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Meeting compliance challenges
Leveraging the value of outsourcing

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Contents

Executive summary

Demands on compliance functions are rapidly increasing, and so are the risks associated with failing to meet these demands. An organization's risks for non-compliance with regulatory requirements can result in legal sanctions, consent decrees, prosecution, liability suits, failed business strategies, and damage to reputation and brand. In extreme cases, non-compliance can threaten the existence of the organization. Compliance mandates can come from various regulatory bodies. Recently the banking and life sciences industries have come under particular scrutiny from regulatory and enforcement agencies. In banking, the Federal Reserve, Federal Deposit Insurance Corporation (FDIC), Office of the Comptroller of the Currency (OCC), and the newly-formed Consumer Financial Protection Bureau (CFPB) have been very active in rule development and enforcement. Similarly, the life sciences industry has faced additional scrutiny, including new U.S. and global regulations and enforcement by the Office of Inspector General (OIG), Centers for Medicare and Medicaid Services (CMS), the Food and Drug Administration (FDA) and its international equivalents (e.g., MHRA, EMA) in areas such as anti-corruption / anti-bribery in promotional practices, reporting of transfers of value to healthcare professionals, and new post-market safety surveillance requirements.

In order to mitigate these risks holistically, companies may have to:

1. Invest extensively in compliance talent, regulatory experts, training, process excellence, quality, and technology
2. Seek an outside solution such as outsourcing
3. Design a program that combines these two approaches (selective outsourcing)

Compliance is not a revenue generating business function. However, it is a core component of managing enterprise risk and successfully executing business strategies. Hence, due to the extent of compliance demands, many organizations maintain large and growing compliance functions that increase their overall operational costs. The increasing number and complexity of regulations, continuing shortage of talent, and constant pressure from shareholders to reduce operating costs makes this a good time to consider alternative sourcing strategies.

Compliance outsourcing can help organizations to address compliance demands while staying focused on their core business functions and go-to-market strategies. Chief compliance officers, chief financial officers, and chief risk officers should consider the potential value of compliance outsourcing to the organization and how it can address compliance challenges at country-specific and global levels.

Specific questions to consider include the following:

- What is compliance outsourcing?
- What drives compliance outsourcing?
- What is the business case for compliance outsourcing?
- How should organizations approach compliance outsourcing?

What is compliance outsourcing?

Compliance outsourcing is the outsourcing of business functions and processes associated with compliance to a party other than an in-house compliance department — usually to a third-party provider or vendor located domestically or offshore. Compliance processes may be outsourced to a captive organization, such as a subsidiary owned by an organization or its parent company, or to a third-party provider. On a continuum between a wholly owned captive and a third-party provider there are several variations. These variations include an assisted captive, which is a wholly owned facility, built, and/or managed with a third party; an outsourcing relationship with a third party chosen for subject matter competencies and local market experience, local regulatory knowledge; or build-operate-transfer facilities, which are initially owned by a third party and then transferred to full ownership by the organization.

Specific compliance activities to outsource may include:

- Collecting compliance data and information from systems and individuals
- Assisting with internal and external compliance reporting
- Testing and monitoring business processes and systems for compliance
- Performing trend analysis and predictive modeling for compliance operations

Organizations unfamiliar with compliance outsourcing might view the practice as impractical or even impossible. Challenges in areas such as data privacy, regulatory complexity, reporting accuracy, responsiveness, and infrastructure might initially appear to rule out compliance as a candidate for outsourcing. Yet, some of those very challenges argue in favor of compliance outsourcing, as they may in fact be addressed more effectively by specialists outside of the organization. Having the challenges addressed effectively and economically is a major benefit of compliance outsourcing. Outsourcing does, however, bring its own requirements for a suitable vendor risk management program. Such programs should outline appropriate controls in alignment with the organization's vendor management policies and associated regulatory requirements.

Potential benefits of compliance outsourcing

The right compliance outsourcing provider should provide the following benefits:

- Gains in efficiency and quality achieved by leveraging structured processes
- Access to subject matter specialists
- Seamless execution of end-to-end processes, from compliance assessment through corrective action
- Flexibility to scale deployment of skilled resources up or down as needed
- Data analytics and reporting tools that provide predictive trends and insights
- Reduced burden on internal infrastructure and resources
- Reduced cost

A strategy of selective outsourcing — choosing which compliance processes to conduct in-house and which to outsource — can enable the organization to improve its allocation of resources. This reflects the overall goal of outsourcing — to place operational functions with a third party who can execute them at high levels of quality, with responsiveness, cost-effective delivery models, and to free up internal resources for revenue-generating activities.

