

# 2007/08 Compliance Better Practices Project: Final Survey, Interview Results and Polling Questions

# Table of contents

Section		Page
1	Scope and Methodology	3
2	Survey, Polling & Interview Findings	6
3	Analysis and Discussion	30
4	Questions?	36
Appendix	Company Demographics	37

# Section 1

## Scope and Methodology

# Scope and Methodology

## Electronic Survey (Spring 2008)

- Thirty-two companies participated
- Developed in consultation with AdvaMed and DDCG Working Group
  - With input from PwC survey professionals
- Confidential – data was aggregated, not linked to individuals/companies
- Survey builds on prior efforts – current survey is most rigorous and comprehensive

## Follow-Up Interviews (Fall 2008)

- Sought additional information on key compliance topics (e.g., program structure, reporting)
- Looked into the “why” behind some compliance practices, challenges
- Incorporation into presentation required some subjective judgments by PwC and King & Spalding

## Webcast Polling Results (Spring 2009)

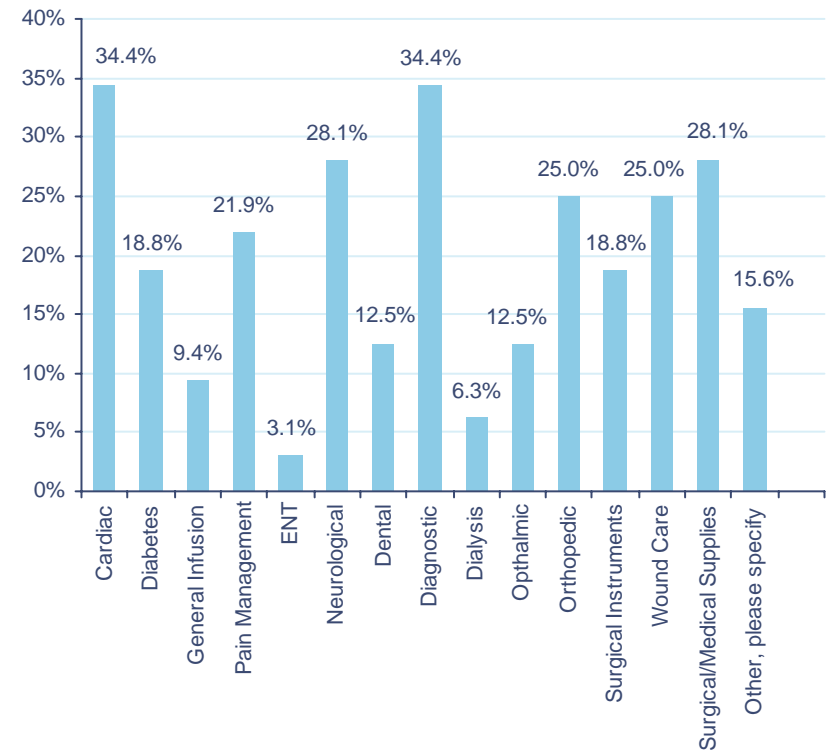
- Supplemental information captured via webcast polling, helping to identify specific answers on key compliance points (e.g., implementation of new Code, meal values)

# Scope and Methodology

## Principal markets of survey respondents

(Respondents were allowed to choose multiple responses)

Response	Frequency	Count
Cardiac	34.4%	11
Diabetes	18.8%	6
General Infusion	9.4%	3
Pain Management	21.9%	7
ENT	3.1%	1
Neurological	28.1%	9
Dental	12.5%	4
Diagnostic	34.4%	11
Dialysis	6.3%	2
Ophthalmic	12.5%	4
Orthopedic	25.0%	8
Surgical Instruments	18.8%	6
Wound Care	25.0%	8
Surgical/medical supplies	28.1%	9
Other, please specify:	15.6%	5



