GOODWIN

EARLY- AND LATE-STAGE DRUG + BIOLOGIC FDA REGULATORY SERVICES

As drug and biologic product candidates move from the bench to the clinic, Goodwin's FDA regulatory team is there every step of the way, helping clients navigate FDA's regulatory pathways and understand regulatory obligations. Our experienced FDA regulatory team works closely with executive management, regulatory affairs and clinical operations teams throughout the pre-approval stage to achieve regulatory compliance and further their business and product development goals. Learn more about our early- and late-stage services below.

PRODUCT DEVELOPMENT PATHWAYS & INTERACTIONS

- Product development strategy, including clinical trial design, accelerated approval/Subpart H, endpoint selection and combination product requests for designation
- Expedited program designation requests, including fast track, breakthrough therapy & regenerative medicine advanced therapy requests
- Orphan drug designation requests & orphan drug exclusivity
- Priority review vouchers and rare pediatric disease designation requests
- Companion diagnostic requirements & development
- FDA meeting request & briefing package preparation
- Information request responses & preparing for formal meetings with FDA
- Formal dispute resolution requests

CLINICAL DEVELOPMENT

- Clinical research organization interactions and clinical trial agreement preparation
- Interactions and agreements with clinical investigators, including on investigator-initiated trials
- Good clinical practices (GCP) requirements and related issues
- ClinicalTrials.gov entries and compliance
- Patient informed consents, recruitment materials and enrollment incentive programs
- Special protocol assessment requests and negotiations
- Serious adverse event reporting
- Resolution of partial and full clinical holds
- Investigator communications
- FDA financial disclosure reporting obligations
- Health care professional consulting and advisory arrangements
- Expanded access policy preparation and establishing expanded access programs
- Right to try access policy preparation and establishing right to try programs
- Master services, vendor and quality agreement negotiations

COMPANY COMMUNICATIONS

- Company website reviews
- Company poster presentation and abstract reviews
- Corporate presentation, including investor presentations, and press release reviews
- Exhibit booth panel development
- Social media policy development and review of posts

COMMERCIAL RAMP-UP

- Patient advocate program setup and contracting
- Disease awareness program development and launch
- Label negotiations and preparation of initial launch materials
- U.S. healthcare compliance program build-out
- Risk Evaluation and Mitigation Strategy (REMS) requirements and negotiating single shared system REMS
- Advisory Committee meeting strategy and preparation
- Non-patent exclusivity (including 3-year, 5-year, pediatric and GAIN)
- FDA inspections and resolution of 483 observations and warning letters

TRANSACTIONS & CAPITAL RAISING

- Data room build-out
- Preparation of regulatory terms for license agreements, including clinical collaboration and co-development agreements
- Regulatory diligence in asset purchases and mergers and acquisitions
- Regulatory disclosure preparation for initial public offerings and follow-on offerings

Rankings + Recognition

- Named **Biotechnology Law Firm of the Year** for five out of the past six years by *U.S. News-Best Lawyers*
- Named **2019 Corporate Firm of the Year** by *LMG Life Sciences*
- 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*

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