In addition, recruiting and training qualified professionals has become extremely difficult. The supply of compliance specialists is small relative to the demands of highly regulated organizations. Organizations are becoming deeply concerned about the risks posed by the talent deficit in light of regulatory complexity and change, global scope of operations, and levels of investment needed to recruit, train, and retain people with the required knowledge and expertise.

Perhaps the real question is not whether an in-house compliance function could address many of the challenges, but whether it should try to address them?

Types of outsourcing

Compliance outsourcing is a type of knowledge process outsourcing (KPO), which in the past several years has joined its long-established counterparts — information technology outsourcing (ITO) and business process outsourcing (BPO) — as an accepted practice. KPO activities tend to be more complex than those associated with ITO and BPO. KPO calls for the application of knowledge, such as industry knowledge, understanding of regulations, compliance frameworks, valuation, actuarial experience, and data analytics to generate knowledge-intensive deliverables. Some of the key deliverables in the highly regulated healthcare and financial industries include, but are not limited to: compliance reports for regulatory filings, clinical research, Financial Industry Regulatory Authority (FINRA) reporting, and credit and investment analysis.

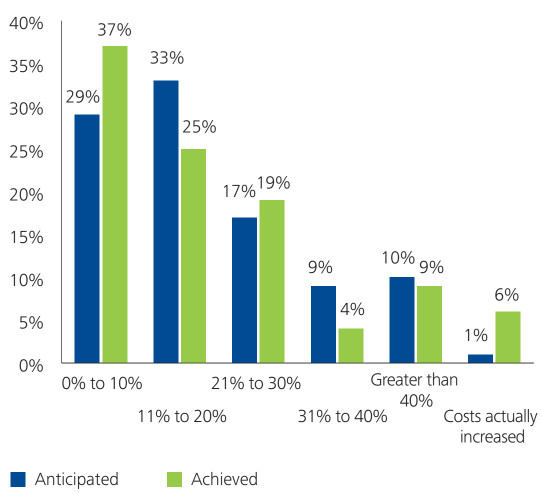
A KPO provider can yield high-quality results to an organization, particularly in an area as complex as regulatory compliance. Organizations should clearly understand the KPO providers' capabilities, experience, culture, values, and ability to work with them as their extended enterprise. To realize the full value of outsourcing, a cost-benefit analysis should be conducted prior to selecting the outsourcing provider. It should cover the full duration of the outsourcing contract and establish applicable service level agreements (SLAs). The KPO provider can generate reports and other information for regulatory and compliance submissions. However, the organization remains accountable — as it would for any outsourcing arrangement — for meeting its regulatory and compliance reporting requirements.

In general, properly planned and implemented outsourcing provides strategic as well as tactical benefits. Among these are the potential to generate positive structural change — or even transformation — in the organization by encouraging management to identify, analyze, and rationalize activities from both cost and value generating perspectives. On that basis, management can then decide which core and non-core operational and non-operational activities to execute in-house and which to execute through outsourcing.

Over time, the organization can foster strategic relationships with the right outsourcing providers, relationships that add strategic value — that is, value beyond simple provision of services. For example, providers of outsourced services can encourage innovation and increase competitiveness. They can do so not only by providing leading practices in their areas of specialization, but also by enabling management to focus on the true strategic agenda of the enterprise. Management can do this because outsourcing frees up executives' attention and "intellectual bandwidth," as well as financial, human, IT, and other resources. This can also enable leaders to pursue the strategic agenda more vigorously and with fewer distractions.

In addition, outsourcing provides well-documented cost benefits. The *Deloitte 2012 Global Outsourcing and Insourcing Survey* found 57 percent of respondents — 111 companies representing 22 primary industries with $1 billion to $5 billion median revenue — achieved cost savings of more than 10 percent and only 6 percent experienced increased costs.[1]

Anticipated and achieved cost reductions due to outsourcing



Source: Deloitte 2012 Global Outsourcing and Insourcing Survey

What drives compliance outsourcing?