## Section 2

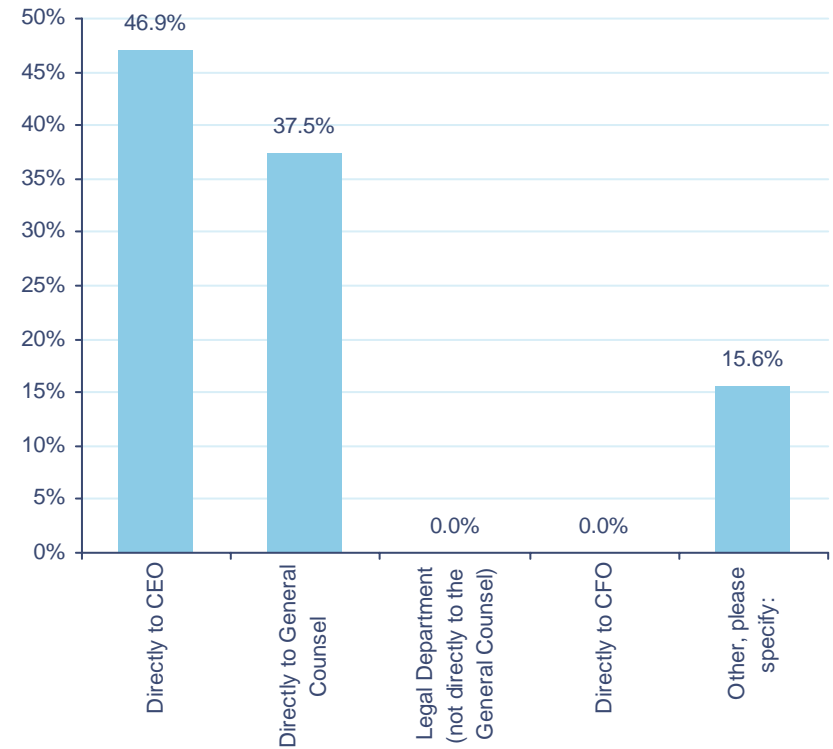
# Survey, Polling & Interview Findings

# Survey, Polling & Interview Findings

To whom does the most senior compliance officer in your company report?

(Respondents could only choose a single response)

Response	Frequency	Count
CEO	46.9%	15
General Counsel	37.5%	12
Legal Department (not directly to the General Counsel)	0.0%	0
Directly to CFO	0.0%	0
Other, please specify:	15.6%	5

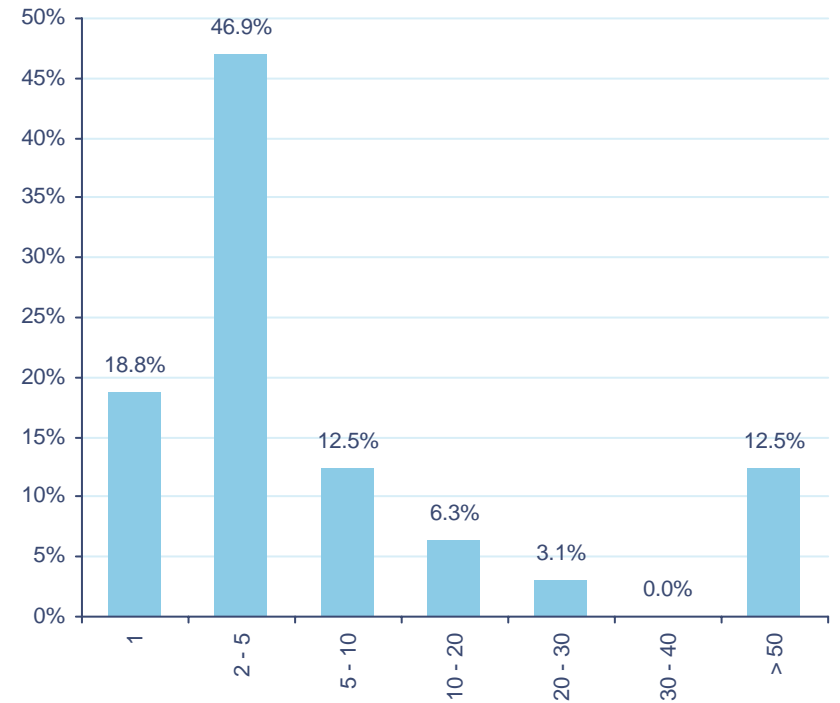


# Survey, Polling & Interview Findings

What is the number of full time (or equivalent) compliance staff members in your company?

