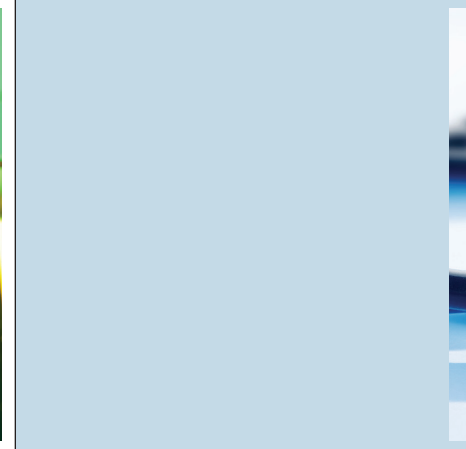
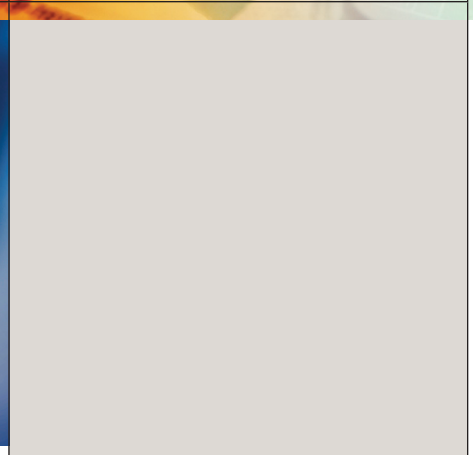
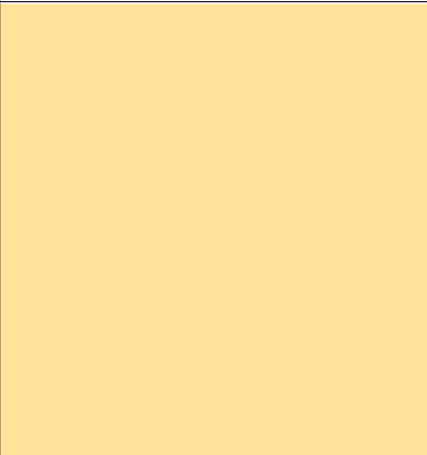
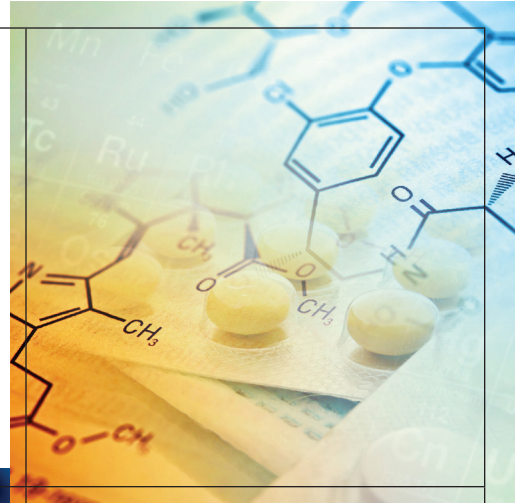


GLOBAL HEALTH CARE COMPLIANCE



Navigating the
Global Regulatory
Regime



ROPES & GRAY

COLLABORATING ACROSS PRACTICES and geographies, our team of Ropes & Gray attorneys has benchmarked and implemented global compliance programs for some of the world's largest pharmaceutical and medical device companies. Whether you are building a program from

scratch or updating and modifying existing policies, our interdisciplinary team has the skills to meet your organization's needs. Firmwide, we have lawyers and staff fluent in 42 languages, and have close relationships with local counsel around the world.

