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Health Care Compliance and Risk

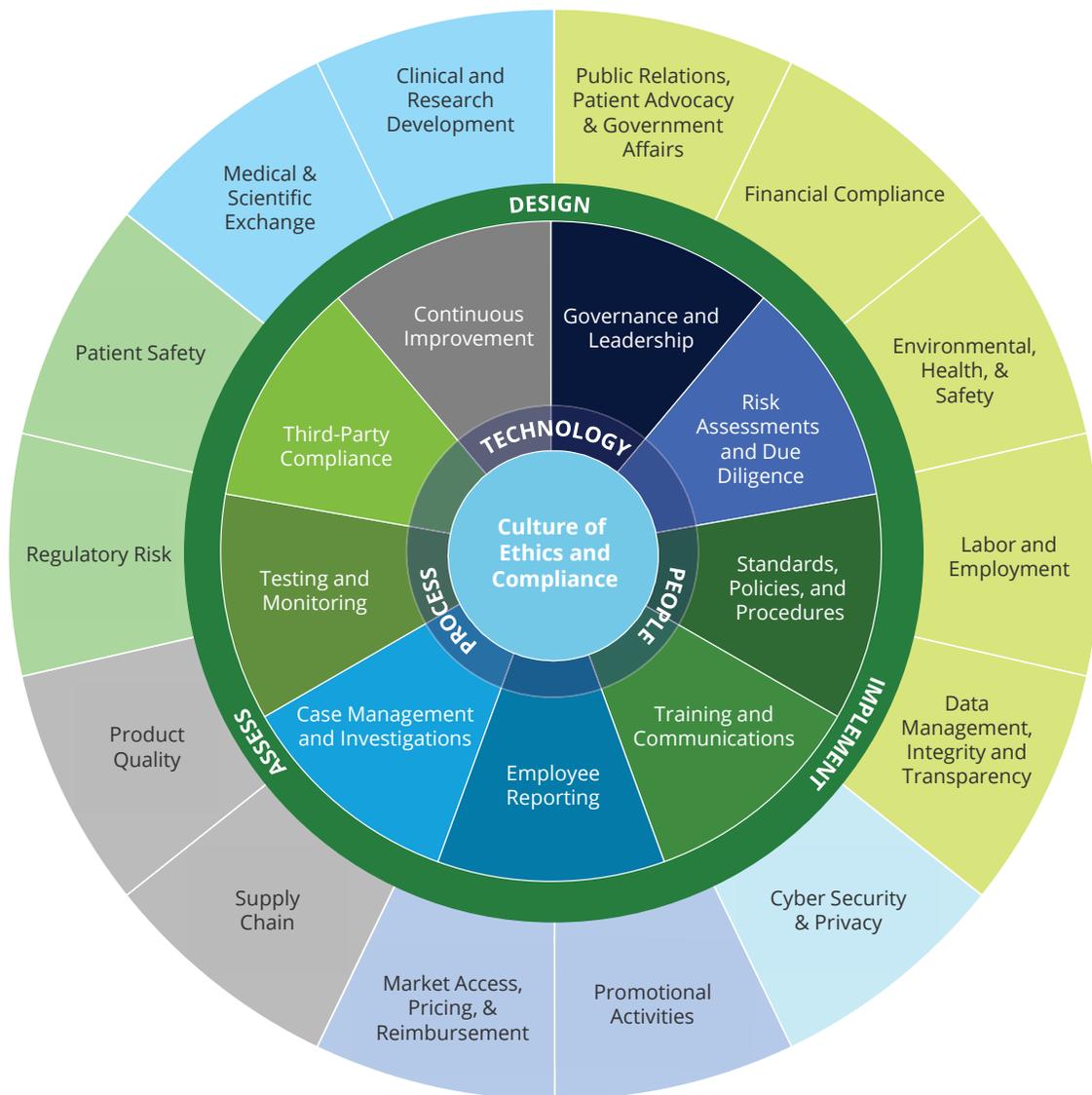
Advisory Services

Identify risks, build governance, design processes

Knowledge of the regulatory landscape and evolving risks is critical to your company

Turn complex business issues into opportunities for growth, resilience, and long-term advantage

How we can serve you



Embrace risk to power performance

“Today’s CCO is a leader who can build alliances, enhance trust both inside and outside the organization, and work to strengthen brand and reputational value.”

