McGuireWoods

LIFE SCIENCES REGULATORY & COMPLIANCE

McGuireWoods' Life Sciences Regulatory & Compliance Team provides comprehensive strategic advice and representation before federal and state agencies, and handles government and internal investigations, warning letters and violations, compliance program design and assessment, and litigation for manufacturers, importers, distributors, sellers, investors, financers, and trade associations for all products and businesses regulated by the FDA. We apply our deep knowledge of life sciences businesses and the applicable legal and regulatory requirements to our **Life Sciences Transactional Practice** to ensure that deals are appropriately structured to account for company-specific risks and opportunities.

WHY McGUIREWOODS:

The 2024 *U.S. News-Best Lawyers* "Best Law Firms" survey ranked McGuireWoods as a National Tier 1 Law Firm for its real estate law practice.

McGuireWoods was named as a **top three firm** for our collaborative approach to client service by the *BTI Consulting Group*.

McGuireWoods ranked among the elite law firms for client service for the 18th time in BTI Consulting's 2023 **"Client Service A-Team"** report and was singled out by corporate counsel as **"Best of the Best."** McGuireWoods is one of only five firms to rank among the top 30 for 12 consecutive years in BTI's annual survey.

Clients and peers alike recognize McGuireWoods and our individual lawyers as among the top practitioners, *Chambers USA* describes our partners as **"very exceptional," "totally dedicated,"** and focused on **"looking for solutions to problems."**

OUR CAPABILITIES

Our interdisciplinary team is comprised of lawyers and former regulators practicing in multiple offices who have dedicated their careers to specializing in Life Sciences. The team members have deep experience with, and knowledge of, the laws, regulations, business practices, and transactions in this sector, and include:

- Pharmacists, engineers, and science professionals
- Former in-house counsel to food, drug, and medical device companies
- Former FDA regulatory counsel, DOJ attorneys, and counsel to other overlapping agencies
- Former legislative staff, including health policy advisors for key congressional members, involved in healthcare reform, reimbursement, and finance

Collectively, our team's skill set and diverse experience allows us to navigate the often complex and continually changing regulations and guidelines coming from the HHS, OIG, FDA, CMS, TTB, DEA, USDA, FTC, and State governmental agencies.

We represent a broad spectrum of clients involved in the life sciences, including:

- Pharmaceutical companies (including small molecule, biologics, injectables, OTC drugs, and drug/device combinations)
- Radiopharmaceutical companies
- Medical device firms including IVD (in vitro diagnostics) companies
- CROs (contract research organizations)
- CDMOs (contract drug manufacturing organizations)
- CMOs (contract medical organizations) and CSOs (contract sales organizations)
- Hospitals and Universities
- IND/NDA/BLA/510k/DeNovo Sponsors
- Manufacturers
- Pharmacies (traditional pharmacies, specialty pharmacies, tele-health, and compounding)
- Importers, distributors, and sellers
- Patient advocacy and charitable organizations
- Industry associations

We represent a broad spectrum of clients involved in the life sciences, including:

- IND, NDA, SNDA, 510k, de Novo, GRAS and other submissions to FDA for product exclusivity, fast track or breakthrough designation, PRVs and labeling changes. OTC drug matters including monograph compliance.
- Legal and regulatory matters affecting CROs, CDMOs, radiopharmaceuticals, stem cell treatments, pharmacy compounding, dietary supplements, cannabis and other natural substances, foods, alcoholic beverages, and cosmetics.
- Product development and clinical development strategies and protocols and labeling, including preparing for and assisting with internal and public FDA meetings, including advisory committee meetings.
- Drug pricing and reporting, Medicaid and Medicare, private/public reimbursement, IRA, MDRP, BFSF, 340B.
- Development of pharmacovigilance and risk management programs including risk evaluation and mitigation strategies (REMS), some with elements to assure safe use (ETASU).
- Marketing and promotion (including advertising, labeling, off-label use), scientific exchange, publications, CME, grants and sponsorships.
- Pre-Clinical and Clinical trials design, contracting, IRB and patient consents, and good clinical practices (cGCPs) and good laboratory practices (GLPs) compliance.
- FDA inspections and responses to FDA Form 483s, untitled letters, warning letters and "Dear Manufacturer" and "Dear Doctor" letters.
- Recalls, product withdrawals, and media relations.
- Corrective action plans, including negotiation of FDA Consent Decrees, responses to FDA compliance notifications, and identification of key concerns that should be addressed to ensure ongoing compliance.
- Litigation, including defense of individuals and companies in FDA-related recalls, product detention, seizures, import alerts, subpoenas, injunctions, grand jury investigations, civil actions and criminal prosecutions, and APA litigation at all levels of government.
- Development of manufacturing and distribution facilities both within the United States and overseas in compliance with applicable laws and cGMP regulations, ISO.
- Advising on and preparing appropriate contracts and program design involving transfers of value to HCPs, Payors, Wholesalers, Distributors and others in compliance with Anti-Kickback and False Claims statutes and applicable Safe Harbors.
- Advising on and preparing contracts to address issues relating to HIPAA, data privacy, data breach notifications and remediation in the specific setting of Life Sciences businesses.
- Compliance program development, assessment, and implementation to align with DOJ and OIG guidance.
- Establishment licenses, state distribution licensing, Sunshine and state law transparency reporting requirements.
- Advising on SEC offerings and disclosures related to life sciences products and businesses.