(Respondents could only choose a single response)

Response	Frequency	Count
1	18.8%	6
2 - 5	46.9%	15
5 - 10	12.5%	4
10 - 20	6.3%	2
20 - 30	3.1%	1
30 - 40	0.0%	0
> 50	12.5%	4

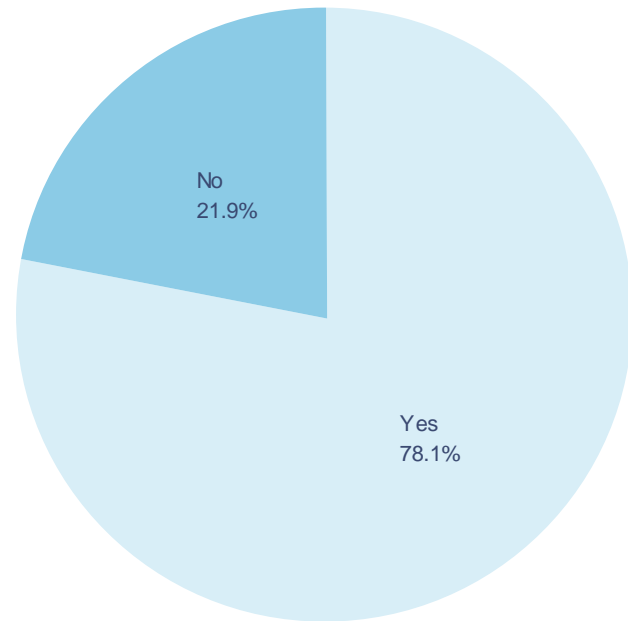


# Survey, Polling & Interview Findings

Does the Board, or a Board Committee, have oversight responsibility for compliance in your company?

(Respondents could only choose a single response)

Response	Frequency	Count
Yes	78.1%	25
No	21.9%	7

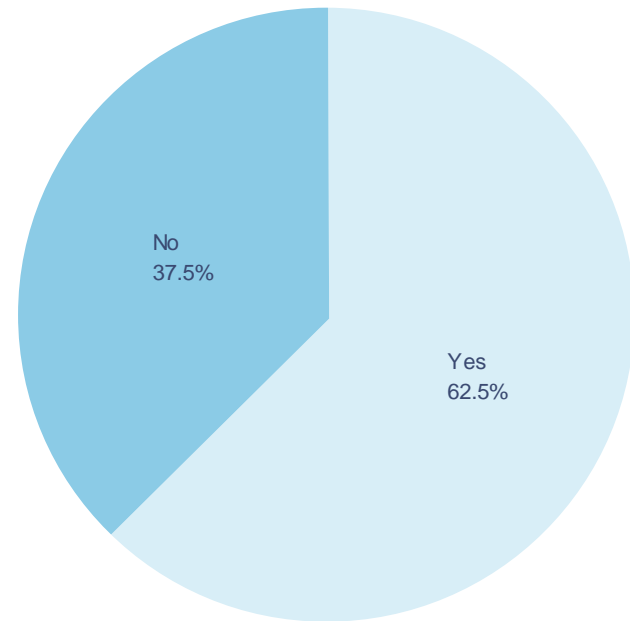


# Survey, Polling & Interview Findings

Does your company have a written policy/procedure or established practice for notifying the Board of compliance related investigations or issues?

(Respondents could only choose a single response)

Response	Frequency	Count
Yes	62.5%	20
No	37.5%	12



# Survey, Polling & Interview Findings

## Policies the Compliance Function Owns

- Business Code of Conduct
- Interactions with Healthcare Professionals (HCPs)
- Ethics and Compliance Procedures
- No Charge Products Policy
- Demonstration Units Policy
- FCPA (Anti-Bribery/Anti-Kickback)
- Privacy or HIPAA policy and training
- Bio-ethics
- Government Officials

# Survey, Polling & Interview Findings

## Adoption of the AdvaMed Code of Ethics

Industry has been quick to adopt, implement and give further definition to the AdvaMed Code of Ethics and its provisions. Companies have adopted the Code and now have implemented corresponding policies, standards and processes.

