



## Who we are

We're educators, builders, and blunt truth-tellers.

Cosm® exists to make the hard parts of health/medical product development and commercialization feel a little less overwhelming – and a lot more doable. We work shoulder-to-shoulder with teams navigating strategy, safety, regulation, and real-world performance. Whether you're launching something entirely new or evolving on what's already in motion, we meet you where you are.

We partner best with early-stage to mid-size teams who care deeply about building the right thing, not just building fast.

Know Your Way Forward

## Services we offer

### Regulatory

We help you decode the regulatory maze and create a strategy that your product to market faster. With a global perspective and experience, we help you understand current & evolving requirements, and give you a clear path forward.

### Quality Management System

Your QMS should grow with you. We tailor compliant, scalable systems for traditional devices, SaMD, and digital health products that meet FDA QSR, ISO 13485, and beyond

### Usability

We provide comprehensive Human Factors and Usability services aligning with FDA expectations and IEC 62366 to ensure that your medical devices are safe, effective, and user-friendly.usability

### Product Development

We align product design, safety, and strategy from day one. Whether you're building hardware, software, or both, we help you define requirements, avoid surprises, and accelerate development – without cutting corners.

### Clinical Evidence

Choosing the right clinical study plan, design, and execution takes foresight. We unpack this from the start, so your product development and regulatory decisions are made together.

### Cybersecurity, Privacy & Risk

We make sure your product is safe, secure, and trustworthy. From threat modeling to aligning with HIPAA, GDPR, FDA cybersec expectations, ISO 14971, and TIR 34971 we help you get it right early

## Contact us

+ 1 (415) 255-5516

[www.cosmhq.com](http://www.cosmhq.com)

[info@comhq.com](mailto:info@comhq.com)