Deloitte.

The challenge of compliance in life sciences
Moving from cost to value

Deloitte Centre
for Health Solutions

Contents

The Deloitte Centre for Health Solutions

The Deloitte Centre for Health Solutions, part of Deloitte UK, generates insights and thought leadership based on the key trends, challenges and opportunities within the healthcare and life sciences industry. Working closely with other centres in the Deloitte network, including the US centre in Washington, our team of researchers develop ideas, innovations and insights that encourage collaboration across the health value chain, connecting the public and private sectors, health providers and purchasers, and consumers and suppliers. In this publication, references to Deloitte are references to Deloitte LLP, the UK member firm of DTTL.

Foreword

Welcome to the Deloitte UK Centre for Health Solutions' report on *The challenge of compliance in life sciences: Moving from cost to value*.

Seeing the challenges that life sciences clients face in responding to an increasingly complex regulatory environment led us to launch an independent research initiative which set out to identify:

- how well the industry understands the totality of its compliance risks
- how compliance is managed and implemented within life sciences companies
- what the future of compliance looks like.

Life sciences companies are having to address an increasing number of regulatory requirements which span multiple geographies, business activities and functions. Companies face particular compliance challenges as they seek to push the boundaries of innovation, developing and launching new products which address unmet patient needs, but for which there is often little or no regulation. Compliance failures can be costly, both in terms of fines, remediation costs and reputational damage. Therefore, identifying, analysing and mitigating compliance risks are essential in developing an effective compliance programme and ensuring the future sustainability of the industry.

This report presents our initial research findings, based on the views of senior compliance leaders in the life sciences industry and Deloitte's own specialists. It focuses on the challenges life sciences companies are currently facing and considers how compliance is likely to evolve over the next few years. We do not claim to offer definitive solutions to the challenges of life sciences compliance; indeed, our research is ongoing with a view to publishing more definitive findings next year.

We hope our assessment provides valuable insights into the current state of compliance in the industry and welcome your feedback and views.

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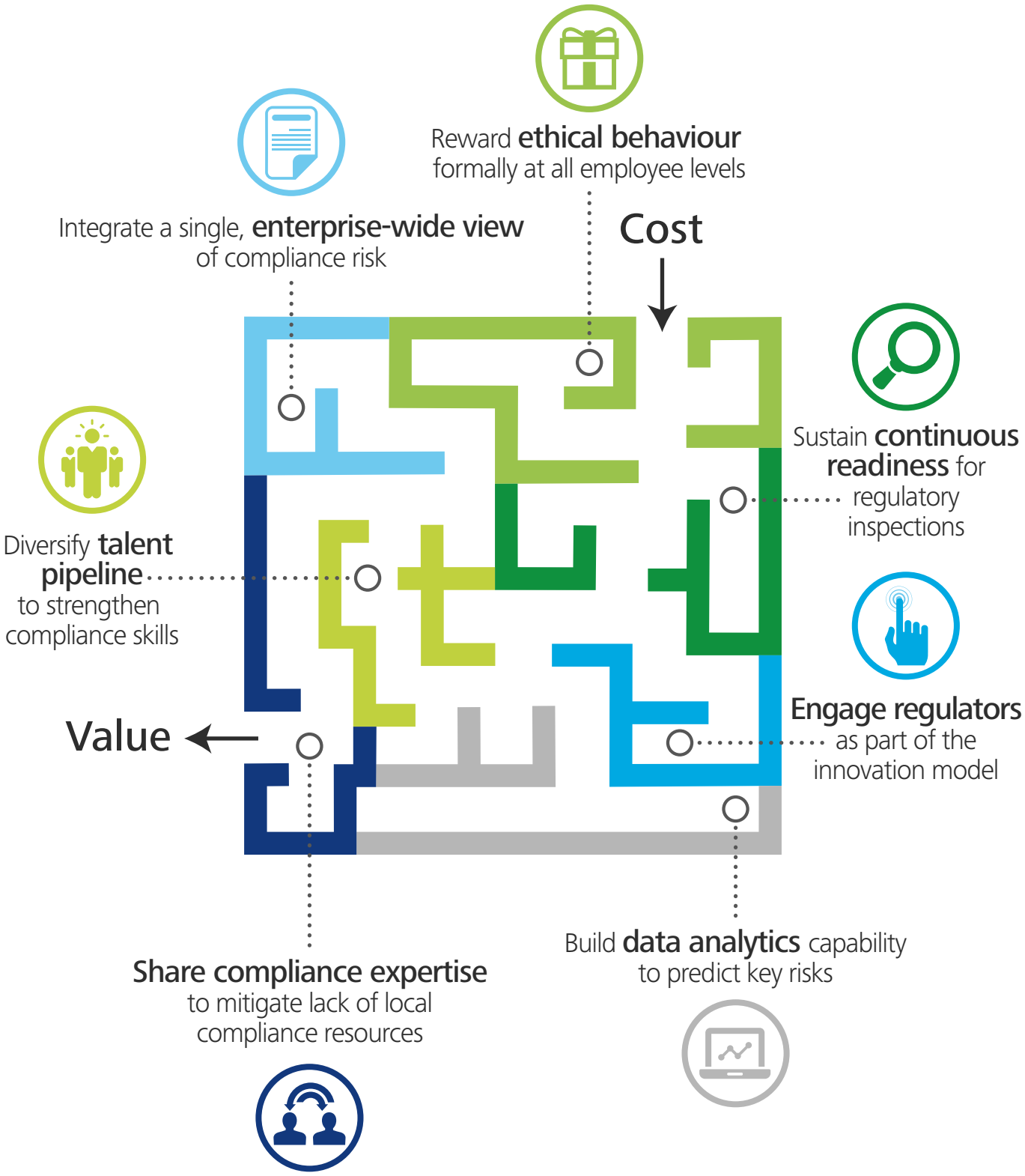
Navigating the challenge of compliance
Seven routes to value



