

State of Compliance 2014

Pharmaceutical and life sciences industry brief

*Delve into the full analysis
of the 2014 State of
Compliance Survey at:
[pwc.com/us/
stateofcompliance](http://pwc.com/us/stateofcompliance)*



Introduction

The pharmaceutical and life sciences industry continues to walk a delicate balance between being reactive to risk, taking random approaches to putting out fires, and being proactive with risk by actually anticipating new risks to better manage and mitigate them in real time. With one eye on the present, their keeping one eye on the future, and their planning for emerging risks prove to be just as challenging.

1 *Risk priority remains cyclical, and companies' energies generally focus on the risk du jour: the one that gets the sharpest focus by regulators.*

Antibribery/anticorruption and global transparency are top of mind

The pharmaceutical and life sciences industry continues to prioritize risk in a way that aligns with regulator activity, and it generally focuses its energy on the risks that get the most press and that suffer the highest levels of prosecution. One of the main challenges the pharmaceutical and life sciences industry faces is the need to shift attention and resources to new and emerging risks in a more proactive and predictive manner, primarily because managing the present influx of risk—represented by increased numbers of investigations and regulations—can require an all-consuming effort. Two such areas of risk in particular were top of mind in the survey: antibribery/anticorruption and global transparency, which are demanding significant attention by senior leadership and which are hindering compliance organizations' efforts to be more forward-looking and proactive with respect to risk management.

Compliance organizations are investing significant budgets and human capital (as demonstrated in the survey with the uptick in compliance budgets and resources) into putting out these more immediate fires by conducting audits, designing new processes and controls, and implementing new, system-based solutions. The past few years have witnessed a new wave of global antibribery and anticorruption enforcement that has put the pharmaceutical and life sciences industry on notice. High-profile investigations and settlements in such countries as China have focused on alleged corruption that was going on over the course of many years involving (1) the bribing of health officials and physicians so as to significantly boost sales and (2) engagement in other improper drug-marketing tactics.

The message being sent is very clear: the regulators are not only going after companies by imposing heavy fines and penalties but also placing heavier emphasis on the detainment and prosecution of individuals, resulting in longer prison sentences. That kind of enforcement is further complicated by the fact that companies are placing big bets on new and emerging economies, many of which—like China, Russia, India, and Turkey—have significantly higher risk profiles than many of the established markets. Many of those higher-risk countries may be the more significant and fastest-growing markets, but they also pose tough challenges, from healthcare systems that are owned and controlled by the state and from traditions and customs that reward patronage and gift giving.

Compounding the formidable task of antibribery and anticorruption enforcement are the significant efforts that pharmaceutical and life sciences companies are exerting to design and implement processes and systems that meet spend transparency and disclosure requirements. Spend transparency is a global phenomenon and one that is not showing any signs of waning. In the United States, under freedom-of-information laws, companies are required to track and report, on both an aggregate and an individual basis, all payments and transfers of value to US healthcare professionals and organizations made by them or their subsidiaries outside the United States. Also in the United States, a handful of individual states have their own spend transparency and/or disclosure laws. In Europe, companies are contending with the European Federation of Pharmaceutical Industries and

Associations' newly published code on spend transparency and disclosure that is similar to the US law. The code requires companies to track and report payments and transfers of value that they or their subsidiaries make to their healthcare professionals and organizations. This is in addition to the many European countries' own individual laws and regulations—like those of states in the United States—that usually require different levels of transparency reporting. And this risk is not limited to the United States and Europe; rather, we're seeing fast-growing globalization of spend transparency, with many Asia Pacific countries already having passed similar laws.

Taken together, and not even considering the myriad of other risks faced daily, it's easy to see why compliance organizations are distracted from being more proactive and forward-looking with their risk-mitigating activities. That's not to say the industry does not put stock in the need to be more proactive by identifying, managing, and mitigating new and emerging risks. In fact, as the survey demonstrates, the pharmaceutical and life sciences industry already identifies strategic risk as a risk that requires priority focus. Despite the naturally *reactive* nature of the industry to respond to the most-intense areas of regulator attention, there is clearly a growing interest in shifting attention so as to address compliance risk in the areas of strategy and business transformation. That interest has been generated in large part by the many complex demands of healthcare reform and the rapidly changing business model in response to those demands.

The pharmaceutical and life sciences industry identifies strategic risk as a risk that requires priority focus.

2 Despite the reactive nature of the industry to respond to the most-intense areas of regulator attention, there is clearly a growing interest in addressing compliance risk in the areas of strategy and business transformation.

The evolving healthcare landscape is changing the framework of traditional pharmaceutical and life sciences customers. Individual healthcare providers, payers, and hospitals are organizing into new customer types such as integrated health systems or integrated providers and payers, with localized market dynamics, access challenges, and varying decision models. Both that reorganization and recent market changes are the results of a shift in payment model from fee for service to a range of risk-based payment structures such as pay for performance, universal capitation, and accountable care designs. To engage customers more effectively in that market, companies are seeking ways of developing meaningful value propositions, companion services, and technology offerings that align with those payment structures, decision models, and outcomes-based disease management. To succeed, companies are identifying new ways to engage the market, including targeting new, centralized decision makers and procurement functions; entering into real-world data partnerships to

determine the best courses of care and the best interventions for specific patients; and providing clinical-decision support tools in combination with their products to better risk-stratify patients, monitor disease progression, and, ultimately, improve outcomes.

As new ideas and strategies continue to form, new compliance risks and new views of the more traditional compliance risks are fast emerging. Compliance organizations need to recognize that this is only the beginning of an evolutionary process in commercial transformation and should engage now with their business stakeholder partners to evaluate the impact of the transforming business model on the existing compliance-strategy-and-control framework. These market changes come at a time when ensuring confidence in the industry's reputation is vitally important. And among the main issues that compliance organizations must address as part of that emerging strategic risk are:

- Readiness of the compliance organization to be a proactive and effective business partner
- Application of often outdated guidance to new strategies (e.g. Section 114 of the FDAMA and FMV) Interactive and engaging methods for communicating and training on changes
- Evolution of existing compliance programs (e.g. controls, program review, monitoring, and auditing)
- Timely and effective risk mitigation strategies

With a strong partnership between compliance organizations and commercial organizations—in conjunction with increased awareness and education—pharmaceutical and life sciences companies' compliance organizations can effectively anticipate the changes required for meeting the needs and regulations of the new healthcare landscape.