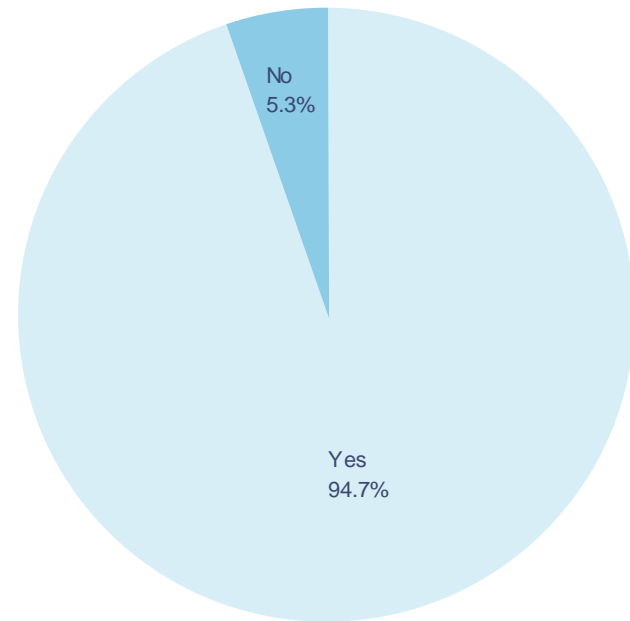
- Ninety percent (90%) of respondents have policies in place that address all provisions of the AdvaMed Code.
  - Sixty seven percent (67%) of respondents have given further definition to the Code.
  - Sixty seven percent (67%) of respondents have an approval process for its related activities per Code provision.
- Close to twenty five percent (25%) of survey respondents in 2005 had no prior corresponding compliance policies in place. They created a new internal company policy in response to the AdvaMed Code.

# Survey, Polling & Interview Findings

Will your company be implementing new policies and procedures to reflect the changes of the new 2009 AdvaMed Code of Ethics, effective July 2009?

Placeholder for text

Choice	Number of Votes per Option	% of Total Votes cast
Yes	18	94%
No	1	5%

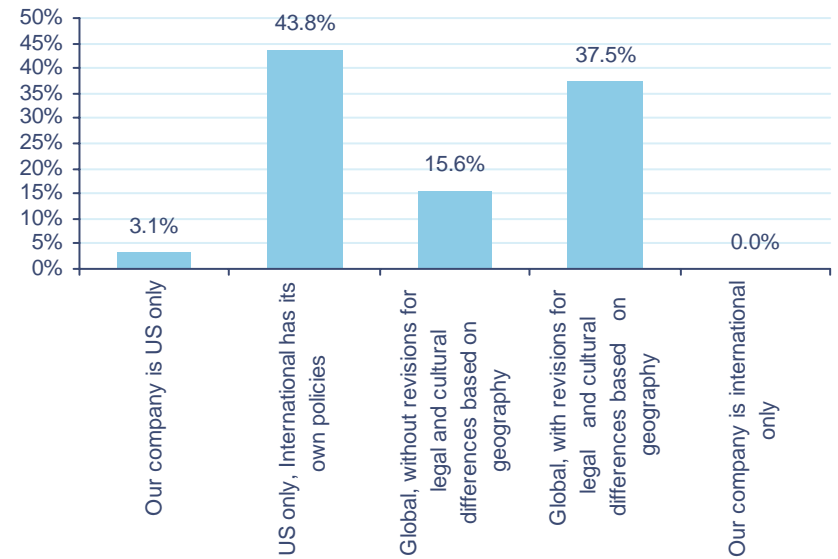


# Survey, Polling & Interview Findings

Do you apply the AdvaMed Code (and related policies) US operations, ex-US operations, or both?

(Respondents could only choose a single response)

Response	Frequency	Count
US only	3.1%	1
US only (international has separate policies)	43.8%	14
Global	15.6%	5
Global (with revisions for legal and cultural differences)	37.5%	12
Our company is international only	0.0%	0