LIFE SCIENCES TRANSACTIONAL PRACTICE

The McGuireWoods Life Sciences Team has experience in a broad spectrum of transactions involving life sciences companies, investors and service providers, including mergers and acquisitions, debt and equity financings, venture capital, initial and subsequent public offerings, licensing and joint ventures, corporate and limited liability buy/sell agreements, stock option or other equity plans and agreements, employment agreements, confidentiality and noncompete agreements, and tax advice related to the foregoing.

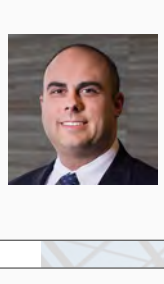
For emerging growth companies with highly developed intellectual property, we get the appropriate protections in place to limit or block misuse by employees, investors or competitors. We also assist clients with transferring intellectual property rights from individual owners to entities, and with protecting and maintaining those rights during mergers, acquisitions or joint ventures.

In cases where our clients purchase or make significant investments in Life Sciences operating companies, we often stay on board to ensure that the company is appropriately counseled on a range of compliance matters that arise during daily operations, strategic planning, and sales and marketing planning, including federal and state anti-kickback laws, FDA regulations, and other regulations governing the manufacture, sale, distribution and marketing of pharmaceuticals, medical devices, diagnostics and other products.

McGuireWoods Life Sciences: Core Competencies and Sectors

Regulatory & Compliance
Investigations & Litigation
Corporate Transactions
Data Privacy
Intellectual Property
Cosmetics
Rx and OTC Pharmaceuticals
Diagnostics
Digital Health
Nutraceuticals and Dietary Supplements
Food
Cannabis
Medical Devices
Artificial Intelligence
Pharmacy

OUR CORE LIFE SCIENCES TEAM



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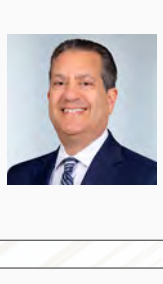

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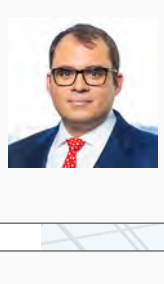

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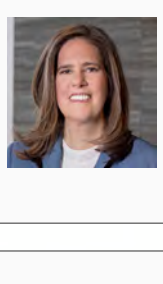

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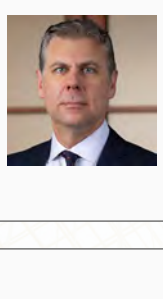

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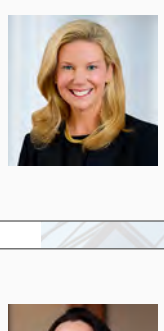

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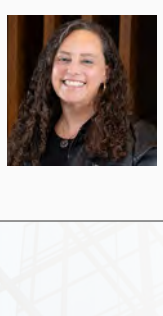

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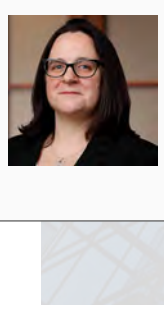

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