3 To elevate the impact of reporting, CCOs must invest more in data analysis and metrics monitoring.

One way compliance organizations in the pharmaceutical and life sciences industry can immediately increase the effectiveness of their compliance programs is by using robust data for enhanced monitoring and more-effective stakeholder reporting. As the survey reveals, training-completion rates and hotline calls are still the top two measures used for monitoring. This is one area that continues to challenge compliance organizations because senior executives and board members, more engaged with and savvy about compliance risks, expect a higher level of competent reporting on the effectiveness of the company's compliance program. True compliance monitoring—specifically, the ability of the compliance function to correlate and analyze multiple points of data in real time so as to be more predictive of risk—is considered the holy grail of compliance program effectiveness. Companies that successfully invest in and embrace true compliance monitoring will elevate the impact of compliance monitoring and, ultimately, the quality and effectiveness of stakeholder reporting.

Compliance organizations now more than ever have greater access to meaningful and robust data about how their respective companies engage with customers. With advances in global spend transparency, as discussed, many companies are building and maintaining—in real time—repositories of data about customer interactions. Combined with other existing sources of data such as sales demographics, compliance organizations can perform data analysis to discover trends that speak to the directionality and likelihood of the occurrence of risk. Data analysis relies on metrics as basic performance measures and key performance indicators because metrics can provide real-time transparency into business performance and management compliance with business rules.

Armed with data, compliance organizations can be thoughtful and effective about the use of the limited budget and human resources available to them and can dedicate those resources to targeted, higher-likelihood risks. In the end,

compliance organizations can shift from being *reactive* to risk (i.e. responding after the fact) to being *more proactive* about managing—and, ultimately, mitigating—risk before it becomes an issue. Additionally, by applying the more robust metrics and key performance indicators present in this treasure trove of data, compliance organizations can now provide more-insightful reports for senior leadership and board members on the effectiveness of the compliance program as well as the state of risk across the value chain.

Consequently, the compliance organization can be a more effective business partner and exert a greater impact on the main elements of an effective compliance program by investing more in data analysis and metrics monitoring and by utilizing data that can serve to significantly enhance compliance and risk management, inform business operations and strategy, and support operational efficiency and excellence.

4 Related data

The majority of Pharmaceutical & Life Science respondents state that they have a CCO (84%)

Q3a Does your organization have a Chief Compliance Officer/Head of Compliance?

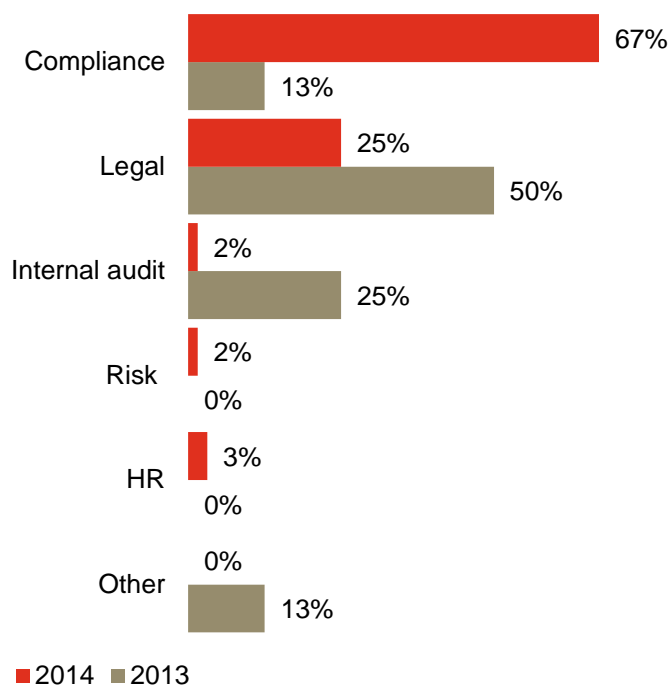


Base: (64, 38)

4 Related data

Pharmaceutical & Life Science respondents state the compliance department provides leadership for compliance, followed by legal departments

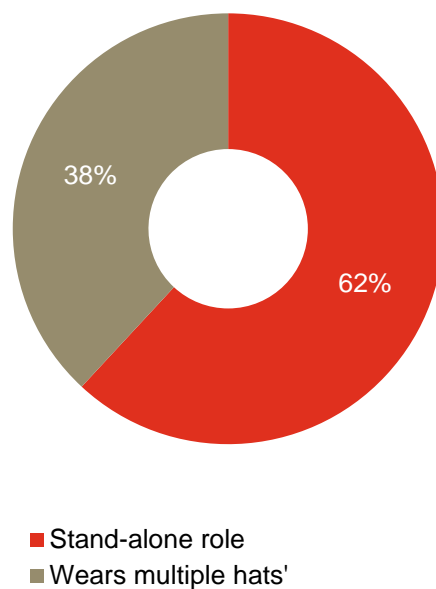
Q3b Which department provides leadership for the compliance program?



Base: (64, 8)

The majority of Pharmaceutical & Life Sciences respondents agree that the person with the most responsibility for compliance has a stand-alone role

Q3d Is the position of the person with the most responsibility for compliance a stand-alone role, or does s/he 'wear multiple hats'?

