NELSON MULLINS

FDA Counseling & Compliance

Insights & practical guidance for clients on FDA regulations

We are committed to helping you achieve your business goals, stay on budget, and maximize return on investment by

- Assisting you to develop your target product profile, conduct targeted clinical trials, and get to market
- Assisting you to register your establishment, list your device, obtain investigational approval, determination of substantial equivalence, and pre-market approval
- Navigating FDA and OHRP laws, regulations, and policies
- Representing your interests before, during, and after the FDA contacts you, and
- Anticipating and avoiding regulatory and litigation risks.

Interdisciplinary team and collaborative approach

Our team consists of experienced attorneys who collaborate with other professionals when needed to advise or solve our clients' problems

- Lawyers, pharmacists, and nurse consultants who have worked in the public and private sectors and developed a keen understanding of the real issues that our clients face when navigating the FDA regulatory scheme
- Member of Institutional Review Board, which is charged with review and approval of industry-sponsored clinical trials
- Clinical Trials Counsel to drug, medical device, and nutraceutical/dietary supplement companies and healthcare providers, including clinical research physician practices and groups, both in and outside the United States
- Former Senior Trial Counsel, United States Department of Justice, Criminal Division
- Former in-house counsel for global pharmaceutical company
- Former in-house counsel for the largest pharmacy chain in the United States
- Patent lawyers to protect your intellectual property

Related Practice Areas

Corporate & Securities

E-Discovery - Encompass

E-Discovery & Information Governance

Emerging Growth & Venture Capital

Health IT

Healthcare

Healthcare Compliance & Operations

Healthcare Government Investigations & Litigation

Healthcare Providers & Suppliers

Healthcare Transactions

Intellectual Property

Intellectual Property Litigation

Life Sciences - IP

Litigation

Products Liability - Pharmaceuticals & Medical Devices

White Collar Defense & Government Investigations

Related Industries

Healthcare

Pharmaceuticals & Medical Devices

Technology

- Patent, intellectual property, and products liability litigators to anticipate and avoid litigation risks
- Network of consultants and experts, including former FDA regulators

Our diverse clients share the common goals of successfully navigating FDA requirements while meeting their business objectives

- Public and private healthcare and service providers and large, mid-cap, and start-up drug, medical device, biotech, and dietary supplement/nutraceutical manufacturers and distributors at all stages of the product life cycle
- Pharmaceutical companies (Human and Animal Health)
- Medical Device companies
- Biotech companies
- Nutraceutical/Dietary Supplement companies
- Drug manufacturers, importers, and distributors
- Excipient manufacturers
- Hospitals and healthcare systems
- Clinical research facilities, including private practice groups
- Analytical laboratories
- Food packaging

The Nelson Mullins FDA Counseling and Compliance Team has the experience to address the challenges faced by and opportunities presented to FDA-regulated industries

Our team has experience advising general counsels, executives, clinical research professionals, physicians, and other healthcare providers. From preparing our clients for meetings with the FDA to identifying creative regulatory solutions, our team is committed to standing with our clients at every step of the regulatory process.

Our Team is solution-oriented and committed to identifying practical approaches to challenges posed by regulations, statutes, guidance documents, and policies

- Target Product Profile to help you achieve your commercial goals, plan your clinical trials and studies, and competitively position your product upon approval
- Clinical Trial Playbook to expedite negotiations between sponsors and sites and IRB approval
- Preparation for FDA Inspections to facilitate a positive interaction
- Preparation for and meeting with FDA to represent your interests and maximize your impact
- Response to FDA-483s to facilitate resolution of observations and comments

- Preparation of Corrective Action Plans, including assisting clients with internal investigations
- Competitive positioning and monitoring to assist with clinical trial design, label claims, and approval issues
- Guidance regarding adverse events, including reporting requirements
- Resolution and tracking of Import Alerts
- Compliance with CGMP requirements, including quality control issues

Why Nelson Mullins?

- Track record of resolving FDA compliance issues to reduce regulatory exposure
- Significant work on clinical trials and regular exposure to FDA comments and concerns related to clinical trials
- Practical approach to navigating the FDA regulatory scheme
- Deep pharmaceutical and medical device litigation experience and insight to help clients develop proactive regulatory and risk avoidance plans

Experience

Following is a selected sampling of matters and is provided for informational purposes only. Past success does not indicate the likelihood of success in any future matter.

- Represented client from initial clinical trial through pre-market approval to labeling approval for Class III medical device
- Represented client in obtaining medical device IDE and biologic IND approvals
- Represented client in pre-market Section 510-K clearance
- Guided companies through FDA inspections, meetings, and submissions
- Guided companies through FDA-483 process with no official action indicated
- Guided companies through recall and market withdrawal
- Facilitated development of target product profile with a concentration on competitive product positioning and health economics, including reimbursement issues
- Developed clinical trial playbooks for pharmaceutical, medical device, dietary supplement/nutraceutical manufactures and healthcare facilities
- Guided companies through resolution of import alerts
- Assisted companies with labeling and promotions
- Served as agent for foreign device manufacturer
- Obtained USP listing for client
- Submitting and updated DMF for client
- Assisted in obtaining medical device ban from FDA