Executive summary

The life sciences industry continues to face unprecedented challenges amid increasing regulatory scrutiny. Globalisation, alliances and partnerships, heightened transparency expectations, increased emphasis on innovative technologies, and the ever evolving needs of existing and emerging customers are driving companies to re-examine their approach to compliance.

This Deloitte report focuses on the compliance challenges life sciences companies face in ensuring a strategic balance between compliance risk and value. The report, which is based on interviews conducted with senior compliance leaders in 11 major life sciences companies and Deloitte's experience working with the industry, sets out seven key insights:

1. Life sciences companies often lack an enterprise-wide view of compliance risk

Governments and agencies around the world have created a hugely complex regulatory environment. As a result, life sciences companies sometimes struggle to understand the full scope of the compliance risk landscape. Obtaining an enterprise-wide view of compliance risk or a single view of overall 'compliance health' is often a challenge.

2. Big Data's role in compliance is often overlooked

Life sciences companies tend to analyse and report based on historical data. Applying advanced data analytics techniques could enable companies to identify and quantify – proactively – new and/or emerging risks.

3. The competitive advantages of ethics-driven cultures are being recognised

Companies with mature compliance functions emphasise ethical behaviours, acting with integrity as the norm, as opposed to simply focusing on rules. 'Tone in the middle' needs to gain as much emphasis as 'tone at the top', if not more. Culture change programmes will be a critical success factor.

4. Companies with the most mature compliance functions will win the talent war

The compliance skill set is changing and mature compliance functions have implemented initiatives to develop talent. Successful companies will be those that are able to sustain their compliance talent pipeline to meet the increasing demand for, and changing nature of, compliance skills. Those with a strong compliance culture will attract more high performing employees.

5. A lack of dedicated, local compliance resources presents a significant risk for global companies

Increasing levels of regulation in smaller, local markets requires appropriate compliance resources to ensure compliance standards are not compromised. Companies with mature compliance functions have created compliance excellence clusters among larger affiliates that smaller affiliates with limited compliance skills can consult, and are also introducing new global e-learning programmes.

6. Major opportunities exist to optimise compliance effectiveness and efficiency

Compliance inspections and audits represent a significant cost to companies with a 'mobilise-prepare-host-remediate-disband' operating model. Continuous readiness models are inherently more efficient and would drastically lower overall compliance costs. Combining this model with effective compliance risk assessments and management would further improve the effectiveness of compliance functions.

7. Leading companies build regulatory engagement into their innovation models

The industry needs to take the initiative to negotiate a balanced position with regulators. While most companies are embracing new technologies to deliver enhanced patient outcomes, the ambiguity of regulations relating to converging and emerging technologies results in a myriad of compliance challenges. Mature companies build engagement with regulators into their innovation models to develop enhanced regulatory pathways.

Life sciences companies currently face the dilemma of trying to achieve their business goals while striving to remain in full regulatory compliance. By developing strategies to address the above insights, life sciences companies should be able to transform compliance activity from a cost to something that delivers value and sustainable competitive advantage for the organisation. Overall, even though the compliance challenges facing the industry are numerous, the timing could not be better for compliance functions to transform themselves from tactical enforcer to strategic advisor.

Overview of compliance

Being part of a highly regulated industry, life sciences companies have a particularly onerous task of complying with a myriad of rules and regulations across all aspects of their business. The number and complexity of regulatory requirements has increased substantially over recent years and this trend is set to continue in the near term. Responding to this increasingly complex regulatory environment is extremely challenging, especially as non-compliance can have a profound effect on cost, corporate reputations and, ultimately, patients' lives.

Life sciences companies have struggled to address the needs of regulators and remain compliant. In an attempt to understand better the complexity of life sciences compliance and how the different compliance functions intersect, Deloitte has developed a compliance framework (see Figure 1) which sets out an overall life sciences compliance risk architecture. It identifies a culture of ethics and integrity at the core, surrounded by compliance programme elements that could be applied across 14 risk areas and which define the life sciences compliance universe.

