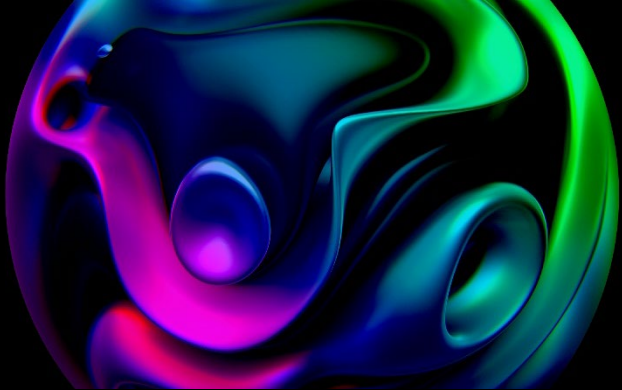




Regulatory Risk and Compliance Services for the life sciences industry



Life sciences risk and compliance officers are being asked to navigate, manage, and respond to an evolving regulatory risk environment. Deloitte’s Regulatory Risk and Compliance services are designed to help clients by providing modern approaches that may elevate risk management efforts across an organization.

Navigate. *Regulatory Change*

Navigate, plan, and predict changes in the regulatory environment

Modernize. *Risk Management Operations*

Modernize approaches to respond to regulatory changes and risk management by leveraging enabling technologies

Elevate. *Organizational Value*

Elevate the value provided by compliance and risk management activities across the organization

COMPLIANCE AND LEGAL

- ☐ Culture of compliance
- ☐ Policies, procedures and training
- ☐ Corporate sponsorships
- ☐ Charitable donations
- ☐ Transparency reporting: state, federal, country specific
- ☐ Third-party vendor relationships
- ☐ Adverse events and product complaints

CLINICAL/R&D

- ☐ Clinical trial registries and results databases
- ☐ Investigator-initiated studies
- ☐ Research grants
- ☐ Real-world evidence/reliance on outcomes research
- ☐ Clinical research organizations

MARKET ACCESS

- ☐ Hub and specialty pharmacy relationships
- ☐ Third-party service fees and fair market value (FMV)
- ☐ Field reimbursement activities
- ☐ Samples, co-pay cards, vouchers
- ☐ Pricing and contracting: government pricing and reporting and value-based contracting

TECHNOLOGY

- ☐ Aging IT Infrastructure and systems
- ☐ Data privacy
- ☐ Cyber security
- ☐ Electronic Communications
- ☐ Social media
- ☐ Records retention

MEDICAL AFFAIRS

- ☐ Medical advisory boards
- ☐ Medical education grants
- ☐ Medical information requests
- ☐ Medical science liaison activities/proactive vs. reactive
- ☐ Off-label medical communications
- ☐ Globalization of the medical science liaison role

SALES & MARKETING


- ☐ Interactions with health care professionals (HCPs) including FMV bona fide fee-for-service payments
- ☐ Joint HCP interactions with commercial and medical affairs
- ☐ Joint payer interactions with commercial and market access
- ☐ HCP utilization and programs
- ☐ Promotional material review and dissemination




PATIENT ENGAGEMENT

- ☐ Direct-to-patient marketing and education
- ☐ Patient advisory groups interactions
- ☐ Patient assistance programs
- ☐ Patient advocacy groups


Deloitte’s offerings

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Compliance strategy, design, and operations


 - Assess, design, and build compliance programs to help meet the critical elements of an effective program
 - Develop and implement policies, procedures, and training
 - Develop and implement risk assessment and mitigation process (RAMP) program
 - Assist clients in fulfilling their compliance responsibilities for companies in transition
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Investigations and settlement support


 - Conduct damage analysis
 - Provide corporate integrity agreement (CIA) readiness assessment
 - Provide independent review organization (IRO) and mock-IRO services
 - Help clients monitor third parties/HCPs for anti-bribery / anti-corruption compliance (ABAC)
 - Provide risk intelligence and forensics services
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Third-party risk


 - Assess, design, and build third-party risk management (TPRM) programs
 - Conduct third-party assessments
 - Assess contract compliance

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Compliance auditing & monitoring

 - Design and help execute monitoring programs (field/virtual ride-alongs, speaker/patient programs and webinars, hub and patient support vendors, records reviews monitoring of high-risk activities)
 - Perform internal compliance systems and transactions reviews assessing for residual risk, quality of existing controls, and areas for improvement across functions (e.g., marketing, market access, medical, clinical, and quality)
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HCP interactions and payments

 - Assess, design, and help transform HCP engagement end-to-end processes, including underlying data/IT infrastructure (e.g., data lake, aggregation for reporting)
 - Assess, develop, and implement FMV programs specific to HCP FMV, clinical FMV and bona fide services FMV
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Patient interactions

 - Conduct patient assistance program risk assessments
 - Develop and transform patient support services functions with controls specific to compliance risks



Analytics-empowered innovation to assist with modernizing compliance and risk management operations:

Deloitte provides and implements innovative and technology-enabled solutions to help organizations manage regulatory and operational risk. We use emerging technologies to enable your compliance organization to automate as many repeatable processes as possible, both in the detection and remediation of risk.

- Ask us more about our enabling technologies including:
- Artificial intelligence (AI)
 - Robotic process automation (RPA)
 - Natural language processing (NLA)
 - Natural language generation (NLG)

The Deloitte US firms serve...

90% of the Fortune 500® Life Sciences companies

Nearly 95% of the medical device manufacturers

The top 12 largest pharma companies

The top 10 largest biotech companies

Dozens of emerging growth and rare disease companies

Related services

- FORENSICS AND INVESTIGATIONS
- GOVERNMENT PRICING AND CONTRACTING
- INTERNAL AUDIT
- GXP COMPLIANCE
- PRIVACY AND CYBER SECURITY
- TRANSPARENCY REPORTING AND ANALYTICS
- R&D TRANSFORMATION

Let’s talk.



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