Henry Ristuccia, Global Governance, Regulatory & Risk Leader, Deloitte Touche Tohmatsu Limited

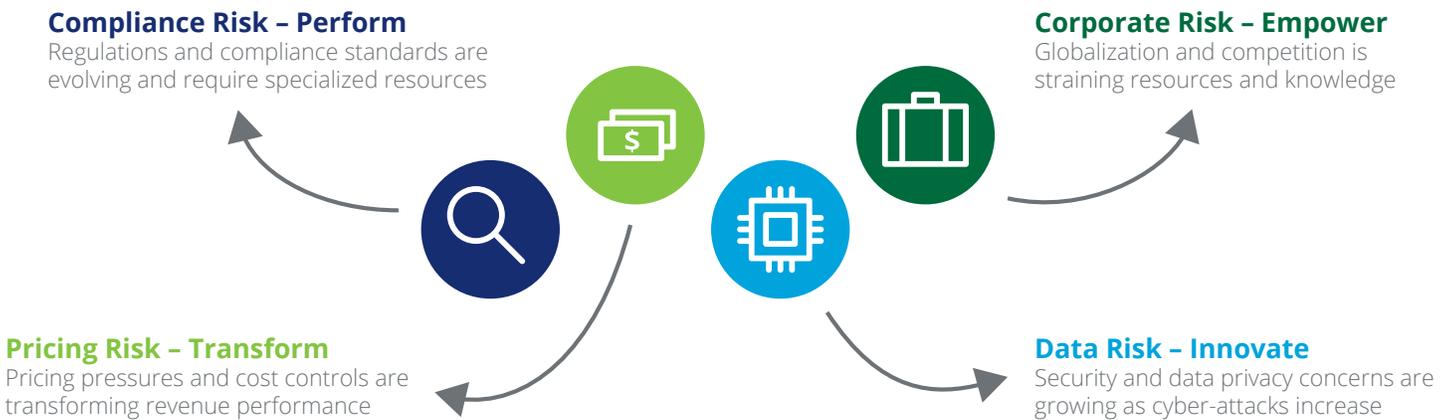
Risk has traditionally been viewed as something to be minimized or avoided, with significant effort spent on protecting value. We believe that risk can also be a creator of value and, approached in an effective way, can play a strong role in driving business performance.

Today’s life sciences manufacturers operate in an environment that is increasingly regulated and scrutinized. They are challenged with pricing pressures from government agencies and politicians, the rapid adoption of social, mobile, and cloud-based technologies, increased competition, and the changing demographics of patients and payers.

Leading organizations anticipate these challenges and recognize the opportunity to create value through risk management. We can help you transform your organization into a place where risk powers performance.

We have the regulatory knowledge, deep industry experience, and problem-solving culture to help you anticipate the changing health care landscape and navigate complex regulations and commercial challenges. We collaborate with you to identify potential risk areas and help build governance and processes to increase efficiency and gain business insight.

Life sciences risk areas





Compliance Risk – Perform

Regulations and compliance standards are continually evolving and require specialized knowledge and resources to manage day-to-day oversight and drive business performance.

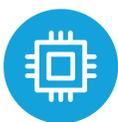
Industry drivers	Market access and the evolution of the payer relationship	Global transparency reporting	Foreign Corrupt Practices Act (FCPA) compliance
	Evolution of agency and regulatory position on product promotion	Evolving global compliance considerations	Identification of Medicinal Product (IDMP) requirements
Our value	<ul style="list-style-type: none"> • Assess compliance program effectiveness and implement methodologies to mitigate risk • Increase your awareness of global regulatory changes that may impact business processes • Converge compliance teams across subsidiaries, develop standardized processes, and facilitate adoption • Help reduce instances of regulatory action, fines, and reputational damage 		



Pricing Risk – Transform

Reform-driven pricing pressures, cost controls, and the desire to shift from volume to value have created opportunities to transform the intersection of compliance and revenue performance.