The decision to outsource may be driven by one or more of the specific challenges that compliance functions currently face, including the following:

- **Coping with talent shortages:** Increased regulatory compliance complexity requires individuals who are skilled in risk management and have knowledge of regulatory and compliance operations. These professionals are in short supply and high demand. Organizations have to deal with increased operational budgets to provide training, an extended talent pool to manage continued compliance, and high attrition issues.
- **Sub-optimal compliance processes:** Organizations want to focus on improving and streamlining to make their compliance processes predictable. However, continuous changes in the regulatory landscape can make investments in compliance processes reactive. This often leads to a challenge for the organization whereby compliance processes may not follow the leading practices. This can result in a higher cost of compliance, lower quality levels, and possibilities of rework.
- **Investing in technology infrastructure:** Organizations are continuously investing in technology and related infrastructure to help facilitate meeting compliance needs. With the continuous changes in existing regulations, as well as new regulations, technology investment needs are both one-time and continuous.
- **Addressing global compliance needs:** International organizations are making extensive investment in hiring and training global talent pool. Additional investments are needed to develop a global knowledge base and expertise to address differences in regulatory requirements and successfully drive their global compliance operations.
- **Increasing operating costs:** Increased resource requirements (people, processes, and technology) due to significant changes in regulatory environments are having significant impact on operating costs.

In recent times, these compliance challenges have been amplified due to increased regulatory requirements such as the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank), U.S. healthcare reform, the Physician Payment Sunshine Act, the Foreign Account Tax Compliance Act (FATCA), Markets in Financial Instruments Directive II (MiFID II), as well as longer standing, and often changing, regulations in areas such as product safety, quality, Anti-Money Laundering (AML), and many others.

Considerations in life sciences and financial services

The more regulated an industry and the more dynamic its regulatory environment, the stronger the motivation to consider compliance outsourcing. Two such industries include life sciences and financial services.

Life sciences

Life sciences and healthcare organizations face particularly high regulatory and compliance demands — and consequences:

- Eleven major pharmaceutical companies paid a total of more than $6 billion in fines to the U.S. government over regulatory non-compliance in 2010 and 2009.[2]
- The FDA issued a total of 1,720 warning letters in 2011, a dramatic 155 percent increase over the total of 673 warning letters in fiscal 2010.[3]
- Heightened regulatory scrutiny has increased the need for full and timely regulatory reporting. Companies may need to provide new product submissions to the FDA when significant changes are made to their products. They may be required to report adverse events and recalls to the agency. Reporting requirements under the Sunshine Act and FCPA require companies to improve their oversight of U.S. and global operations.
- Regulations such as U.S. healthcare reform have increased the complexity of compliance management while putting revenues at risk. By 2015, the impact could be a 14 percent decrease in revenue and a permanent shift toward less profitable business.[4]

Financial services

Financial services organizations face intensified regulatory attention:

- In the United States, Dodd-Frank passed in July 2010. Some of the many rules are in effect and others are still being developed – to increase the compliance workload in affected financial services companies.
- MiFID II, once implemented, may fundamentally change the way securities markets can operate in Europe by significantly impacting the entire securities value chain.[5]
- In 2011, the SEC initiated a record number of enforcement actions — 735, an 8 percent increase over 631 cases initiated in 2010. This resulted in more than $2.8 billion in penalties and disgorgement.[7]
- Companies face risk with trade reporting rules. If information is reported incorrectly, they are subject to fines and sanctions for failing to comply with the reporting rule.
- The Volcker Rule imposes prohibitions and requirements on banking entities that engage in proprietary trading or have investments in, or certain relationships with, hedge funds or private equity funds.

What is the business case for compliance outsourcing?

Each organization must develop and consider its individual business case for outsourcing compliance, versus supporting compliance with an in-house operation, which may require ever-increasing investment in talent and IT resources. Demand for compliance systems and talent has raised the cost of maintaining compliance infrastructure. Even with proper funding, an organization's ability to scale up compliance operations may be limited by the availability of adequately qualified people to an in-house compliance function.

In contrast, external providers focus on developing and maintaining the required knowledge as a core competency, often by hiring former regulators and compliance officers and developing industry-aligned talent pools. The external providers also bring their process frameworks, knowledge from performing similar services for other clients, and accelerators to the delivery of value-based compliance outsourcing services.

Outsourced compliance providers can offer several potential advantages over in-house compliance functions, mainly due to the specialization and systems they must maintain as service providers.

A comparison: In-house and outsourced compliance

Considerations	In-house	Outsourced
Cost	Fixed	Variable/reduced
Staffing flexibility	Limited	Just-in-time
Competency/skills	Constrained	On demand
Talent availability with industry knowledge	Limited	Readily available
Training impact	Time and cost	None
International challenges (language, local laws, travel time, and costs)	Significant	Minimal
Leading practices	Siloed	Holistic
Speed of change	Slower	Proactive

How should organizations approach compliance outsourcing?