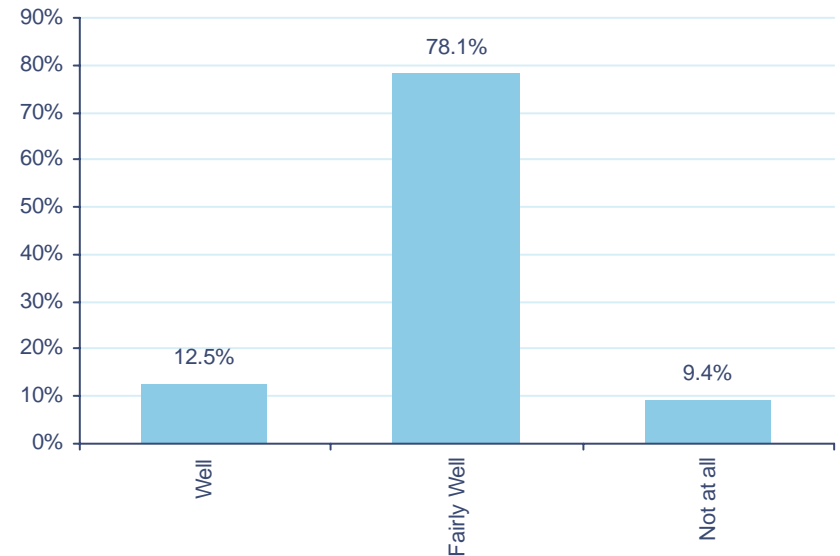


# Survey, Polling & Interview Findings

How well do you believe other medical device companies comply with the AdvaMed Code within your industry?

(Respondents could only choose a single response)

Response	Frequency	Count
Well	12.5%	4
Fairly Well	78.1%	25
Not at all	9.4%	3

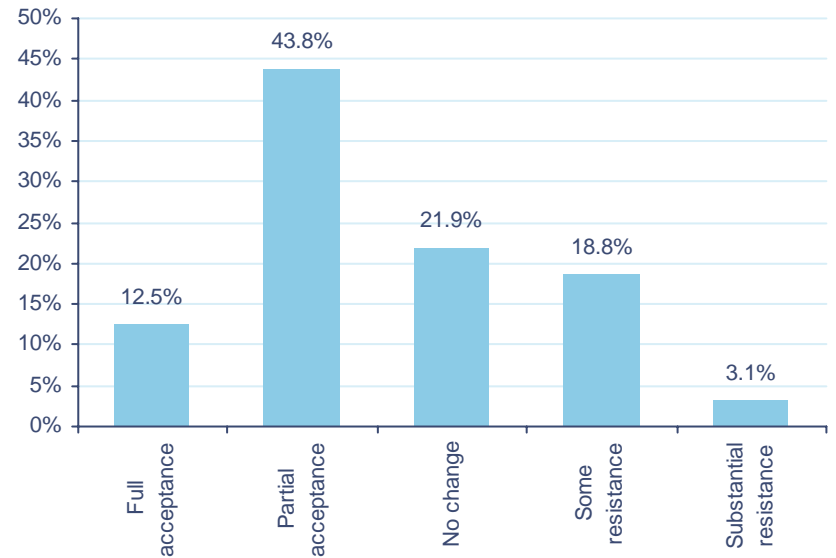


# Survey, Polling & Interview Findings

How have your customers reacted to your compliance with the AdvaMed Code?

(Respondents could only choose a single response)

Response	Frequency	Count
Full acceptance	12.5%	4
Partial acceptance	43.8%	14
No change	21.9%	7
Some resistance	18.8%	6
Substantial resistance	3.1%	1

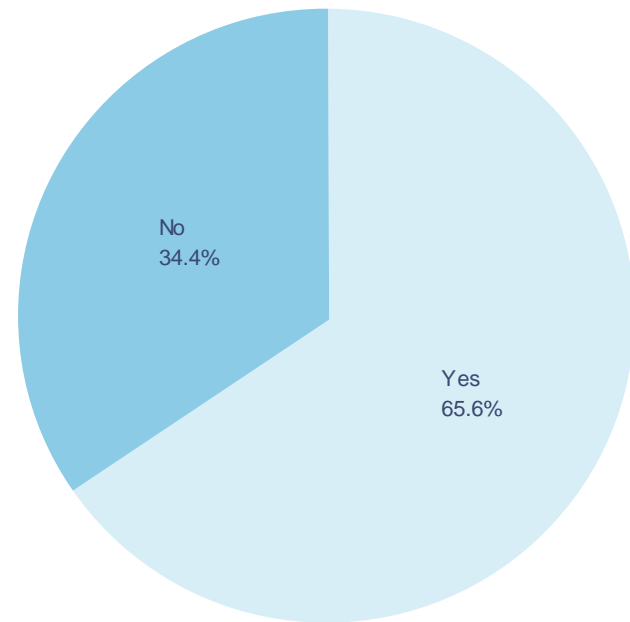


# Survey, Polling & Interview Findings

Does your company have a policy regarding Fair Market Value (FMV) for HCP services?