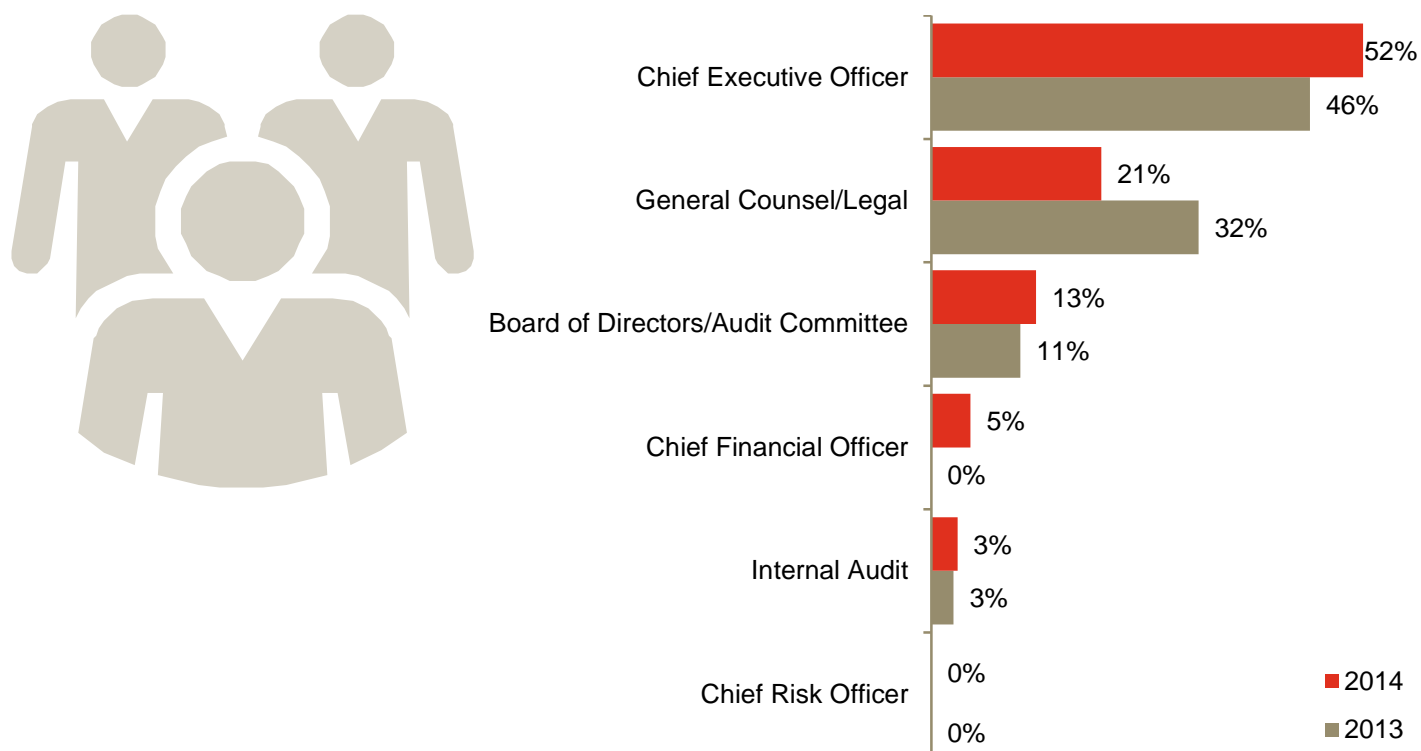


Base: (63)

4 Related data

Just over half of Pharmaceutical & Life Sciences respondents formally report to the CEO in their organization

Q4 To whom does the person with most responsibility for compliance formally report in your organization?



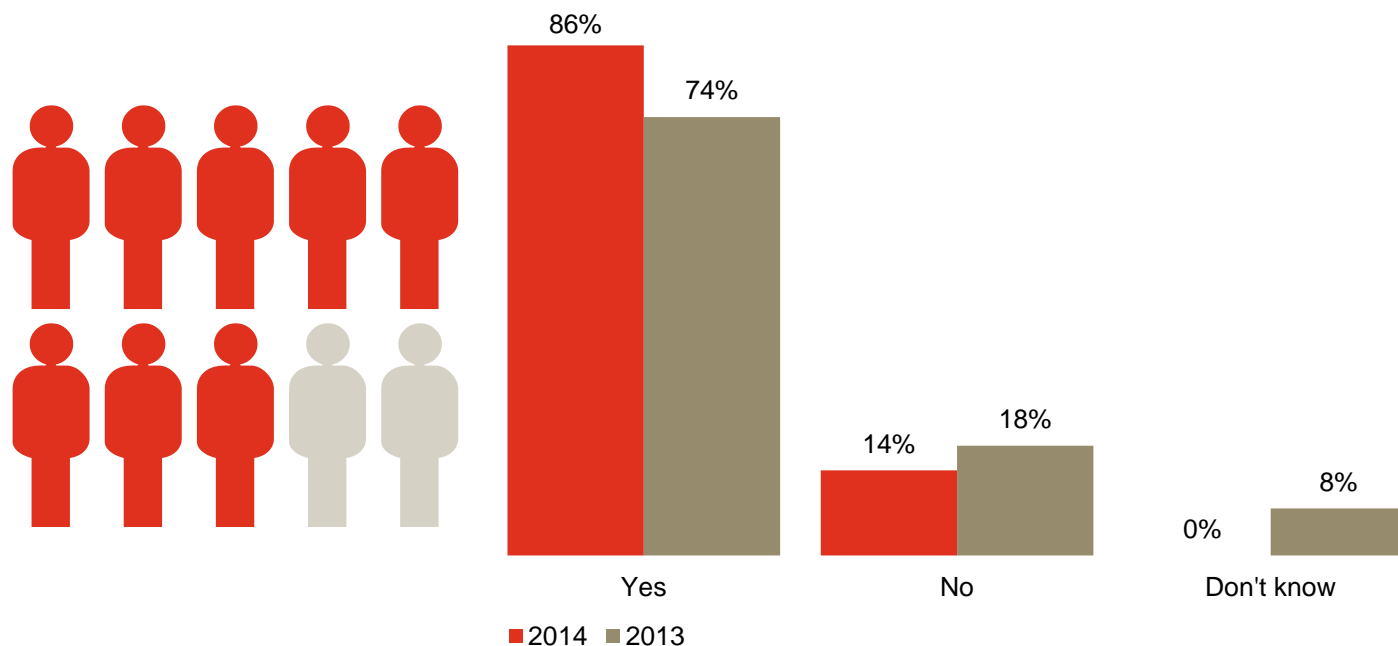
Base: (63, 37)

4 Related data

Compliance Committees are well established within the Pharmaceutical & Life Sciences sector...

Q6a Does your company have an in-house Compliance Committee to support compliance efforts?

