Ora

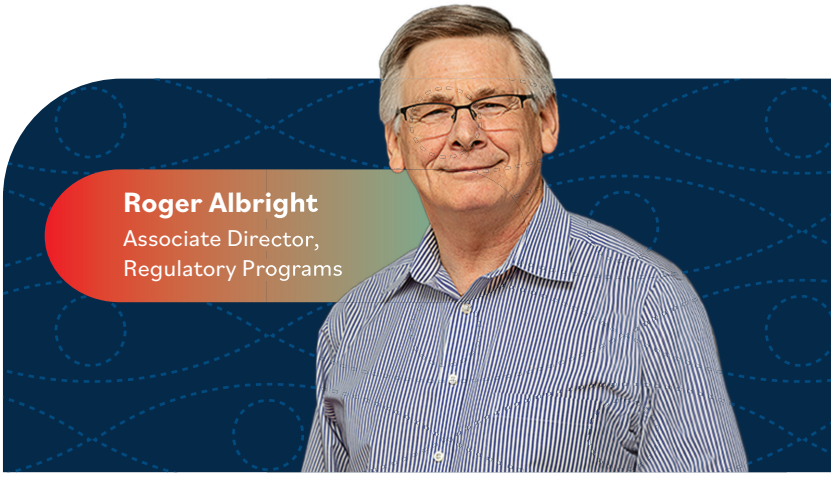
Creating vision
beyond what we see

Ophthalmic Device Regulatory Experience at Ora: Let Our Device Expertise Guide You Through the Regulatory Gauntlet of Clinical Research

With almost 150 years of combined experience, Ora's medical device team has proven expertise in ophthalmic medical device regulatory consulting, including pre-submissions to the Food and Drug Administration (FDA) and conducting clinical trials to support device approvals around the globe. In the last 7 years, we have conducted 65 projects including 36 FDA pre-submissions and 15 marketing applications — both IDE and 510(k).

Ora's Medical Device Regulatory Group

Our Medical Device Regulatory group is led by Roger Albright and 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 strong foundation in international standards, enables the development of effective regulatory strategies that streamline the process of bringing products to market.



Roger has a robust background in the ophthalmic industry, where he started his careers as a Clinical Trial Assistant (CTA) at a contact lens manufacturer. During that time, Roger gained invaluable experience in all facets of clinical development for both therapeutics and devices. Holding an MBA in International Business and as an active member of RAPS (Regulatory Affairs Professionals Society), Roger brings a wealth of knowledge to the device team. The Ora Medical Device Regulatory group, 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

IDE Package Support

15

in recent years

HUD Applications

3

in recent years

EFS Pathways

2

in recent years

Pre-submissions

30+

in recent years

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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 45+ years of experience, the company has assisted in bringing more than 85+ 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.