Using this framework to structure our research, we set out to identify:

- how well the industry understands the totality of its compliance risks
- how compliance is managed and implemented within life sciences companies
- what the future of compliance looks like.

This report summarises our initial research findings, outlining the compliance challenges for life sciences companies and setting out seven key insights for compliance leaders. Our findings are based on interviews with senior executives, with responsibility for the different aspects of compliance, in 11 global life sciences companies, combined with points of view from Deloitte specialists in the life sciences regulatory and compliance fields.

The research is ongoing with interviews planned to continue into 2016. However, we felt that it was important to publish our early findings to stimulate dialogue and seek your feedback. A subsequent report, to follow in 2016, will focus on solutions to enable life sciences companies to optimise their compliance organisations.

Figure 1. Deloitte compliance risk tool

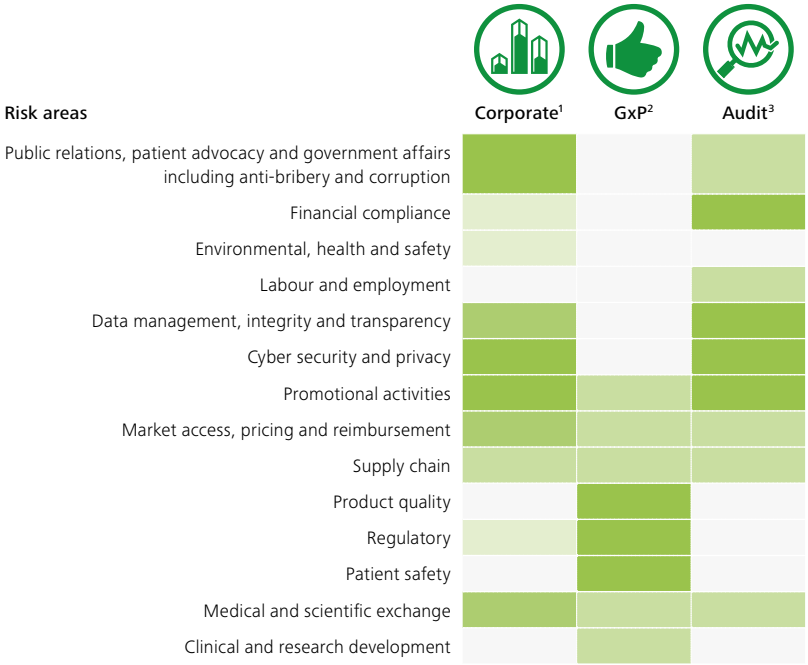
Source: Deloitte Enterprise Compliance and Life Sciences Compliance Advisory, 2015

Compliance insights

1. Life sciences companies often lack an enterprise-wide view of compliance risk

Compliance needs have grown organically from a plethora of disconnected rules and regulations affecting the industry. Traditionally, life sciences companies have addressed these needs within the silos of individual operational or business functions. As a result, each area has tended to develop its own discrete compliance agenda and management programme. However, as life sciences business models have evolved, compliance risks have become more interconnected across the 14 risk areas.

Figure 2. The main focus of compliance leaders interviewed



Notes:
1 Corporate compliance includes: CCOs, Chief Ethics Officers, Compliance Officers, CIOs
2 GXP compliance includes: CMOs, Heads of Quality, Heads of Safety and Heads of Regulatory
3 Audit includes: Internal Audit

Source: Deloitte UK Centre for Health Solutions, 2015

Our initial research found that, as a consequence of this fragmented approach, most companies do not possess a full understanding of the universe of compliance responsibilities, and there is a pressing need to develop a more integrated compliance view. The problem is exacerbated by the lack of a common definition of compliance responsibility, with "compliance" meaning different things to different people, depending on their primary roles and responsibilities. Some of the more mature companies have recently set up 'Compliance Committees' or Forums to bring together the executive leaders responsible for the various domains of compliance risk and introduce a consistent company view of compliance. In these companies, the role of Chief Compliance Officer (CCO) has gained greater oversight, prominence and authority, broadening the view of compliance and the typical remit of a CCO elsewhere in the industry.

However, the responsibility of the CCO still differs from company to company and does not usually cover the entirety of the compliance universe. Likewise, we found a wide variation in how responsibilities for compliance are assumed by other executives who have a lead role for compliance (see Figure 2).

> "I'm just one silo out of a whole foundation of compliance."
>
> **Chief Financial Officer**

Deloitte's view

We believe that life sciences companies sometimes struggle to understand the compliance risk landscape or obtain an enterprise-wide view of compliance and that there should be a single 'owner' of compliance risk. This ownership could be vested in an individual or a compliance committee.

2. Big Data's role in compliance is often overlooked

Despite large investments of time and money, the exploitation of big data for compliance functions has proved challenging. Our research identified two fundamental barriers that are preventing life sciences companies from using data analytics effectively:

- complexity of legacy IT infrastructures and technologies – which is characterised by a myriad of disparate reporting systems and platforms, owned and housed within separate business functions or geographies. Accessing data is an uphill struggle; integrating and analysing data is even more problematic. Only 47 per cent of compliance leaders surveyed believe their reporting systems give them a comprehensive view of compliance

- a lack of compliance reporting systems that are fit for purpose – the vast majority of compliance leaders are relying on manual reporting systems, which depend on complex, resource-intensive and time-consuming processes.