Over 80% respondents told us they have a Compliance Committee within their organization

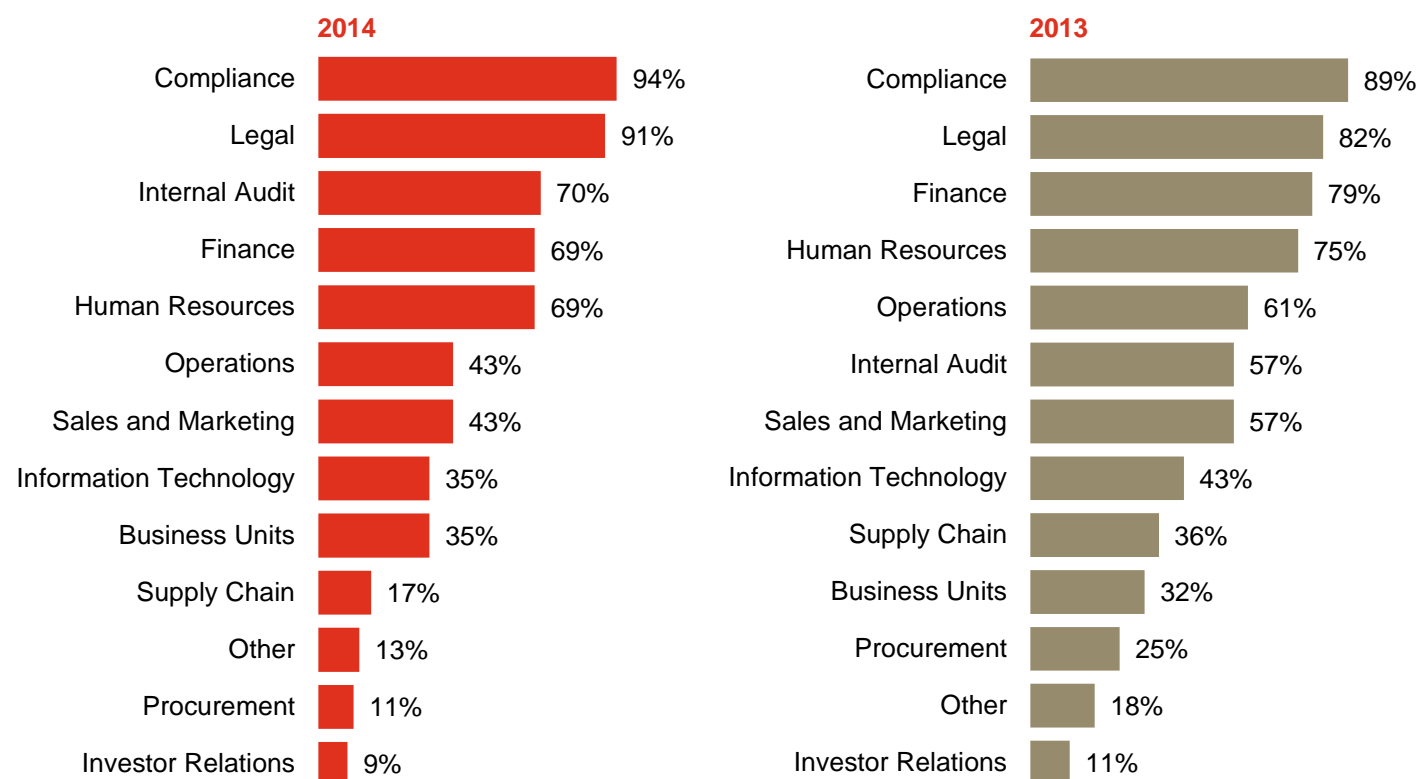


Base: (63, 38)

4 Related data

The majority of respondents report that Compliance and legal departments are the main departments represented on the Compliance Committee

Q6b Which of the following departments or functions serve on the Compliance Committee?



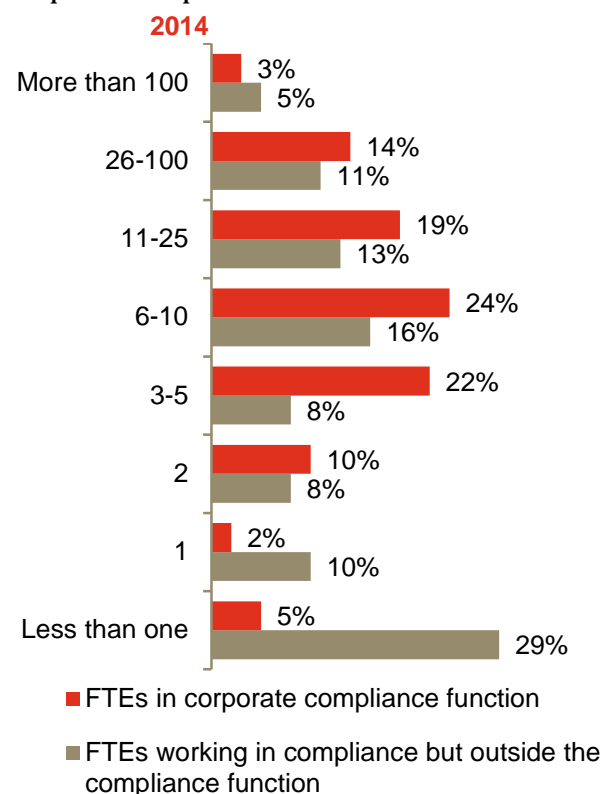
Base: Respondents who stated 'yes' at Q6a (54)

Base: Respondents who stated 'yes' at Q8a (28)

