

Life Sciences Legal, Regulatory, and Compliance



Pharmaceutical



Med Device



Biotech

ABOUT US

Porzio, Bromberg & Newman offers comprehensive legal, regulatory, and compliance counsel to life sciences companies at every stage, from development through commercialization and beyond. Our attorneys, recognized for their innovative and business-oriented approaches, collaborate across diverse practices to address the complex challenges faced by pharmaceutical, medical device, and biotech clients. In conjunction with Porzio Compliance Services (PorzioCS), a wholly-owned compliance and consulting subsidiary of the firm, our team provides practical strategies and solutions to promote efficient operations and adherence.

LEGAL, REGULATORY & COMPLIANCE SUPPORT

- Clinical Trials & Related Activities
- Commercialization
- Compliance Programs, Monitoring & Investigations
- Medical Affairs & Scientific Exchange
- Corporate Communications
- Launch Activities
- Distribution
- Interactions with HCPs, Payors, Patients, & Advocacy Organizations
- Research & Publications
- Market Access & Patient Support Programs
- Grants, Sponsorships, & Donations
- Early Stage, Pre-Commercial & Pre-Approval Compliance
- Privacy & Data Protection

PROVIDING A COMPREHENSIVE RANGE OF SERVICES TAILORED TO MEET YOUR NEEDS.

WHY CHOOSE US?

✓ Deep Industry Experience

Years of in-house and hands-on experience with pharmaceutical, medical device, and biotech companies ensure we understand specific challenges and needs.

✓ People Focused

More than 60 years of client service. Porzio has established a strong track record of success, earning a reputation for excellence, integrity, and client satisfaction.

✓ Maximizing Success

As a mid-size firm, we offer the agility to act swiftly and provide the advantages of in-depth legal analysis to help meet business objectives while managing and minimizing business risk.

✓ Legal Innovation

Porzio is committed to staying at the forefront of legal innovation, leveraging technology, data analytics, and creative problem-solving to deliver efficient and effective legal services.

✓ Business Synergies

Porzio, PorzioCS, and Porzio Governmental Affairs (PorzioGov) form a cohesive family of companies offering legal, compliance, lobbying, and consulting services tailored to our clients' needs in a wide range of industries and practice areas, so that clients receive comprehensive assistance tailored to their specific needs.

TRANSFORMING CHALLENGES INTO OPPORTUNITIES FOR LIFE SCIENCES COMPANIES

Porzio provides comprehensive advice, support, and training across pharmaceuticals, medical devices, and biotech, guiding companies through intricate legal, regulatory, and compliance issues. Key areas include:



CLINICAL

- Clinical Trial & Related Agreements
- Clinical Trial Recruitment
- Conflicts of Interest/Investigator Arrangements
- Expanded Access Programs
- Informed Consent Review
- Clinical Stage Compliance Considerations



COMMERCIAL

- Marketing
 - Advertising & Promotion Review
 - Social Media & Influencer Guidance
 - Speaker Programs & Other Marketing Programs
 - Conference Sponsorships/Booth Activities
 - Disease Education Initiatives
- Sales
 - Compliance Training
 - Incentive Compensation
 - Field Sales Compliance Monitoring
- Market Access & Patient Services
 - Market Access Agreements
 - Payor/Customer Communications
 - Specialty Pharmacy Arrangements
 - Financial Assistance Programs
 - State Price Transparency



CORPORATE COMMUNICATIONS

- Corporate Donations
- Media Packages & Regulations
- Investor Communications
- Press Releases
- Website Compliance
- Social Media Compliance/Influencer Interaction



COMPLIANCE PROGRAMS

- Compliance Program Development & Implementation
- Compliance & Risk Assessments
- Compliance Launch Readiness Assessments
- Compliance Action Plans
- Monitoring & Auditing Plans
- Privacy Considerations & Compliance
- Policies, SOPs, & Business Rules
- Compliance Training Programs
- Investigations



DISTRIBUTION

- State Licensing Strategy & Compliance
- 3PL Agreements
- Wholesaler & Distributor Contracts



HCP INTERACTIONS & ENGAGEMENTS

- Healthcare Provider Engagements & Agreements
- Speaker Program Requirements
- Advisory Board Management
- Travel & Expense Guidelines
- Meal Limits
- Promotional & Medical Communications



MEDICAL AFFAIRS

- Research/Investigator Sponsored Study & Educational Grants
- Review of Medical/Scientific Presentations and Materials
- Medical Affairs/Field Medical Compliance
- Scientific Exchange and Investigational Drug Communications
- Publication & Agreement Review
- Medical Affairs/Field Medical Training



PATIENT & PATIENT ORGANIZATION INTERACTIONS

- Sponsorships & Donations
- Engagements – Consulting/Other Services
- Patient/Caregiver Agreements & Releases
- Patient Programs & Events
- Patient Outreach Strategies & Initiatives



DATA PRIVACY

- Data Privacy Compliance Assessments & Action Plans
- Data Privacy Policies, Notices & Documentation
- Data Subject Consent & Rights Guidance
- Privacy Best Practices
- IT Policies & SOP Analysis
- Comprehensive Data Privacy Compliance Training
- Cross Border Transfer and Data Privacy Framework Guidance

PROVIDING LIFE SCIENCES
COMPANIES WITH THE COUNSEL
THEY NEED TO SUCCEED.

EVERY STAGE OF THE JOURNEY.

