FACT SHEET

Inspiring the Future of Ophthalmic Clinical Development

Medical Devices

Over the past 40+ years, Ora has played a significant role in the development of marketing ophthalmic products. Our experience covers consulting projects and clinical trials in ophthalmology and extends beyond therapeutics to our industry-leading expertise in ophthalmic medical devices. In the last 7 years, we have conducted 65 projects including 36 FDA (Food and Drug Administration) Pre-submissions and 15 marketing applications - both IDE and 510(k).

With almost 150 years of cumulative experience, Ora's medical device team has proven proficiency in ophthalmic medical device regulatory consulting, including pre-submissions to the FDA and conducting clinical trials to support approvals across the globe.

Caitlin Black
VP, Clinical Operations, Anterior Segment & Medical Devices

Caitlin serves as a thought leader for both internal and external clients and partners for Ora. Overseeing all clinical operations for Ora's global medical device therapeutic area ensuring contracted services and expectations are carried out by project teams in accordance with executed contracts, budgets, and clients' expectations. Caitlin has been with Ora for over 10 years and earlier positions at Ora include Senior Clinical Trial Associate, Clinical Project Manager, and Associate Director of Clinical Operations. Caitlin is a board-certified Orthoptist and completed a post-graduate degree in Clinical Vision Science and Ophthalmic Medical Technology.

"Over 1 billion people worldwide have a vision impairment that could have been prevented or has yet to be addressed. Ora partners with ophthalmic medical device companies worldwide to advance diagnostic and therapeutic devices with a patient-minded approach to protect and restore vision. Our global team of ophthalmic experts drive the development of new technologies by offering masterful regulatory strategy and interaction with international regulatory agencies, providing global clinical trial management, data management and biostatistics, and the development of medical device marketing applications. Our team offers technical expertise, passion for innovation, and a commitment to successful outcomes to improve patients' quality of life."

Caitlin Black
VP, Clinical Operations, Anterior Segment & Medical Devices

Areas of Expertise

- Artificial Intelligence
- Contact Lenses
- Diagnostic and Imaging Devices
- Diabetic Retinopathy Screening
- Intraocular Lenses (IOLs)
- Pediatric Amblyopia and Myopia
- Retinal Laser Surgery
- Visual Acuity Testing Platforms
- Glaucoma Implants and Lasers
- Refractive Devices

Clinical Program Management

- Dedicated clinical operations staff focused on device specific regulations, averaging 8+ years of experience in ophthalmology and medical devices
- Oversight in all stages of a clinical study, from start-up and enrollment to closeout
- Key integration of all relevant GCP and ICH standards, as well as excellent documentation standards
- Medical monitoring for protocol design, safety oversight, and data fidelity

Regulatory Strategy

- Multi-region development plans
- Clinical investigation plans
- Non-clinical development plans, including GLP testing and biocompatibility (ISO 10993)
- Identification of key opinion leaders in different global markets
- Identification of relevant ISO/ANSI standards
- Predicate device or control identification
- Global regulatory writing and submission services
- Medical writing services
- Frequent discussions with global regulatory authorities on behalf of sponsors at all stages

Biostatistics

- Statistical Analysis Plan (SAP) development
- Statistical programming (tables, listings, and figures)
- Creation of analysis datasets (ADaM compliant) and SDTM dataset

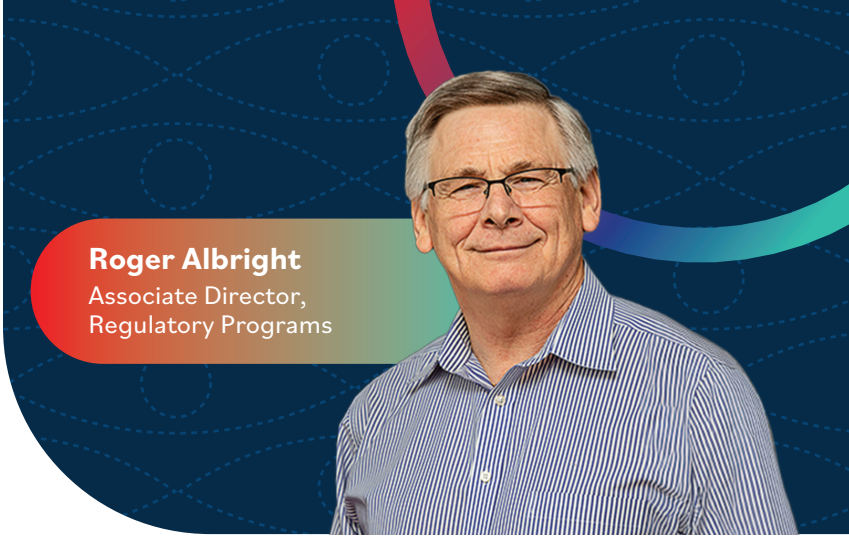
Data Management

- Electronic and Annotated Case Report Form (eCRF/aCRF) design and development using CDASH and SDTM
- eCRF Completion Guidelines (eCCG) development
- Clinical database design and development in a validated, 21 CFR Part 11 compliant electronic data capture (EDC) system
- EDC training and support for all system users

Ophthalmic Device Regulatory Expertise

Ora's Medical Device Regulatory group, led by Roger Albright, has consistently demonstrated excellence across all levels of clinical research. Roger collaborates closely with clients, offering comprehensive regulatory strategy and guidance from initial concept through product launch. His deep understanding of regulatory requirements in the US, coupled with a solid foundation in international standards, enables the development of effective regulatory strategies that streamline the process of bringing products to market.

With a robust background in the ophthalmic industry, Roger began his career as a Clinical Trial Assistant (CTA) at a contact lens manufacturer, gaining valuable experience in all facets of clinical development for both drugs and devices. Holding an MBA in International Business and being a member of RAPS (Regulatory Affairs Professionals Society), Roger brings a wealth of knowledge to the team. The Ora team, under Roger's leadership, has successfully navigated all phases of clinical research to support regulatory filings.



PMA/HDE - 10+ in recent years

- Combination products - contact lens eluding drug delivery systems
- Retinal implant devices
- Surgical pressure measuring devices
- Injectable vitreous substitute
- Intraocular lens
- Minimally Invasive Glaucoma Surgery (MIGS) devices

510(k) - 20+ in recent years

- Optical coherence tomography (OCT)
- Tonometers
- Spectral microscopes
- Confocal microscopes
- Femtosecond lasers
- Excimer lasers
- AI platforms
- Software devices
- Diagnostic strip tests
- Contact lens
- Dry eye devices
- Canalicular plug

IDE Package Support	HUD Applications	EFS Pathways	Pre-submissions
15	3	2	30+
in recent years	in recent years	in recent years	in recent years

Ora

Ora is a global full-service ophthalmic drug and device development firm with vast capabilities through all steps of clinical research, including preclinical, clinical, CMC & regulatory, and patient and site evaluations. Through Ora's 40+ years of experience, the company has assisted in bringing more than 80 products to market. Ora's team of experts utilizes global regulatory strategies, integrated research operations, and extensive site and patient engagement to accelerate product development in anterior and posterior segment, as well as ophthalmic devices.