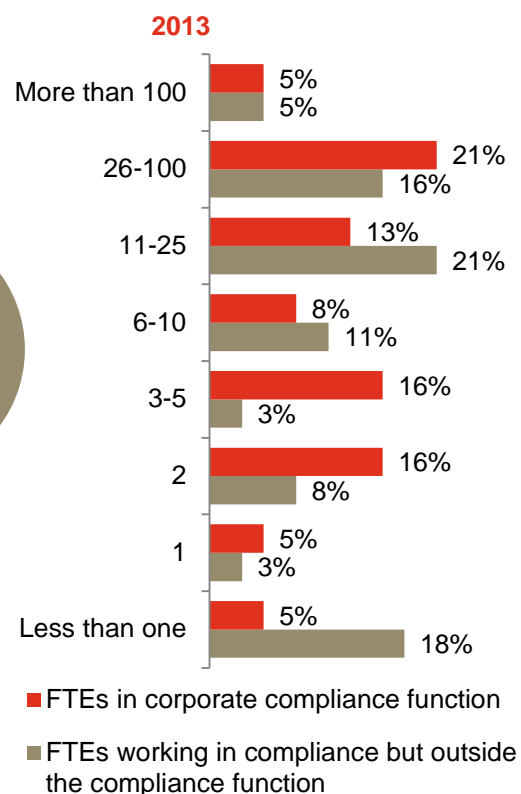
4 Related data

Almost 40% of Pharmaceutical & Life Sciences respondents suggest there are five or fewer FTEs working in their compliance function

Q7a&b How many full time equivalents are working in the corporate compliance function or are based outside of the corporate compliance function?



Base: (63)

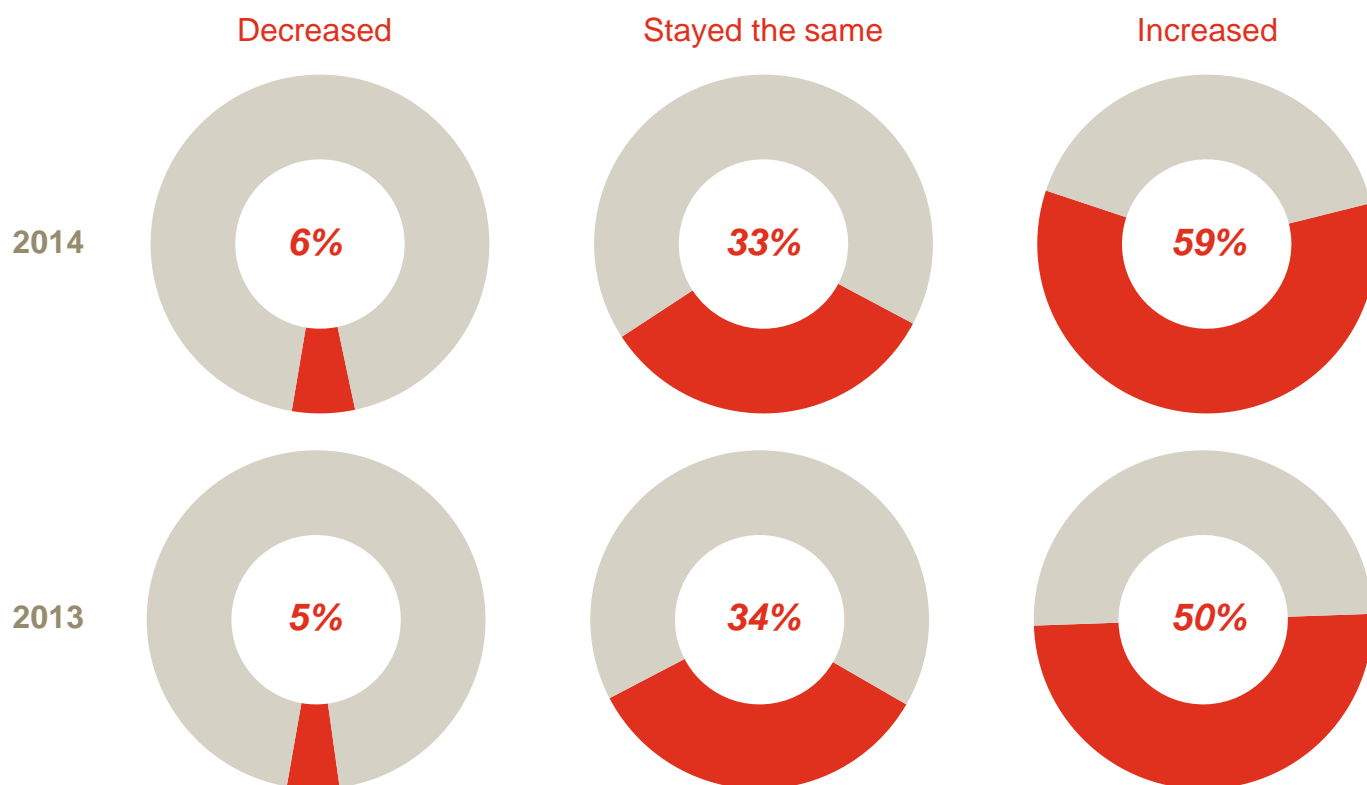


Base: (38)

4 Related data

Over half of Pharmaceutical & Life Sciences respondents stated that compliance staffing levels have increased over the past 12 months

Q7c How has corporate compliance function staffing changed over the past 12 months?

