This is our third annual survey designed to give corporate compliance officers the benchmarking data they need to understand common industry practices today, and to plan for more effective and efficient compliance operations in the future.

September 2013
Pharmaceutical and Life Sciences Industry Report

In April 2013, PwC conducted its State of Compliance 2013 survey. Our International Survey Unit directed the survey to senior executives with responsibility for compliance, including general counsel and chief compliance officers. PwC’s goals are to explore how organizations continue to develop their compliance functions and to better understand how those compliance functions manage many stakeholders’ increasing demands in an effort to position themselves for the future. Participation in the survey gives compliance executives an opportunity to benchmark their programs against the programs of other well-known organizations in their own industries and others. We are proud to announce the results of our State of Compliance 2013 survey, culled from over 780 responses in a three-week period. This report is a summary of our key findings in the pharmaceutical and life sciences industry, based on survey responses from 38 leaders in the pharmaceutical and life sciences field; please also review the full survey results across all industries at http://www.pwc.com/us/compliancebenchmark2013.

Overall commentary

Companies in the pharmaceutical and life sciences industry are dealing with a risk profile driven by a rapidly changing competitive global market with heightened expectations, increasingly sophisticated customers, and greater vigilance around product sourcing. Since passage of the Affordable Care Act, new regulatory and operational strategies are being developed in order to reorient incentives between pharmaceutical companies and payers in order to control costs, define product value, and improve drug utilization. Following are our industry-specific comments.

Governance and resources

The pharmaceutical and life sciences industry is in line with other industries in terms of compliance governance (see page 6, Q3b, Q3c), with 79% of respondents indicating their companies have a dedicated chief compliance officer (CCO), the average of all companies responding being 80%. Pharmaceutical and life sciences is ahead of other industries in organizational positioning, with the majority, 53%, sitting in a separate compliance function, the overall average being 36%. The CCO function has become one of necessity, particularly because of regulators’ constant expansion of the spectrum of risk that a CCO must manage, the challenging and growing global risk landscape, and the fast-changing business model resulting from regulatory reform.

Pharmaceutical and life sciences are on par with the overall sample in regard to reporting structures (see page 7, Q4). Pharmaceutical and life sciences tended to have the highest percentage reporting formally to the CEO (46%), then to the general
Compliance committees are relatively well established within the pharmaceutical and life sciences industry, with 74% of pharmaceutical and life sciences respondents reporting a compliance committee within their organizations versus 59% overall.

counsel/legal (32%), and the board of directors/audit committee (11%) versus the overall sample, wherein the CEO ranked first (27%), followed by the general counsel (25%), and the board/audit committee (23%). This is reflective of the expectations set by regulators—like the Office of Inspector General—who, in their industry guidance, strongly recommend and their corporate integrity agreements essentially mandate that CCOs not report to the general counsel or chief financial officer but, rather, independently, to the CEO and/or the board. Whereas many compliance functions get their start in legal functions—particularly at smaller and emerging companies, whose resources are sparser and where compliance policies and controls have their origins in legal interpretations—they eventually evolve into more-independent compliance functions led by professionals with cross-functional experience in business process, operational controls, application of laws and regulations, and auditing and monitoring.

Ultimately, we anticipate that this percentage will continue to grow. In terms of longevity, a significant percentage (43%) of companies in the pharmaceutical and life sciences industry have had CCOs for 6 to 10 years versus 30% for the overall population (see page 6, Q3b, Q3c). That trend parallels the maturation of the compliance function in the industry—due largely to the driver of industry corporate integrity agreements that began almost a decade ago. On a day-to-day basis (see page 7, Q6), informal reporting tended to be more frequently (40%) to the general counsel (versus 32% overall) and CEO (34% versus 29% total). That trend is expected given that as compliance functions continue to develop, they form stronger partnerships with the business and support functions, like legal, in order to more effectively advise and support those who manage risk daily.

Compliance committees are relatively well established within the pharmaceutical and life sciences industry (see page 8, Q8a), with 74% of pharmaceutical and life sciences respondents reporting a compliance committee within their organizations versus 59% overall. Again, we find this is consistent with the expectations and mandates set by regulators. Every corporate integrity agreement requires, for example, that a company have a cross-functional compliance committee, so it is no surprise to see this industry represent such a high percentage.