When asked about their perceptions of their company's compliance reporting systems (see Figure 3 overleaf), compliance leaders identified two areas of dissatisfaction:

- Only 25 per cent agree that their reporting systems provide real time compliance information and 43 per cent do not believe that current compliance monitoring and reporting systems enable positive intervention – action to avoid or minimise the impact of non-compliance

- Only 19 per cent agree that they have access to systems with drill-down capability – the ability to provide more granular detail on specific issues upon request.

"You need to know the guy who knows the system to get access to the data. We can't go in and get the data out."

Global Head of Quality

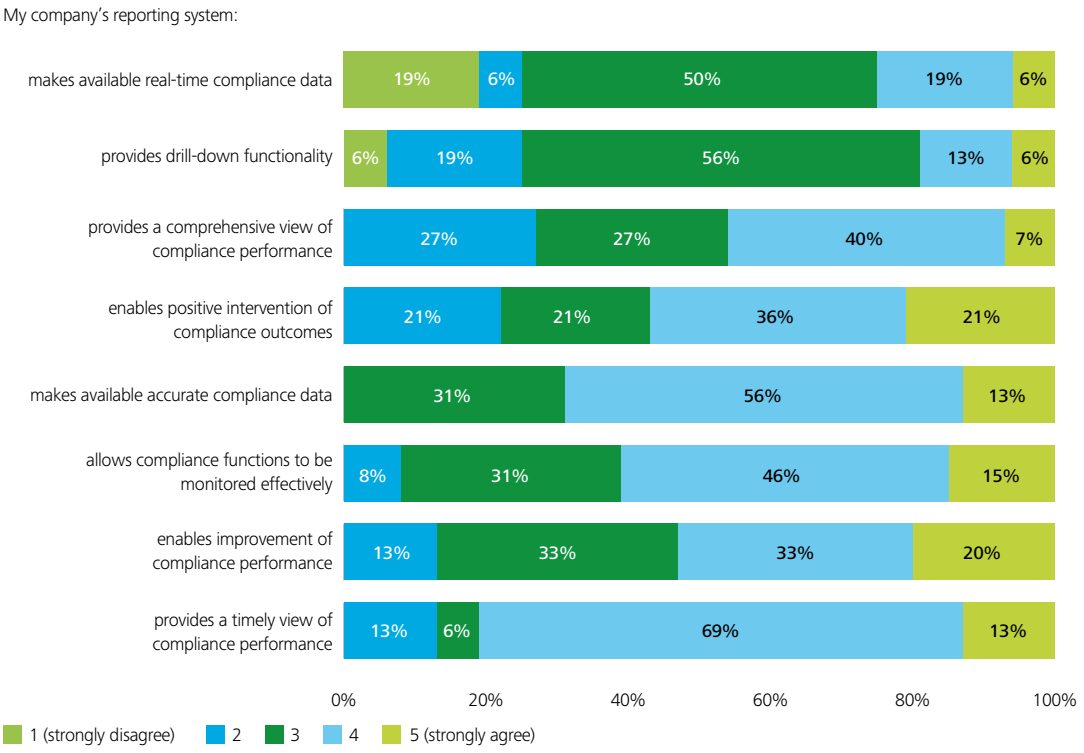
"It's impossible to integrate them (compliance reporting systems/platforms) all because of the differences in the processes and feeds going through different stakeholders."

Chief Compliance Officer

"A couple of years ago with (a supplier), we burned ourselves trying to develop one system."

Global Head of Internal Audit

Figure 3. Perceptions of compliance reporting systems



Source: Deloitte UK Centre for Health Solutions, 2015

The most progressive companies are building data warehouses and using smartphones, tablets and apps with drill-down capabilities for specific functional needs, such as site-specific manufacturing and the monitoring of high-risk local affiliates.

Deloitte's view

There are clear opportunities for compliance functions to extract more value from data by improving IT infrastructure and systems, and partnering more effectively with the business. Life sciences companies need to set out a clear vision to successfully implement data analytics, defining an IT infrastructure strategy that centres on the needs of the compliance system and delivering an enterprise-wide view of compliance risk.

Leading companies are using data analytics to future-proof their compliance strategies

Compliance reporting is often confused with analytics. However, reporting is limited to retrospective analysis of historical data (i.e. violations, product recalls and product complaints) rather than analytical capabilities needed to create forward-looking or predictive insights. The most mature companies are combining horizon scanning capabilities with data analytics to identify and mitigate new or emerging compliance risks.

Only 47 per cent of compliance leaders we interviewed agreed that their company has been proactive at implementing regulatory change, emphasising the need for analytics and horizon scanning capabilities.