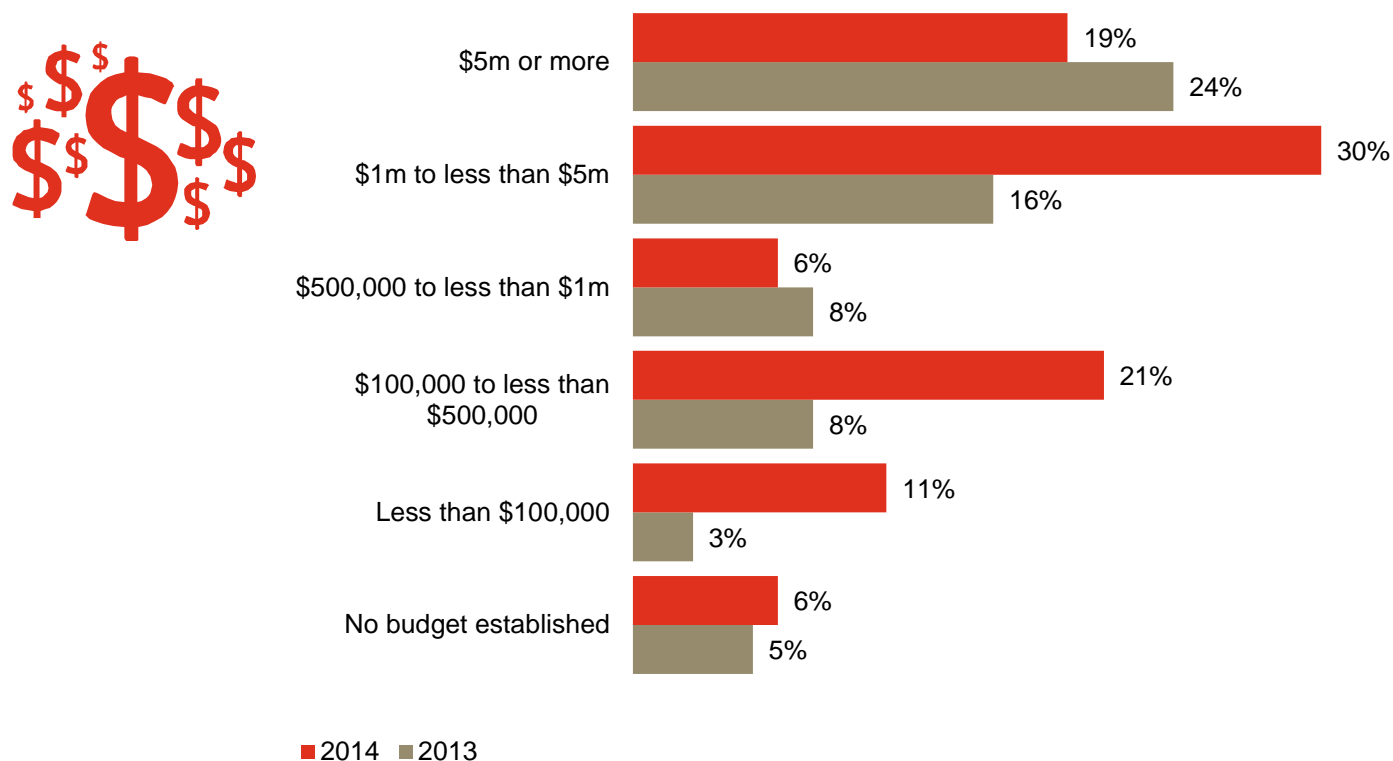


Base: (63, 38)

4 Related data

Almost half of Pharmaceutical & Life Sciences respondents estimate their total annual budget for compliance and related activities to be \$1m or more

Q9a What is the total approximate annual budget for compliance and related activities at the corporate compliance function level?

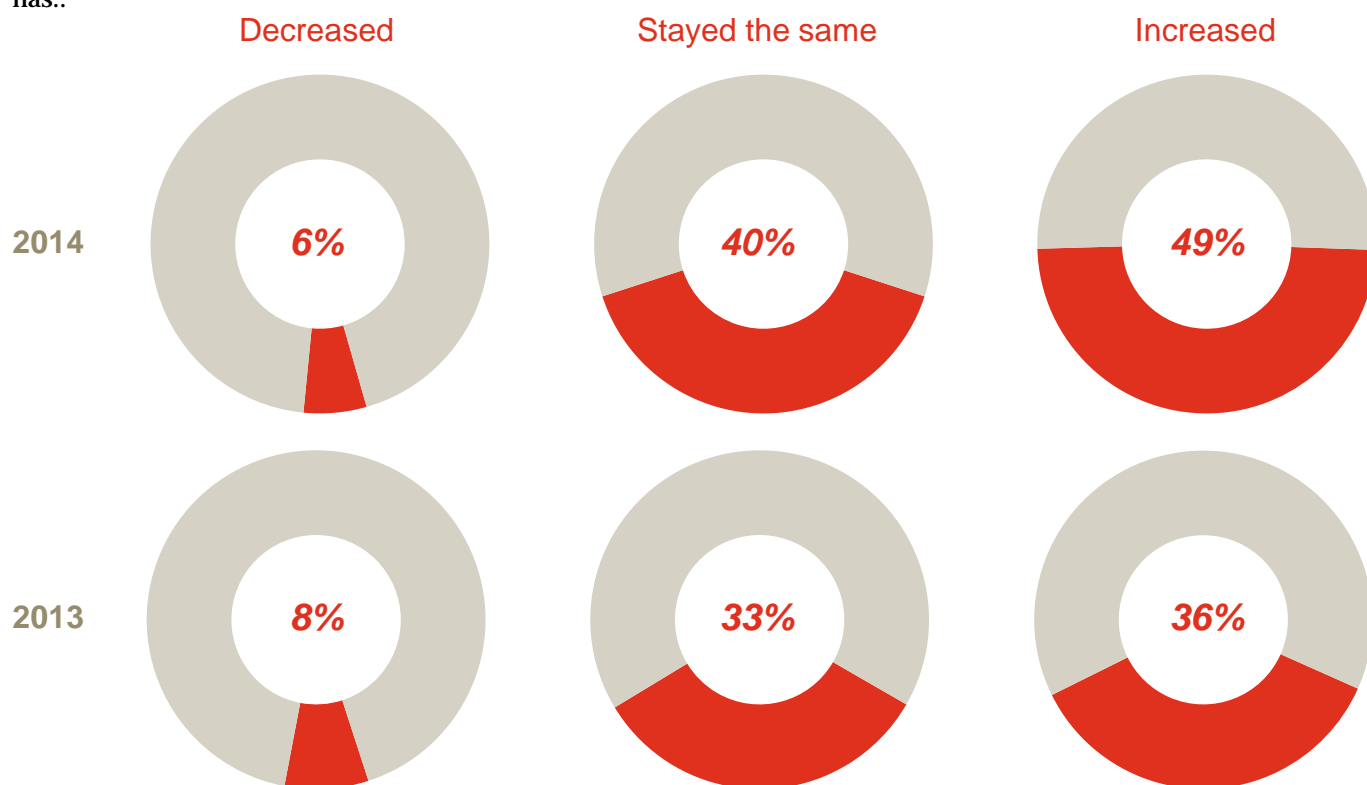


Base: (63, 38)

4 Related data

Nearly half of Pharmaceutical & Life Sciences respondents stated that their compliance budget has increased over the last year

Q9b In the last 12 months the budget for compliance and related activities at the corporate compliance function level has..

