

FDA Regulatory and Compliance



HIGHLIGHTS

An Interdisciplinary Team Anchored by Former FDA Counsel

Wilson Sonsini's Food and Drug Administration (FDA) regulatory attorneys possess firsthand agency experience, including from the Digital Health Center of Excellence, the Center for Devices and Radiological Health (CDRH), and the Center for Drug Evaluation and Research (CDER), and hold advanced scientific and public health degrees.

Strategic Counsel for FDA-Regulated Businesses and Their Stakeholders

We represent innovators, founders, executives, investors, service providers, and other stakeholders across diverse industries, including life sciences, biotech, pharmaceuticals, generic drugs, medical devices, AI/ML-enabled medical technologies, mobile apps, diagnostics, research tools, healthtech, digital health, wellness, and consumer products.

Comprehensive FDA Regulatory Counsel Across the Company Life Cycle

From preclinical research and development through commercial launch and exit, our attorneys work across the firm's Corporate, Patents and Innovations, Technology Transactions, and Life Sciences practices to serve as both regulatory counsel and long-term strategic partners.

OVERVIEW

Wilson Sonsini's FDA regulatory attorneys counsel clients with respect to the full range of regulatory challenges that arise throughout a company's life cycle—from initial product development and clinical strategy through commercialization, corporate transactions, and post-market compliance.

Our attorneys advise companies across the full spectrum of FDA-regulated products and industries, including:

- Biologics and biosimilars
- Cell, tissue, and gene therapies
- Clinical decision support products and platforms
- Clinical Laboratory Improvement Amendments (CLIA) laboratories
- Combination products
- Cosmetics
- Dietary supplements
- Drugs and generics
- General wellness products
- Healthtech and digital health
- In-vitro diagnostics
- Research Use Only (RUO) products
- Medical devices
- Patient engagement tools and platforms
- Software as a medical device (SaMD)

The firm's multidisciplinary team has practical experience in representing clients in regulatory FDA matters, including:

- Advertising and promotional review
- Compassionate use or expanded access requirements
- Citizen petitions
- Go-to-market strategy and business model review
- IDE, 510(k), De Novo, and PMA requirements
- IND, NDA, BLA, and ANDA requirements
- FDA compliance and enforcement
- FDA designation programs
- FDA regulation of clinical trials
- FDA regulatory exclusivities
- FDA regulatory risk mitigation strategies
- Orange Book listing
- Patent Term Restoration/Patent Term Extension
- Preparation for commercial launch, including manufacturer healthcare compliance programs
- Regulatory review of various contracts, including clinical trial agreements, supplier/contract manufacturer contracts, license agreements, and other commercial contracts
- Regulatory review of public disclosures
- Regulatory due diligence during corporate transactions, including financings, M&As, asset sales, and IPOs
- Strategies for expediting FDA review and approval
- Trade complaints to the FDA
- Transfer, sale, or change of ownership for FDA submissions/filings