"Our horizon scanning team saw that regulators around the world were starting to realise that in companies who are getting into trouble there's a cultural element. So they're (the US FDA) really starting to look at: 'Do you understand your culture of quality? Do you understand your culture of continuous improvement? How do you understand that?' We started a process to measure culture and use the information to measure the amount of oversight our suppliers get."

Global Head of Quality

Deloitte's view

A scientific approach to data analytics – more akin to the rigorous scientific approaches used elsewhere within life sciences companies – should be adopted by compliance functions. This will help them to understand the crunchy questions the overall business is trying to solve, which might address, for example, changes in prescription patterns, the impact of rebates on distributor margins and changes in adverse event reporting. Testable hypotheses need to be developed that will enable predictions of behaviour to be analysed, assessed and monitored better. Compliance functions need to consider prospective Key Risks Indicators (KRIs) to create proactive insights and help them to look around the corner and identify and quantify new or emerging risks.

3. The competitive advantages of ethics-driven cultures are being recognised

There is a growing movement across the industry to shift compliance programmes away from simple rules-based compliance to compliance based on ethics and integrity. Life sciences companies have recognised the need to embed ethics and integrity into their 'DNA'. Indeed, as companies have evolved at different rates, compliance cultures have matured at different rates (see Figure 4). While messages from the Board around ethics and integrity are generally cascaded down to senior executives effectively, they can get lost within the middle-management layer, meaning they do not always reach the rest of the organisation or other geographies where the company operates.

"In some countries we have consciously reduced sales targets. Prominent statements (from management) about if we have to choose between sales and compliance, then sales is not the option… You should not surrender your compliance integrity."