(Respondents could only choose a single response)

Response	Frequency	Count
Yes	65.6%	21
No	34.4%	11

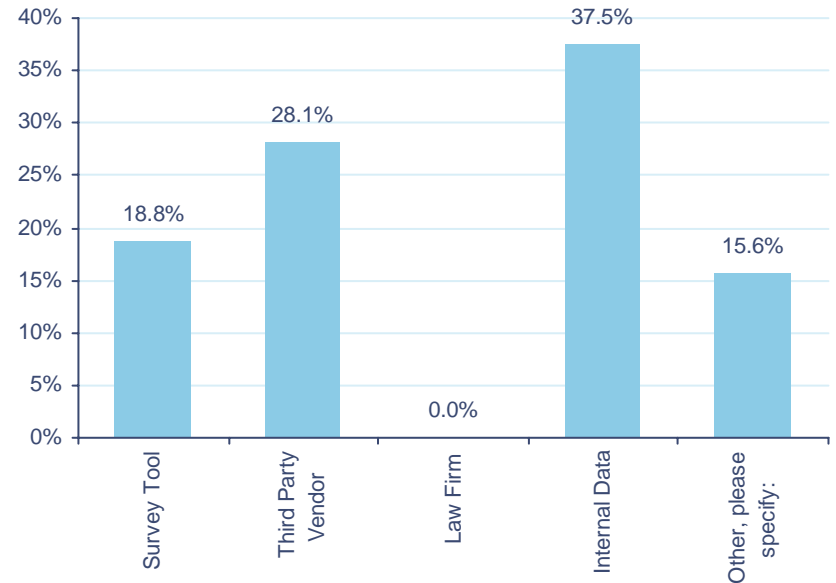


# Survey, Polling & Interview Findings

What method does your company use for determining Fair Market (FMV) amounts/ranges for services?

(Respondents could only choose a single response)

Response	Frequency	Count
Survey Tool	18.8%	6
Third Party Vendor	28.1%	9
Law Firm	0.0%	0
Internal Data	37.5%	12
Other, please specify:	15.6%	5

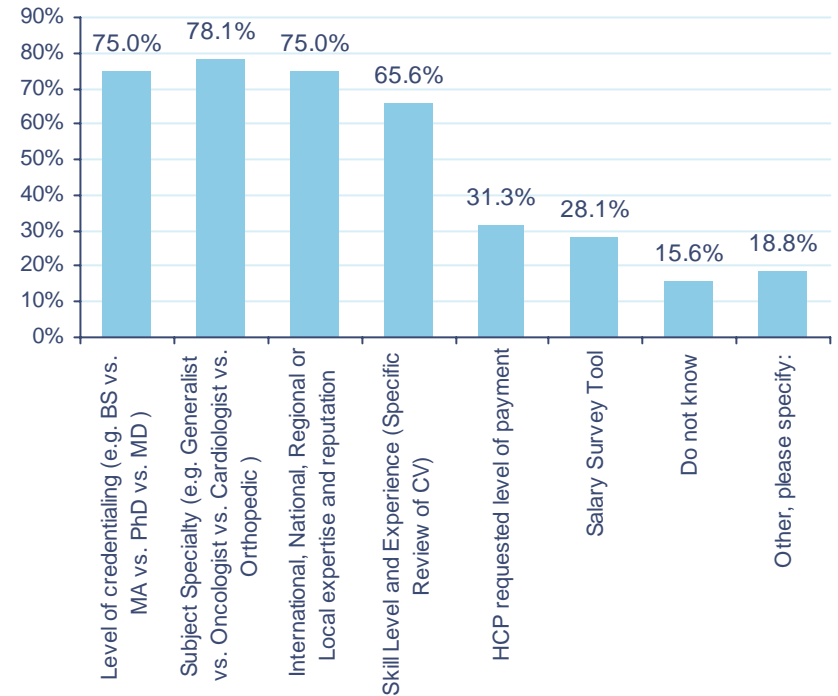


# Survey, Polling & Interview Findings

Please indicate which factors are considered in determining FMV for an HCP engaged to perform work for your company.