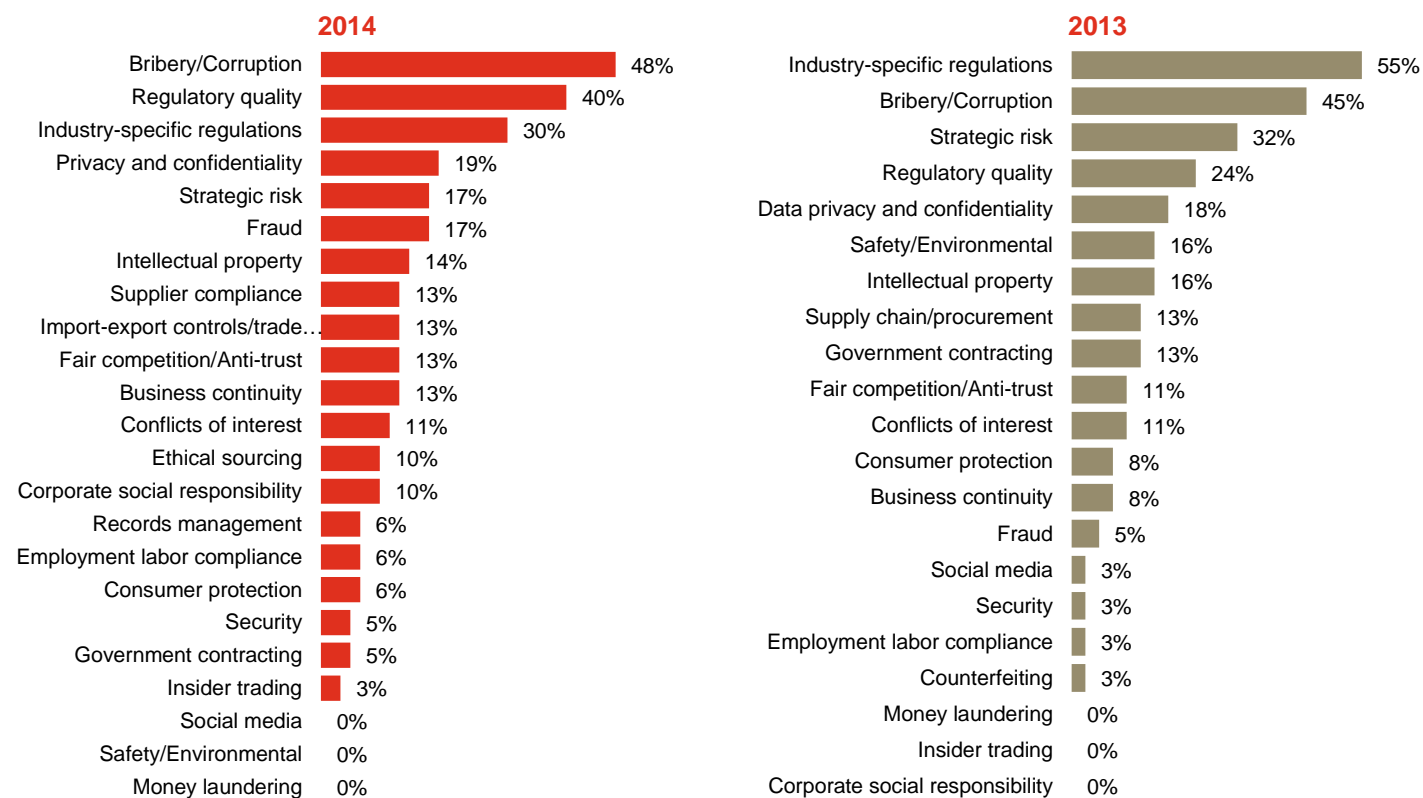


Base: (63, 36)

4 Related data

Bribery and corruption is the top-of-mind risk for Pharmaceutical & Life Sciences respondents

Q10a Please select your top 3 areas in terms of **current** perceived level of risk to your business?