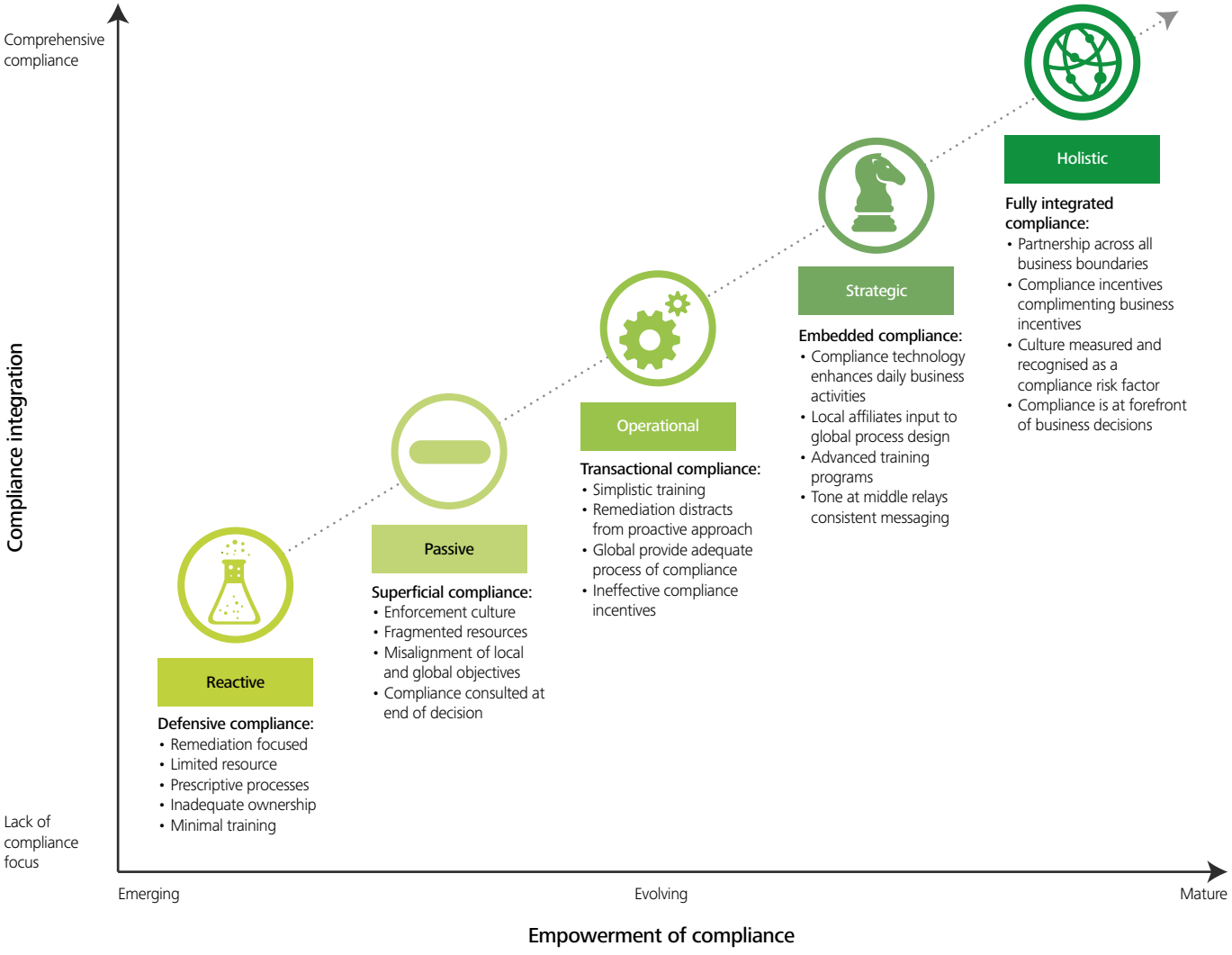
Global Head of Compliance

Some companies are developing innovative approaches, such as peer-nominated compliance awards, which recognise and reward compliant behaviour. Others (42 per cent) formally link job performance to ethical or compliance behaviours. Most have introduced a code of conduct, and an approach to recruitment and training that seeks to instil a compliance culture throughout the company. Over 90 per cent of compliance leaders felt they had a shared understanding of compliance roles and responsibilities with the person to whom they report.

Deloitte's view

Rewards need to be linked directly to compliance, with clear objectives embedded into performance measures at all levels within the organisation. 'Tone in the middle' is now at least as important as 'tone at the top'. Middle-management need to be incentivised formally to disseminate messages throughout their teams; and be trained to instil an ethical mind-set that enables them to balance compliance and business needs appropriately.

Figure 4. Compliance maturity models



Source: Deloitte Enterprise Compliance and Life Sciences Compliance Advisory, 2015

"Attracting the best talent for a company that doesn't have the best reputation for morals is a big disadvantage and many companies suffer from this. Having a very different profile where compliance is very high and your standards are very high can help."

Global Head of Compliance

4. Companies with the most mature compliance functions will win the talent war

The compliance skill set is changing; compliance personnel need to work in partnership with business functions, participating in an open dialogue and exhibiting an ability to balance compliance with commercial needs. They need to be flexible around implementation of compliance policies and guidelines.

Mature compliance functions have implemented various in-house development programmes that run across and between global, regional and local teams. These vary from rotating staff between commercial and compliance functions to running dedicated compliance schools and e-learning initiatives. A key differentiator is a company where people with very good knowledge of the business see compliance as an attractive career path. Compliance leaders feel that Human Resources could do more to support the compliance function to instil a compliance mind-set within the company.

Deloitte's view

Successful companies will be those that are able to sustain their compliance talent pipeline to meet the increasing demand for, and changing nature of, compliance skills. As compliance complexity within life sciences grows, the demand for high quality compliance resources will increase. In addition, companies perceived as having a leading reputation and strong compliance culture will attract more high performing employees to sustain their talent pipeline.

5. A lack of dedicated, local compliance resources presents a significant risk for global companies

A fundamental element for the success of the compliance system is having appropriate, dedicated resources within local affiliates. While larger affiliates are more likely to have full-time, dedicated compliance officers, typically there is insufficient local resource for this to be replicated in smaller affiliates. With regulations increasingly affecting smaller, local markets, a lack of dedicated compliance resources is a significant risk for global companies. The most mature compliance functions address this risk in one of two ways:

- creating 'compliance excellence' clusters among larger affiliates that smaller affiliates with limited compliance skills can consult; and
- bringing personnel from smaller, local affiliates into the global compliance function for training, with the global team absorbing the costs as they recognise the risk is global.

Deloitte's view

Compliance resources at the local level have not kept pace with incremental increases in local regulatory burdens, leading to an increased risk of non-compliance. Companies need to recognise and assess this emerging risk, and determine and implement mitigation strategies.

"At the affiliate level you need to allocate people that are fit for the job and that is often people-based not just role-based. You have to have a diverse uniform there… in some affiliates there is sometimes a very constrained resource base, in terms of skills you can obtain in the market."

Global Head of Compliance

"There is no model where you can just optimise all of the parameters and say this is what we have to do to run our business in the best possible manner but I think it's important to be better than others."

Global Head of Compliance

"Although (an internal and proactive compliance intervention) cost $XX million, I haven't had to do any recalls… which my peers have had to. The benefit is that I can now go back to reduce the costs of my testing and inspecting as we have the right processes and standards in place to mitigate the risk."

Global Head of Quality

6. Major opportunities exist to optimise compliance effectiveness and efficiency

Compliance inspections and audits represent significant cost to companies with a 'mobilise-prepare-host-remediate-disband' operating model. Continuous readiness models are inherently more efficient and would drastically lower overall cost of compliance. Companies that can create lean yet effective compliance systems can gain a strategic advantage over their peers.

The cost of non-compliance is perceived to be far greater than the cost of compliance due to reputational damage, fines and the impact on patients from, for example, disruptions in product supply. However, it is impossible to determine the total cost of compliance accurately due to the fragmentation and complexity of the compliance universe. While CCOs tend to have a clear understanding of numbers and costs of people in their compliance teams, there are a host of less tangible costs, such as individuals whose compliance role is part-time or embedded into their daily tasks and the costs of shared IT services.

