

MEDICAL DEVICE REGULATORY COUNSELING



As technology advances, Goodwin's regulatory team is there every step of the way, helping clients navigate pathways to market and meet their regulatory obligations. The Goodwin regulatory team serves as a core strategic advisor to medical device manufacturers across both hardware and software technologies. Our experienced FDA lawyers work closely with developers, manufacturers and marketers throughout the product lifecycle to identify available market pathways, achieve regulatory compliance and further their business goals.

Our team advises clients on compliance with fraud and abuse laws such as the Anti-Kickback Statute and Stark Law; laws related to healthcare privacy and data security such as the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the General Data Protection Regulation (GDPR); pricing and reimbursement; and a wide range of other issues that cross distribution of regulated products in the healthcare space. We regularly advise clients on the convergence of traditional healthcare services with cutting-edge technologies such as artificial intelligence, machine learning, big data and digital therapeutics. In collaboration with our robust private equity, life sciences and technology practices, we connect innovators with investors and represent medical device and health-tech companies from inception to exit and all points in between.

PRODUCT-SPECIFIC EXPERTISE

- Traditional medical devices
- Diagnostics, including companion diagnostics
- Digital health tools and apps, including digital therapeutics
- Software as a medical device
- Laboratory-developed tests
- Healthcare service platforms

PRODUCT DEVELOPMENT PATHWAYS & INTERACTIONS

- Product development strategy, including pre-submission meeting counseling, briefing package preparation and coordination of regulatory and patent strategies
- Clinical trial design and Investigational Device Exemption (IDE) applications
- 510(k)s, de novo classification requests, premarket approval applications (PMAs) and humanitarian device exemptions (HDEs)
- Companion diagnostic requirements and development
- Information request responses and preparing for meetings with FDA
- Dispute resolution requests
- Regulatory comments and citizen petitions

COMPANY COMMUNICATIONS

- Company website reviews
- Company poster presentation and abstract reviews
- Corporate presentations, including investor presentations and press release review

CLINICAL DEVELOPMENT

- Clinical research organization (CRO) interactions, clinical trial agreement preparation and interactions and agreements with clinical investigators, including on investigator-initiated trials
- Good clinical practice (GCP) requirements and related issues
- ClinicalTrials.gov entries and compliance
- Protocol, informed consent, patient authorization and recruitment material reviews

COMMERCIAL RAMP-UP

- Advisory committee meeting preparation
- Patient advocate program setup and contracting
- Disease awareness program development and launch
- Scientific and commercial advisory board contracting and content development
- Healthcare compliance program build-out and ramp-up

TRANSACTIONS AND CAPITAL RAISING

- Preparation of regulatory terms for license agreements, including clinical collaboration, co-development, master services, vendor, quality and exclusive distributor agreements

- Exhibit booth panel development
- Social media policy development and review of posts

- Unanticipated adverse device effect reporting
- Resolution of partial and full clinical holds
- Investigator communications
- FDA financial disclosure reporting obligations
- Healthcare professional consulting and advisory arrangements

- Labeling development and preparation of initial launch materials
- Compliance training, including for sales representatives
- FDA inspections and resolution of 483 observations and untitled or warning letters

- Regulatory diligence in asset purchases and mergers and acquisitions
- Regulatory disclosure preparation for initial public offerings and follow-on offerings

RANKINGS + RECOGNITION

Lawyers recognized for **FDA Law** by *Chambers* and *U.S. News Best Lawyers*

Lawyers recognized as **Regulatory Stars** and **FDA Rising Star** by *LMG Life Sciences*

Named **Biotechnology Law Firm of the Year** for five out of the past six years by *U.S. News Best Lawyers*



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