Industry drivers	Evolution of the payer system and patient access programs	Drug pricing transparency regulations and industry reputational risk
	Value-based drug pricing and contracting	Market access and reimbursement
Our value	<ul style="list-style-type: none"> • Ability to understand commercial drivers in combination with compliance risk to design appropriate governance • Guidance to commercial and finance teams related to pricing and contracting decisions • Compliance audits of payers and third-party contracts • Help facilitate relationships with stakeholders (HCPs, distributors, GPOs, managed care, wholesalers) 	



Data Risk – Innovate

Cloud-based platforms and enhanced data integration capabilities are driving business innovation, but security and privacy are top priorities as the frequency and pace of cyber-attacks increase.

Industry drivers	HCP privacy related to transparency reporting	Security and privacy controls
	General Data Protection Regulation (GDPR) data privacy	Third-party access to data
Our value	<ul style="list-style-type: none"> • Data security backed by more than 300 Deloitte cyber security specialists • Facilitate an increase in data privacy compliance across your organization • Take a measured, risk-based approach to data security • Leading technology for more efficient data integration 	



Corporate Risk – Empower

As globalization and competition strains resources, manufacturers are seeking opportunities to improve efficiencies and empower staff to focus on more strategic business priorities.

Industry drivers	M&A and product integration	Expense and resource pressures	Ethics, values, and culture
	Investment in data analytics	Political climate and patient outcome improvements	Competitive landscape
Our value	<ul style="list-style-type: none"> • M&A assessments to identify potential compliance risk pre- or post-acquisition, support integration, and harmonization • Project management to increase efficiencies and establish standardized methodologies • Drive governance and process to enable efficiency, standardization, and simplification • Enable a shift from transactional processing to data analysis for business insights 		

Compliance and Ethics Programs

Maintain compliance obligations while empowering the business to achieve strategic goals

We understand industry leading practices, agency guidance, and US and global regulations. We help you align your compliance program with your company's existing culture and develop solutions that complement your strategic business priorities.

How we help

- Compliance program design and implementation
- Risk and business process assessments
- Policy and procedure development
- Promotional and non-promotional content management
- HCP engagement processes
- Training and supplemental staffing
- Market access and specialty product compliance
- Medical affairs services
- Independent Review Organization (IRO) preparedness
- Enforcement/CIA remediation and transformation assistance
- Affiliate/subsidiary gap assessments

Compliance Audits and Risk Assessments

Reduce risk and achieve greater efficiency through compliance audits and risk assessments

We provide compliance audit and risk assessment services that enable you to identify potential risk and predict future risk. The ability to move from reactive to proactive risk management allows your compliance function to become an enabler to the business and drive value.

How we help

Risk assessments

- Compliance
- Strategic
- Operational
- Financial
- Reputational

Compliance audits and assessments

- PhRMA and AdvaMed Code
- Promotional and non-promotional activities
- Pharmacy Benefit Manager (PBM)/ managed care
- Government pricing
- Transparency
- Product sampling
- Market access programs
- Pricing strategy
- Patient safety
- FCPA

Top 4 issues keeping Chief Legal Officers up at night

-  Ethics and compliance
-  Regulatory issues/challenges
-  Data breaches
-  Privacy law and regulation

Source: ACC Chief Legal Officer 2016 Survey

Risk areas for internal audit leaders

Priority risk areas

-  Government affairs including anti-bribery and corruption
-  Financial compliance
-  Data management and transparency
-  Cyber security and privacy
-  Promotional activities
-  Market access, pricing, and reimbursement
-  Supply chain
-  Medical and scientific exchange

Source: Deloitte, "The challenge of compliance in life sciences," 2015

Transparency Reporting

Reduce the effort to meet reporting requirements and lower compliance risk

We offer a managed services approach and advisory services that provide compliance knowledge, fully-resourced processes, quality operations, and a technology-driven solution for transparency activities.