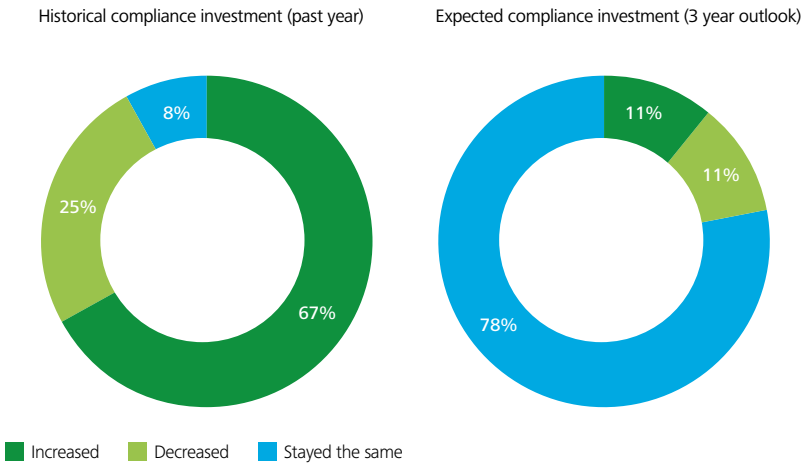
Mature compliance functions are more able to focus on and realise efficiencies within the compliance function. Incremental compliance budget is made available more readily as Boards and Executive Management recognise the value that compliance brings to the organisation. Also, compliance leaders are more adept and empowered to identify opportunities to outsource and/or offshore established compliance tasks and processes, thereby freeing up internal resources which can be redirected to focus on mitigating new or emerging risks proactively.

Compliance budgets are viewed as adequate by most compliance leaders we interviewed and, although budgets have tended to increase over the last year, they are not expected to increase in real terms over the next three years (see Figure 5). In real terms, several companies have seen a reduction in budget as increases are lower than inflation or do not consider additional resources required to address compliance activities associated with business growth and increased regulator activity.

Increases in commercial compliance budgets have been due to the significant growth in regulator activity and enforcement in, for example, Healthcare professional (HCP) interaction and transparency regulations. Impact of legislative EU changes such as Identification of Medicinal Products have also led to companies investing across functions in areas such as regulatory, supply chain and data management.

In the US, a Corporate Integrity Agreement (CIA), is an enforcement tool used by the Office of the Inspector General within the Department of Health and Human Services, to improve compliance to health care regulations. Companies served with a CIA are required to develop and implement codes of conduct, policies, procedures and training within specific timeframes. While the industry views these as a significant resource burden (such as employing 100s of lawyers), in the long-term they offer transformational opportunities. Although CIAs often result in companies adding compliance headcount, in a number of cases they have helped the company realise long-term efficiencies through an overarching restructuring of their compliance function.

Figure 5. Trends in compliance spending



Source: Deloitte UK Centre for Health Solutions, 2015

Deloitte's view

Continuous readiness models for regulatory inspections are more cost-efficient than the 'mobilise-prepare-host-remediate-disband' cycles used by most companies in the industry but, this approach has not yet been implemented consistently. Currently, most compliance leaders are being asked to do more with less. Deploying compliance tools and technologies will support more efficient risk mitigation through real-time evaluation of global and local issues and trends.

"There are all kinds of authorities: FDA, my local regulators, China and for the first time, Turkey, Brazil, South Korea. They follow different directions and it's difficult to satisfy them all… they may have conflicting requests. It's really, really complex."

Global Head of Quality

"A regulatory body began inspecting off-label allegations and, mid-inspection, changed to focus on drug safety and HCP engagement. There's a perception that a regulator can always find something if they look hard enough, so how can life sciences companies mitigate against this risk in practice?"

Global Head of Regulatory

7. Leading companies build regulatory engagement into their innovation models

The global life sciences regulatory and compliance landscape has evolved over the past decades to become highly complex, inconsistent and sometimes contradictory. This landscape is continuing to grow in complexity across a wide range of functions, activities and geographies. As well as expansion in large, mature markets (such as the US and Europe) and large developing markets (such as Brazil, Russia, India and China), smaller national regulators (such as Kenya, Algeria and Kazakhstan), are increasing their presence and placing disproportionate regulatory demands on life sciences companies.

There is a pressing need for regulatory harmonisation whereby regulatory demands converge and reduce the burden on industry. Constantly changing regulatory goalposts are preventing good compliance and gaining a balanced position with regulators will promote more sustainable compliance strategies.

Our research identified four key challenges for industry:

- inconsistency between regulatory bodies in different geographies; and even individual inspectors within the same regulator;
- regulators appear to lack visibility of the impact of increasing regulatory burden on life sciences companies;
- regulators changing the focus of an inspection mid-way through the process; and
- the retrospective application of regulations to events that happened several years ago.

Most companies are embracing new technologies to deliver enhanced patient outcomes. However, the ambiguity of regulations relating to converging and emerging technologies results in a myriad of compliance challenges. Mature companies build engagement with regulators into their innovation models to shape regulatory policies and guidelines, and regulatory pathways. Those at the forefront of compliance maturity have dedicated functions that represent the company's views on current compliance challenges as well as future innovation.