WHAT WE DO

We advise on a wide range of topics, including:

- **Compliance with the Foreign Corrupt Practices Act (FCPA), U.K. Anti-Bribery Act and other anti-corruption laws**
- **Regulatory compliance with the U.S. Food and Drug Administration (FDA), China FDA, China National Health and Family Planning Commission, China State Administration for Industry and Commerce, and EU regulatory bodies**
- **Data privacy and cybersecurity**
- **U.S. and EU sanctions**
- **Diligence and monitoring processes for third parties**
- **HCP consulting arrangements**
- **Marketing material review and approval processes**
- **Product discounting practices, including process for approvals**

- **International medical affairs**
- **Exhibit booth and conference sponsorship practices**
- **Compliance department structure**
- **Patient assistance programs**
- **Compliance program integration (post-acquisition)**

Within these areas, our work typically encompasses:

- **Policy development and implementation**
- **Compliance training**
- **Internal and government-initiated investigations**
- **Risk assessments**
- **Day-to-day "help desk" compliance support**
- **Due diligence for corporate transactions**
- **Industry benchmarking**
- **Compliance monitoring and auditing**

MARKET PERCEPTION

- **Chambers USA**

Corporate Crime & Government Investigations Client Service Award (2016)

Health Care Firm of the Year (2015)

- **China Business Law Awards**

Compliance & Anti-Corruption Firm of the Year (2016)

- **Law360**

Named "Privacy Group of the Year" for the fourth time (2016)

- **U.S. News-Best Lawyers**

Recognized as a "top-tier" firm in 21 categories, including: Biotechnology, Health Care and M&A Law (2017)

"Firm of the Year" for Biotechnology Law (2016)

- **Latinvex**

Ranked in the top 10 for FCPA & Fraud in Latin America (2016)

Ranked in the top 10 for Corporate M&A Latin America (2016)

GLOBAL COMPLIANCE AND ANTI-CORRUPTION EXPERIENCE



North America

Diligence: 59
Internal Investigations: 10
Government Investigations: 7
Compliance: 165

Total: **241**

Latin America & Caribbean

Diligence: 83
Internal Investigations: 34
Government Investigations: 21
Compliance: 15

Total: **153**

Europe

Diligence: 277
Internal Investigations: 37
Government Investigations: 14
Compliance: 65

Total: **393**

Sub-Saharan Africa

Diligence: 42
Internal Investigations: 7
Government Investigations: 10
Compliance: 5

Total: **64**

MENA

Diligence: 42
Internal Investigations: 19
Government Investigations: 2
Compliance: 12

Total: **75**

Asia/Asia Pacific

Diligence: 352
Internal Investigations: 234
Government Investigations: 63
Compliance: 98

Total: **747**

OUR TRACK RECORD

- **DEVELOPING** a global FCPA compliance program for a multinational medical device manufacturer with operations in 70 countries.
- **ASSISTING** a biotechnology company by coordinating with various local counsel on providing guidance on local law requirements on pharmaceutical advertising, as well as anti-bribery and corruption developments and risk areas in several key countries/regions.
- **ASSISTING** a leading laboratory systems solution provider in conducting a global anti-corruption and data privacy/security risk assessment. Also conducting a gap assessment of the company's global compliance program.
- **COUNSELING** a Chinese medical device manufacturer following an inspection of the company's facilities by the U.S. FDA on remediation of deficiencies in FDA premarket notifications, U.S. good manufacturing practices and regulatory reporting requirements, and procedures and controls related to consultant selection and retention.
- **ASSISTING** a leading biopharmaceutical company in providing counsel regarding potential regulatory, corruption and other industry enforcement risks when expanding in key markets in Latin America.

WHO WE SERVE

- **Global medical device and pharmaceutical companies**
- **Medical information technology companies**
- **Research institutes/Academic medical centers**
- **Private equity sponsors and other investors**
- **Hospitals and other health care providers**

- **REPRESENTING** one of the world's leading pharmaceutical and medical device manufacturers with substantial operations in Asia in connection with a variety of ongoing compliance matters and internal investigations in China, Vietnam and Thailand.
- **ADVISING** the world's largest independent biotech firm in its global anti-corruption risk assessment.
- **WORKING WITH** in-house counsel of a major pharmaceutical company to conduct internal FCPA and anti-corruption compliance reviews in countries where the company has operating subsidiaries; we have completed reviews in Asia, the Middle East and Eastern Europe.

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