Pharmaceutical and life sciences companies include mainly internal-facing constituents on their compliance committees (see page 8, Q8b), with top participation being from compliance (89%), legal (82%), finance (79%), and human resources (75%) compared with all respondents, at 76%, 77%, 58%, and 53%, respectively. Finance’s increased involvement in compliance is due in part to implementation of the Affordable Care Act, which has operational, financial, and tax-reporting implications, but due largely to the fact that many of the highest areas of compliance risk involve payments being made by companies to a variety of customers and the fast-expanding spend transparency requirements in the United States and globally. A complementary trend finds that core business stakeholders,
representing the core commercial, medical, and research functions, are playing more important roles on compliance committees given that compliance is becoming more and more a day-to-day business partner to these operations.

Consistent with the collaboration theme, pharmaceutical and life sciences organizations (see page 10, Q11) tend to use a hybrid model for resourcing the majority of the time (55%) versus 58% in total. A hybrid model consists of central resources (resources in a central corporate function) and decentralized resources (staff in the business that report either to the central compliance function or directly to business unit leadership).

A central philosophy of many mature compliance functions is the drive to embed ownership of compliance on a day-to-day basis in the business with the people who are accountable for the operations of that business.

Consequently, compliance does not own compliance; rather, compliance becomes a trusted advisor to the business stakeholders, providing guidance, tools, and, as necessary, resources, for the business to effectively own compliance. Additionally, as regulators continue to expand the expected span of control across all parts of the value chain and as global expansion significantly extends the needs for effective risk management, there are fewer and fewer resources within the compliance function alone to address and manage all of the complex risk areas across the enterprise—thus the need to more effectively embed compliance in the business and to empower those stakeholders with the tools and capabilities necessary for them to truly be accountable for compliance.

Pharmaceutical and life sciences organizations tend to be weighted to the lower end of staffing in the central function, with fewer than 10 employees the majority of the time (see page 9, Q9a&b). However, pharmaceutical and life sciences companies are more likely to have relatively higher numbers of compliance resources in the corporate compliance function than the overall sample has, which lends further to the evidence that the pharmaceutical and life sciences industry is establishing compliance leadership.

As it relates to investments in compliance, there appear to be slight differences between the budgets of companies in the pharmaceutical and life sciences space and the budgets of companies in other industries. The largest category of responses (26%) indicated a budget in the $5-million-or-more range versus the total sample, which returned 17% (see page 9, Q10a). It is evident that compliance departments tend to be larger at pharmaceutical and life sciences companies—by observation of the budget sizes of these companies. As noted earlier, this is due largely to regulators’ expanding expectations for span of control of compliance across the value chain, coupled with the fast-growing risk profile of a global market. Even unique compliance challenges, such as the ones created by the Sunshine Act requirements in the Affordable Care Act (i.e. those requiring manufacturers to aggregate and report total transfer of value to healthcare professionals and organizations), can demand significant budget and resource investment over a multi-year time period. We can also observe that despite the economic climate, it appears that compliance budgets are being maintained or indeed enhanced (see page 10, Q10b).
Managing risk and program effectiveness

When considering current risk profiles (see page 11, Q12a), the majority of companies responded that their top risks were data privacy and confidentiality (31%), industry-specific regulations (30%), and bribery and corruption (28%). Pharmaceutical and life sciences companies overwhelmingly ranked their risks focused on stringent regulatory regimes and increased presence in emerging markets. Concerns with industry-specific regulations (55%), corruption/bribery (45%), and strategic risk (32%) are higher among those in the pharmaceutical and life sciences industry (see page 11, Q12a) compared with the overall responses’ 31%, 28%, and 20%, respectively. This is consistent with what we hear our clients tell us are their greatest risk areas of concern: off-label promotion, false claims act violations, spend transparency, and bribery/corruption.

Compliance audits (32%) are the most-often-used measures of compliance program effectiveness in the pharmaceutical and life sciences industry, with hotline/help line metrics (16%) and risk assessment results (13%) rounding out the top three methods (see page 12, Q18). Audits often serve as effective ways to test the effectiveness of policies, controls, and training. This is consistent with the total sample.

Technology

When it comes to leveraging technology to support compliance activities, the pharmaceutical and life sciences industry is somewhat consistent with the broader sample. Training, documentation management, and employee surveys rank as the top three uses for pharmaceutical and life sciences (see page 12, Q22). For documentation management, the increased use of data encompasses powerful tools that store, integrate, and analyze vast amounts of disparate data to make clinical decisions and to store real-world evidence in the evaluation of drug effectiveness.

More and more, compliance is looking to technology to bring about better business process and more-effective compliance controls. As a prime example, one need only look at the industry developments...
involving spend transparency and the need to leverage technology that leads to better business processes for the collection, validation, and reporting of mass quantities of diverse information that often comes from disparate systems. Without leveraging advances in technology and data—found primarily in enhancements to source information systems and data management and quality—companies rely primarily on cumbersome manual processes that do not promote complete and accurate data. Without that, management struggles to validate data quality, and it lacks the ability to demonstrate the adequacy and effectiveness of its respective compliance programs.