Without clear regulatory guidelines, life sciences companies are cautious in bringing technology innovation to patients. Similarly, regulators are reticent in creating regulatory guidelines when they have limited experience of such innovation. Focussing on the needs of patients will provide common ground for regulators and industry to move forwards and promote early access to life sciences innovation.

Deloitte's view

Greater consistency between regulators through regulatory harmonisation will make compliance more achievable for the industry, while raising global compliance standards. The industry needs to take the initiative to negotiate a balanced position, allowing compliance resources to be focussed on major compliance risks. This will, however, necessitate regulators accepting a more risk-based approach to compliance.

Regulators and industry are working actively with patients but in isolation. Life sciences companies and regulators should consider working in a much more collaborative fashion, including with patients, to ensure the future regulatory landscape is centred on addressing patient needs and promoting early access to life sciences technology innovation.

"We get judged on what we do today in 3-4 years' time. It (regulation) is like a moving target."

Global Head of Compliance

"Regulators are completely within their right to apply the highest standards to everything we do, but it's not practical; it's a nightmare to comply. As a consumer I fully subscribe to it, but as a professional having to execute it, it gives me significant headaches because it's not that practical… but that's the tension you have to operate in."

Global Head of Compliance

"We have gained very deep knowledge and authority in some areas (of compliance) which has allowed us to shape our environment better and in a way that suits us."

Global Head of Compliance

The future of compliance

"Compliance is a business hurdle, like access and pricing and talent; and mastering the skill of navigating compliance better than everyone else is a competitive advantage."

Global Head of Compliance

"Innovating in compliance is highly, highly valuable. Finding new engagement models, business and access models and identifying how we handle information from external sources, allows us to have a sustainable research and development model. Compliance is one element of this and a good subject for innovation."

Global Head of Compliance

The rules on return on investment on compliance are changing. The combination of increasing regulatory complexity – as well as the sheer number of regulations – and the changing nature of patient and societal attitudes towards integrity, risk and ethics mean that compliance now needs to be firmly on the Board agenda. Getting compliance right, from the outset, will clearly outweigh the negative impact of failing to implement compliance effectively.

Compliance has traditionally been viewed as simply an insurance policy against risk – and, accordingly, received a proportionately low level of investment and attention. This is no longer sustainable. Compliance has to be viewed as a source of competitive advantage and customer differentiation. So the same approach that a life sciences company might take to innovation, should be applied to compliance.

Deloitte's findings support the view that a conservative approach to compliance will not be sufficient for the future sustainability of the life sciences industry. Compliance systems have to be effective, efficient and future-proofed to support existing compliance requirements and mitigate new and emerging compliance risks. Our findings have identified seven insights that we consider to be important for the future of compliance in the life sciences industry. These will be explored in more depth as our research continues, with a view to presenting potential solutions for optimising compliance in our next publication.

Glossary

CIA The Corporate Integrity Agreement (CIA) is an enforcement tool used by the US Office of the Inspector General within the Department of Health and Human Services, to improve the quality of health care and to promote compliance to health care regulations. CIAs typically require companies to develop and implement codes of conduct, policies and procedures, and training within specific timeframes following the effective date of the CIAs.

EMA The European Medicines Agency (EMA) is a decentralised agency of the European Union, located in London. The Agency is responsible for the scientific evaluation of medicines developed by pharmaceutical companies for use in the European Union. It began operating in 1995.

ERM Enterprise Risk Management (ERM) is the process of planning, organising, leading, and controlling the activities of a company to minimize the effects of risk on a company's capital and earnings. ERM expands the process to include not just risks associated with accidental losses, but also financial, strategic, operational, and other risks.

FDA US Food and Drug Administration (FDA) responsibilities relevant to life sciences industry include: protecting the public health by ensuring that vaccines and other biological products and medical devices intended for human use are safe and effective, advancing the public health by helping to speed product innovations, helping the public get the accurate science-based information they need to use medicines, devices, and foods to improve their health. FDA's responsibilities extend to the 50 United States, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, American Samoa, and other U.S. territories and possessions.

GxP A term whose general meaning is 'good practice in x'. GxP is based on guidelines for the pharmaceutical industry and covers all steps from drug development to production. Where the x is the replacement character, which specifies the stage of drug development or production. Examples include Good Laboratory Practice; Good Clinical Practice, Good Manufacturing Practice. Regulations governing GxP are determined by the industry regulatory agencies.

MHRA UK Medicines and Healthcare products Regulatory Agency (MHRA) regulates medicines, medical devices and blood components for transfusion in the UK. MHRA is an executive agency, sponsored by the UK Department of Health.

RWD Real world data (RWD) is data used for decision-making that is not collected in conventional randomized controlled trials (RCTs), includes clinical and economic data reported by patient registries, claims databases, electronic health records, patient-reported outcomes, and literature review.

RWE Real world evidence (RWE) is organised information informing a conclusion or judgment based on real-world data.

Mature companies Those companies with advanced and well developed compliance functions.

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