A strategic approach to compliance outsourcing is likely to produce high-quality results. The following table presents a strategic, phased approach to implementing compliance outsourcing:

A strategic approach to compliance outsourcing

Create an outsourcing strategy	Select an outsourcing provider	Plan transition of outsourced processes	Transition and operationalize	Conduct ongoing testing and analytics
Key activities				
Develop master list of compliance processes and reports	Develop and issue RFx	Develop a transition plan and craft service-level agreements	Collect data, populate IT systems and tools, and analyze resulting information	Assess processes and systems against compliance requirements
Evaluate processes to keep in-house or outsource	Develop outsourcing provider evaluation framework	Develop shared understanding of risks and priorities with the provider	Compile accurate, timely internal and external reports	Conduct quality reviews, outsourcing provider risk reviews, audits, and onsite visits
Assess potential investments, quality, expenses, and return on outsourcing	Manage the RFP process, evaluate responses, and select provider	Leverage internal and provider tools and technologies to increase efficiencies	Flag potential risks and instances of noncompliance, and escalate as appropriate	Perform data analysis and trend reporting
Evaluate location risk and business continuity risk	Negotiate final contracts and scope of work	Stabilize compliance operations and effect knowledge transfer to provider	Establish mechanisms to respond to changes in regulations and compliance demands	Monitor performance against KPIs
Key considerations				
• Strategic assessment • Risk assessment • Cost benefit analysis • Review compliance outsourcing strategy with relevant government agencies	• Cost benefits and relationships • Capabilities of the provider • Provider's risk management and reporting capabilities	• Shared philosophy regarding risk • Open communication channel • Cultural integration	• Clear reporting and remediation mechanisms • Strong relationship management • Local checkpoint for quality • Internal audit coverage	• Investment in internal IT systems and capabilities • Rationalizing, harmonizing, monitoring, and reporting mechanisms • Internal audit coverage

Managing an ongoing outsourcing relationship requires attention and effort. This may entail periodic checks on the outsourcer's facilities, and monitoring quality and key performance indicators (KPIs).

Achieving data security

Outsourcing can present risks to data security, including risks to intellectual property and information on strategies and operations. As such, an organization will want its third-party compliance provider to take appropriate measures to protect the security of the organization's data. To improve data security when outsourcing compliance, consider these steps:

- At the request for proposal stage or third-party vetting stage, clearly define the data security requirements and expectations for the security environment
- During the provider selection process, assess the providers' IT security and business continuity capabilities and plans
- In contracting, require the provider to maintain a client-specific security and control environment
- In the contract, define the frequency and types of provider audits the organization may conduct (e.g., scheduled or ad hoc, complete, or partial)

Provider selection criteria, service contracts, and service-level agreements should place high priority on data security and specify the tools and techniques that can be employed to achieve it.

Outsourced compliance: An option worth considering

Given the number and complexity of compliance demands — and the resulting stress on internal resources — outsourcing compliance is an option worth considering.

While the organization remains responsible for compliance and any risks, outsourcing can enable management to selectively employ a mix of internal and external resources to meet compliance demands.

In providing compliance as a service, compliance outsourcing providers develop and maintain the necessary talent, knowledgebase, industry knowledge, process frameworks, scalable infrastructure, and global presence. They devote resources to monitoring and understanding regulatory demands. They amortize the costs of compliance across their client base. As a result, compliance needs can be addressed cost-effectively and liberated resources moved to higher value activities. In a nutshell, this is how efficient compliance outsourcing works.

Endnotes

[1] Deloitte 2012 Global Outsourcing and Insourcing Survey Results, Executive Summary; http://www.deloitte.com/assets/Dcom-UnitedStates/Local%20Assets/Documents/IMOs/Shared%20Services/us_sdt_2012GlobalOutsourcingandInsourcingSurveyExecutiveSummary_050112.pdf.

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[3] FDA Enforcement Statistics Summary, FDA Warning Letters, Fiscal Years 2004 – 2011, http://www.fda.gov/downloads/ICECI/EnforcementActions/UCM285781.pdf.

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[5] http://www.marketswiki.com/mwiki/MiFID_II.

[6] SEC Enforcement Division Produces Record Results in Safeguarding Investors and Markets, SEC press release 2011-243; http://sec.gov/news/press/2011/2011-234.htm.

[7] Ibid.

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