This report provides a view of data from the PwC State of Compliance 2013 Survey. In the following section are specific comparisons of industry information with the overall results. While there are some distinct differences discussed in this industry report, please also see the overall report at http://www.pwc.com/us/compliancebenchmark2013 for a broader perspective on the state of compliance.
Q3a Does your organization have a Chief Compliance Officer/Head of Compliance?

- Yes: 79%
- No: 18%
- DK: 3%

Pharmaceutical/Life Sciences

- Yes: 79%
- No: 18%
- DK: 3%

Note: base sizes are too small for Q3d & Q3e as only 18% do not have a CCO

Q3b How long has your organization had a chief compliance officer/head of compliance?

- Less than a year: 3%
- 1-5 years: 25%
- 6-10 years: 30%
- More than 10 years: 34%

Q3c In what area of your organization is the chief chief compliance officer/head of compliance based?

- Legal: 36%
- Compliance (Separate function): 36%
- IA/Business Assurance: 8%
- Risk: 7%
- HR: 3%

Q3d In what area of your organization does oversight for compliance reside?

- Legal: 39%
- Internal audit: 21%
- HR: 4%
- Risk: 3%
- Compliance: 3%

Q3e Within this area, what is the job title of the person with most responsibility for compliance?

- SVP/EVP level Executive: 24%
- VP level Executive: 20%
- Director: 19%
- C-level Executive: 16%
- Other: 8%
Q4 To whom does the chief compliance officer or equivalent formally report in your organization?

![Chart showing the distribution of formal reporting lines for chief compliance officers.](chart1)

Q6 What is the day to day functional reporting line for the chief compliance officer or equivalent?

![Chart showing the distribution of day-to-day reporting lines.](chart2)
Q8a Does your company have an in-house compliance committee to support compliance efforts?

74% of respondents within pharmaceuticals told us they have a compliance committee within their organization.

Q8b Which of the following departments or functions serve on the compliance committee?

- Legal: 77% (Overall), 82% (Pharmaceutical)
- Compliance: 76% (Overall), 89% (Pharmaceutical)
- Internal Audit: 61% (Overall), 57% (Pharmaceutical)
- Finance: 58% (Overall), 79% (Pharmaceutical)
- Human Resources: 53% (Overall), 75% (Pharmaceutical)
- Operations: 45% (Overall), 61% (Pharmaceutical)
- Business units: 37% (Overall), 43% (Pharmaceutical)
- Information Technology: 41% (Overall), 43% (Pharmaceutical)
- Procurement: 19% (Overall), 25% (Pharmaceutical)
- Sales and Marketing: 23% (Overall), 23% (Pharmaceutical)
- Supply Chain: 18% (Overall), 36% (Pharmaceutical)
- Investor Relations: 11% (Overall), 11% (Pharmaceutical)
- Other: 13% (Overall), 18% (Pharmaceutical)
Q9a&b How many full time equivalents are working in the corporate compliance function or are based outside of the corporate compliance function?

<table>
<thead>
<tr>
<th>Overall</th>
<th>Pharmaceutical</th>
</tr>
</thead>
<tbody>
<tr>
<td>More than 100</td>
<td>More than 100</td>
</tr>
<tr>
<td>26-100</td>
<td>26-100</td>
</tr>
<tr>
<td>11-25</td>
<td>11-25</td>
</tr>
<tr>
<td>6-10</td>
<td>6-10</td>
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<tr>
<td>3-5</td>
<td>3-5</td>
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<tr>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Less than one</td>
<td>Less than one</td>
</tr>
<tr>
<td>FTEs in corporate compliance function</td>
<td>FTEs in corporate compliance function</td>
</tr>
<tr>
<td>FTEs working in compliance but outside the compliance function</td>
<td>FTEs working in compliance but outside the compliance function</td>
</tr>
</tbody>
</table>

Q10a What is the total approximate annual budget for compliance and related activities at the corporate compliance function level? (US only)

US

- No budget established: 13% (Overall) 7% (Pharmaceutical)
- Less than $100,000: 7% (Overall) 3% (Pharmaceutical)
- $100,000-$500,000: 10% (Overall) 10% (Pharmaceutical)
- $500,000-$1m: 17% (Overall) 10% (Pharmaceutical)
- $1m-$5m: 25% (Overall) 16% (Pharmaceutical)
- $5m or more: 26% (Overall) 17% (Pharmaceutical)
Q10b In the last 12 months the budget for compliance and related activities at the corporate compliance function level has...