How we help

- Managed services operations for US federal and state transparency reporting
- Sample drug transparency reporting
- Monitoring of spend thresholds and data anomalies
- Development of business rules and standard operating procedures
- Dispute resolution
- Regulatory updates and impact analysis
- Policy and procedural documentation to establish program governance
- Transparency compliance monitoring and auditing
- Global transparency operating and governance model design
- Pre-commercial transparency considerations
- Employee and vendor training

Fair Market Value for HCPs

Simplify the FMV process for greater compliance and business insight

We provide a consistent and streamlined methodology that satisfies government and market expectations when contracting with industry specialists (e.g., HCPs) who perform services such as advisory boards, speaker training programs, and ad-hoc consulting services. We help you develop contracts that reflect regulatory safeguards and a defensible FMV framework, and we provide monitoring of adherence to processes, deliverables, and payment guidelines.

How we help

- HCP stature identification
- Criteria for HCP classifications
- Rate card and methodology development
- Hourly rate analysis
- Policies and procedures
- Staff training and implementation services



The Centers for Medicare & Medicaid Services is considering changes to US transparency reporting requirements and the reporting process that will increase the burden on life sciences manufacturers and GPOs for tracking, recording, and reporting transfers of value to HCPs.



A documented approach can help you determine FMV and reduce risk related to the appearance of inappropriate kickbacks or incentives to HCPs.

Global scale and industry excellence

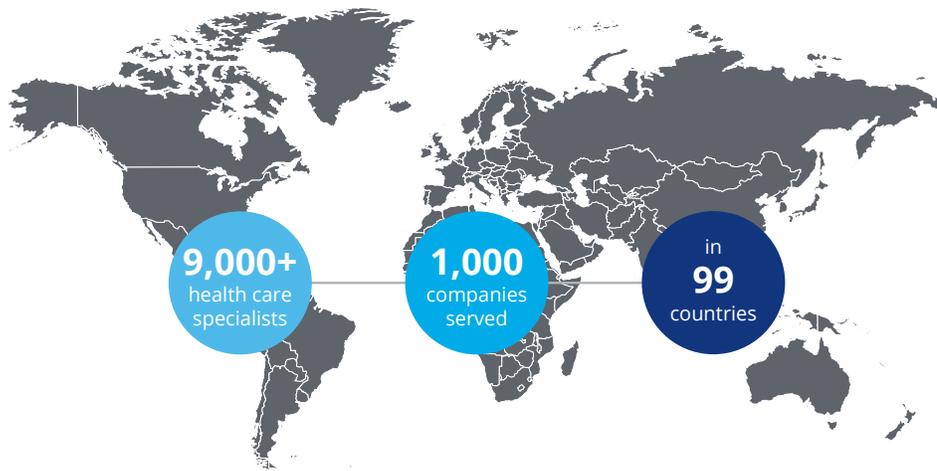
Among the largest health care practice in the world

Global leader in risk advisory services



#1 Market leader

- M&A
- Cyber
- Anti-Money Laundering
- Business Valuation
- FCPA
- Forensics
- Finance Transformation
- Corporate Governance
- Securitization
- Regulatory Consulting



9 of the 10 large biotech (Med Ad News)



15 of the 15 large pharma (FiercePharma)

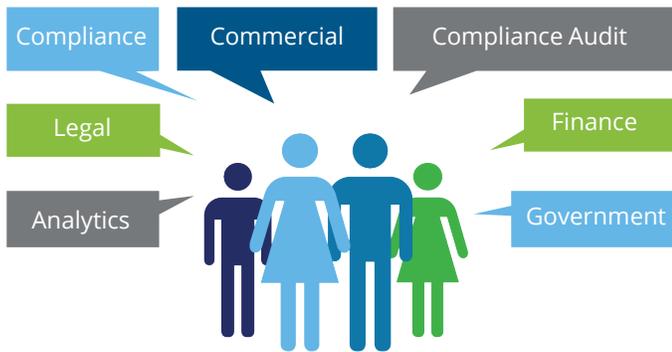


10 of the 10 top medical device (Medical Product Outsourcing)



Serve 90% of the Fortune US 500

Subject matter specialists and deep industry experience



Repeatable processes, standardized methodologies, greater efficiencies



Help deploy technologies to accelerate innovation and meet compliance needs



Substantial investments in innovation, state-of-art technology, and data security



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