Regulatory Affairs Services

LANDRICH GROUP

Expert Support at Every Milestone – Your Streamlined Path to Promising Approvals

Why Do You Need Us?

At Landrich Group, we combine global regulatory expertise with hands-on support to guide your product from early development to successful submissions. Whether you're preparing for an FDA Pre-Submission meeting, or engaging with global health authorities, or presenting to investors, our team delivers clear, accurate, and informative information at every milestone—so you plan ahead, stay compliant, and on track to your pathway to achieving market authorizations in the U.S. and other key global markets.

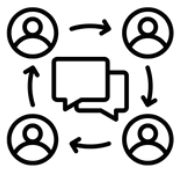
Strategic Planning & Guidance:

Develop clear, tailored regulatory strategies that align with your program goals and target markets. We help you develop Global Regulatory Strategies and plans to identify regulatory requirements for effective and efficient product development, regulatory submissions and achieving market authorization.

Regulatory Submissions & Documentation:

Produce, review, QC, and submit high-quality documents for IDE/IND, FDA Pre-Submission meetings, 510(k), De Novo 510(k)s, PMAs, and other regulatory filings. We ensure timely and high quality submissions to ensure efficient regulatory reviews.

Ongoing Regulatory Support:



Provide continued expertise as your program progresses. From attending internal team meetings to advising on regulatory strategy in real time, we're your trusted partner in every phase.

Partner & Investor Engagement:

Create and review regulatory materials for investors, licensing partners, and due diligence activities. We support your communication with clarity and confidence.

Agency Meetings & Follow-up:

LLead FDA and other National Competent Authority interactions, including , IDE/IND, Pre-Sub, or submission review meetings. We coordinate meeting requests, prepare briefing packages, and capture meeting minutes and action items to maintain alignment and accountability.

We guide your development from early engagement to clearance or approval, turning regulatory complexity into practical solutions—so you can stay focused on delivering innovation. Let's move product development forward and bring safe and effective healthcare products to market together! ***Contact us for a free consultation at admin@landrichgroup.com***