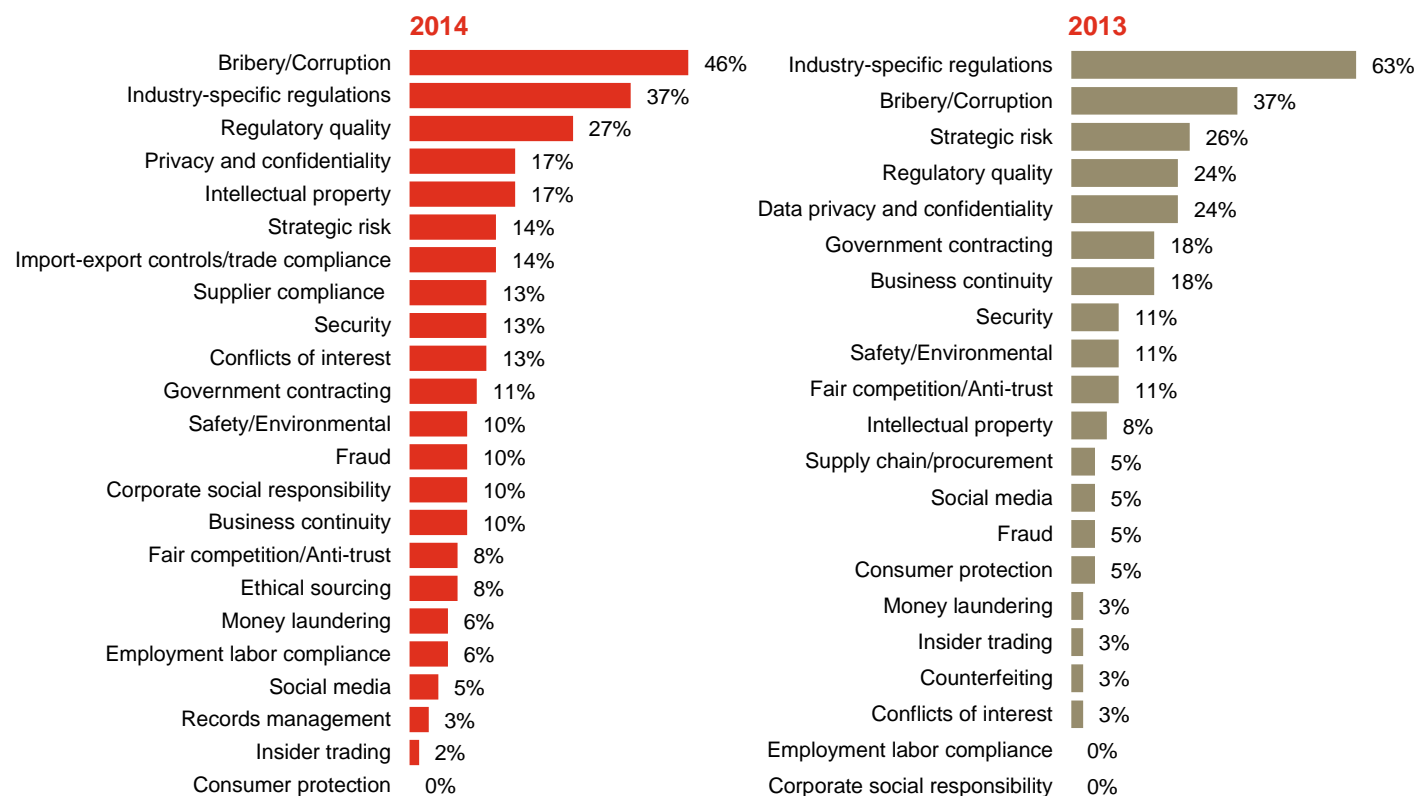


Base: (63, 38)

4 Related data

When looking to the future, Pharmaceutical & Life Sciences respondents believe bribery and corruption will remain the top risk to their business

Q10b Please select your top 3 areas in terms of **future** perceived level of risk to your business?

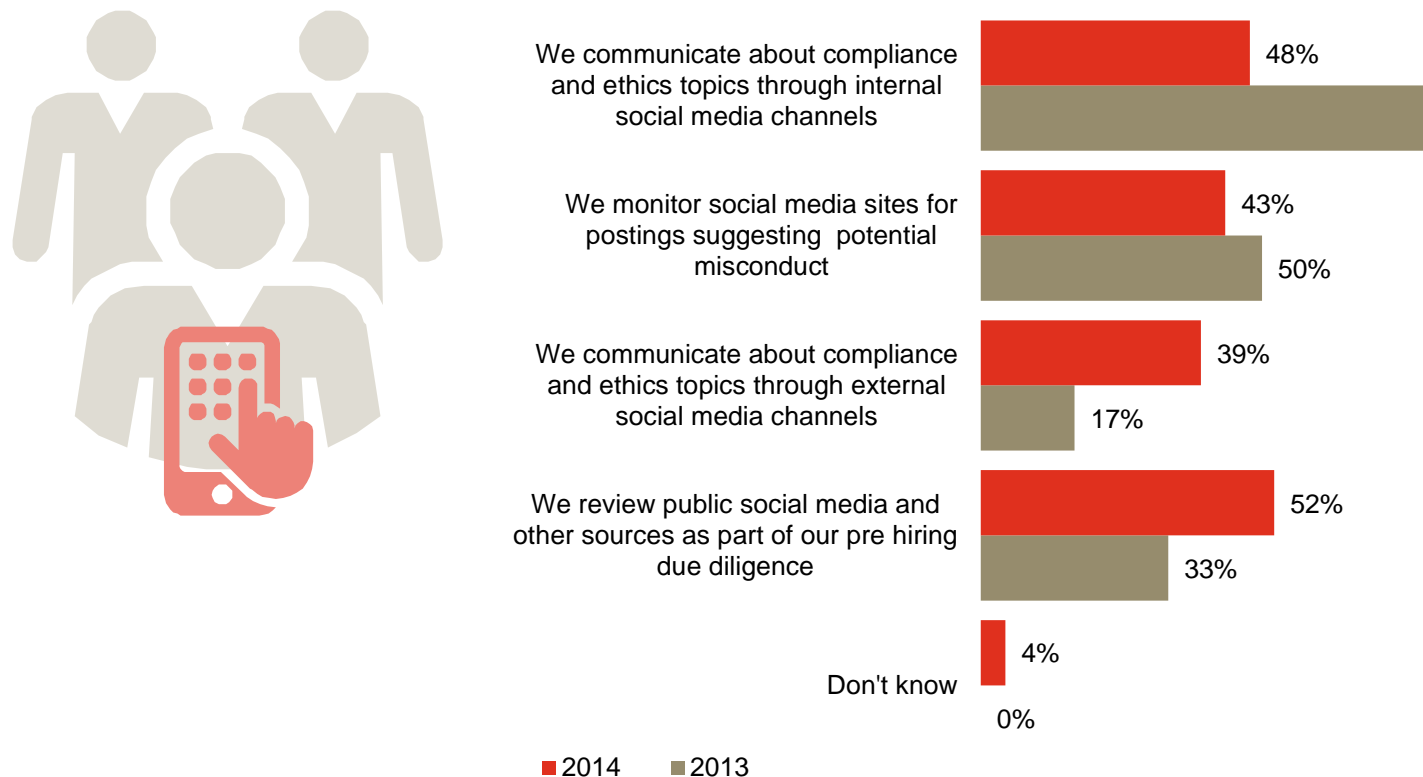


Base: (63, 38)

4 Related data

Use of external social media channels is growing within Pharmaceutical & Life Sciences organizations in relation to policy and compliance & ethics programs

Q19 In which of the following ways does your company use social media in your compliance and ethics program?



Base: (23, 6)

*Comparisons with last year's survey should be undertaken with caution due to the 2013 small base size

***To have a deeper conversation about how
the evolution of compliance may affect
your business, please contact:***

Principal Pharmaceutical and Life Sciences Contributor

Jonathan Kellerman

Principal

(973) 236 7880

jonathon.l.kellerman@us.pwc.com

Principal State of Compliance Survey Contributors

Sally Bernstein

Principal

(617) 530 4279

sally.bernstein@us.pwc.com

Andrea Falcione

Managing Director

(617) 530 5011

andrea.falcione@us.pwc.com

www.pwc.com