Q11 Which of the following best describes the compliance structure in your organization?
Q12a Please select your top 3 areas in terms of current perceived level of risk to your business?

<table>
<thead>
<tr>
<th>Area</th>
<th>Overall</th>
<th>Pharmaceutical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data privacy and confidentiality</td>
<td>18</td>
<td>32</td>
</tr>
<tr>
<td>Industry-specific regulations</td>
<td>31</td>
<td>45</td>
</tr>
<tr>
<td>Anti-corruption / Anti-bribery</td>
<td>28</td>
<td>32</td>
</tr>
<tr>
<td>Strategic risk</td>
<td>20</td>
<td>18</td>
</tr>
<tr>
<td>Safety / Environmental</td>
<td>18</td>
<td>17</td>
</tr>
<tr>
<td>Conflicts of interest</td>
<td>16</td>
<td>11</td>
</tr>
<tr>
<td>Security</td>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td>Fraud</td>
<td>14</td>
<td>8</td>
</tr>
<tr>
<td>Business continuity</td>
<td>14</td>
<td>8</td>
</tr>
<tr>
<td>Regulatory quality</td>
<td>24</td>
<td></td>
</tr>
<tr>
<td>Employment labor compliance</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>Intellectual property</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>Consumer protection</td>
<td>11</td>
<td>11</td>
</tr>
<tr>
<td>Supply chain/procurement</td>
<td>10</td>
<td>13</td>
</tr>
<tr>
<td>Government contracting</td>
<td>9</td>
<td>13</td>
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<tr>
<td>Fair competition / Anti-trust</td>
<td>8</td>
<td>8</td>
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<tr>
<td>Money laundering</td>
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<td></td>
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<tr>
<td>Corporate social responsibility</td>
<td>0</td>
<td>6</td>
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<tr>
<td>Insider trading</td>
<td>0</td>
<td>4</td>
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<tr>
<td>Social media</td>
<td>3</td>
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</tr>
<tr>
<td>Counterfeiting</td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>

Q12b Please select your top 3 areas in terms of future perceived level of risk to your business?

Overall:
- Data privacy and confidentiality: 33%
- Industry-specific regulations: 31%
- Strategic risk: 24%

Pharmaceutical:
- Industry-specific regulations: 63%
- Anti-corruption/Anti-bribery: 37%
- Strategic risk: 26%
Q18 Please rank the top 3 indicators and metrics that in your opinion are most important in evaluating the effectiveness of your ethics and compliance program

32% Compliance audit results
16% Hotline/helpline metrics
13% Risk assessment results

<table>
<thead>
<tr>
<th>% ranked 1st</th>
<th>Pharmaceutical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compliance audit results</td>
<td>32%</td>
</tr>
<tr>
<td>Hotline/helpline metrics</td>
<td>16%</td>
</tr>
<tr>
<td>Risk assessment results</td>
<td>13%</td>
</tr>
<tr>
<td>Results from regulatory visit</td>
<td>11%</td>
</tr>
<tr>
<td>Training data (completion rates, competency tests etc)</td>
<td>11%</td>
</tr>
<tr>
<td>Cost of non-compliance (penalties, litigation and other consequences of non-compliance incidents)</td>
<td>5%</td>
</tr>
<tr>
<td>Employee disclosures (e.g. conflicts of interest and gift reporting)</td>
<td>3%</td>
</tr>
<tr>
<td>Employee questionnaires or culture surveys</td>
<td>3%</td>
</tr>
<tr>
<td>Customer &amp; other third party feedback/complaints (not reported through hotline/helpline)</td>
<td>3%</td>
</tr>
<tr>
<td>Aging and disposition of litigation and enforcement</td>
<td>0%</td>
</tr>
<tr>
<td>Cost of compliance program activities</td>
<td>0%</td>
</tr>
<tr>
<td>Monitoring of press and public statements</td>
<td>0%</td>
</tr>
</tbody>
</table>

Q22 What activities do you most rely on technology to assist with?

- Training (delivery, testing, and tracking): 82%
- Documentation management (e.g., policies, procedures, templates): 74%
- Employee surveys: 74%
- Policy management: 58%
- Case/incident management: 47%
- Audit management: 47%
- Risk assessment: 40%
- Legislative/regulatory information tracking: 36%
- Vendor/third-party management: 32%
- Regulatory visit tracking and related outcomes (inspections, violation notices, fines/penalties): 32%
- Don't know: 7%
- Other: 2%
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