular Bioavailability

Case Details	Key Highlights
Consulting and formulation development for start-up company Lead candidate being considered for clinical development Salt and pro-drugs investigated with the goal of improving ocular bioavailability	Novel salt was developed which increased aqueous solubility of the drug 20 times relative to the initial compound, resulting in higher ocular bioavailability Pro-drug analogs were also developed which yielded similar ocular bioavailability levels with lower drug concentrations API synthesis strategically outsourced for rapid test article creation and preclinical testing

Ora is your value-added partner – from molecule to marketplace:

Global R&D

- Strategic Consulting
- Study and Clinical Program Design
- Formulation/CMC Management
- Pharmacology/Toxicology
- Preclinical Models
- Clinical: Phase I – IV
- Regulatory Submissions and FDA Interface
- Biostatistics and Data Management
- Medical Writing and Publication Support
- Marketing, Advertising, and Product Commercialization

Models & Methods

- Conjunctival Allergen Challenge (CAC℠)
- Hybrid Conjunctival Allergen Challenge (Enviro-CAC®)
- Late Phase CAC℠ Model
- Controlled Adverse Environment (CAE℠)
- Allergen BioCube℠ (ABC)
- Conjunctival Biopsy
- Clinical Scales

Business Development & Creative Business Models

- Product/Pipeline Analysis to Evaluate Assets for Re-Purposing into Ophthalmic Indications
- New Product Incubator
- Strategic Business Planning
- Due Diligence
- Network of Investors and Pharmaceutical Partners

Contact Us:
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Ora®