(Respondents were allowed to choose multiple responses)

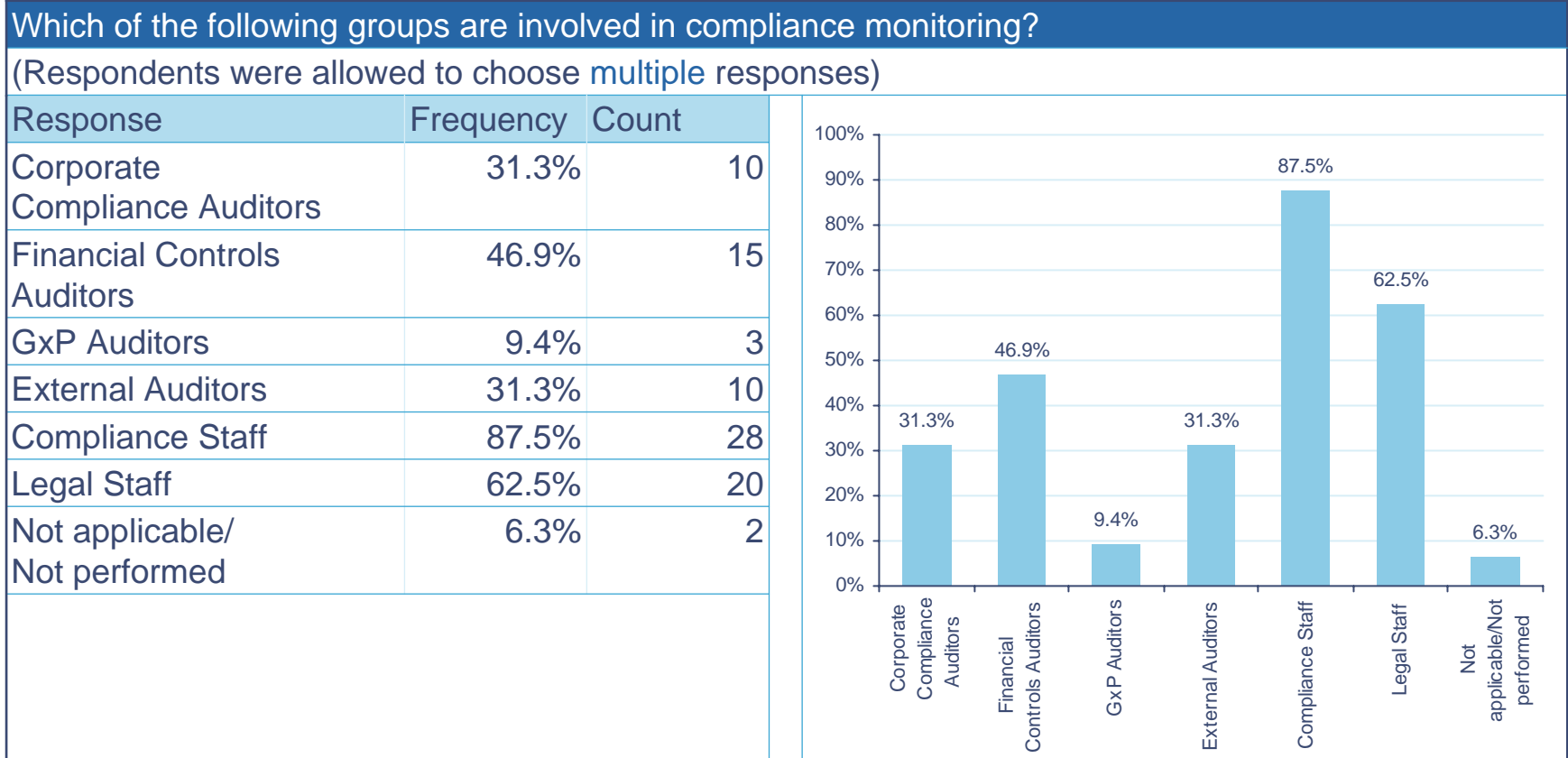
Response	Frequency	Count
Level of credentialing (e.g. BS vs. MA vs. PhD vs. MD )	75.0%	24
Subject Specialty (e.g. Generalist vs. Oncologist vs. Cardiologist vs. Orthopedic )	78.1%	25
International, National, Regional or Local expertise and reputation	75.0%	24
Skill Level and Experience (Specific Review of CV)	65.6%	21
HCP requested level of payment	31.3%	10
Salary Survey Tool	28.1%	9
Do not know	15.6%	5
Other, please specify:	18.8%	6



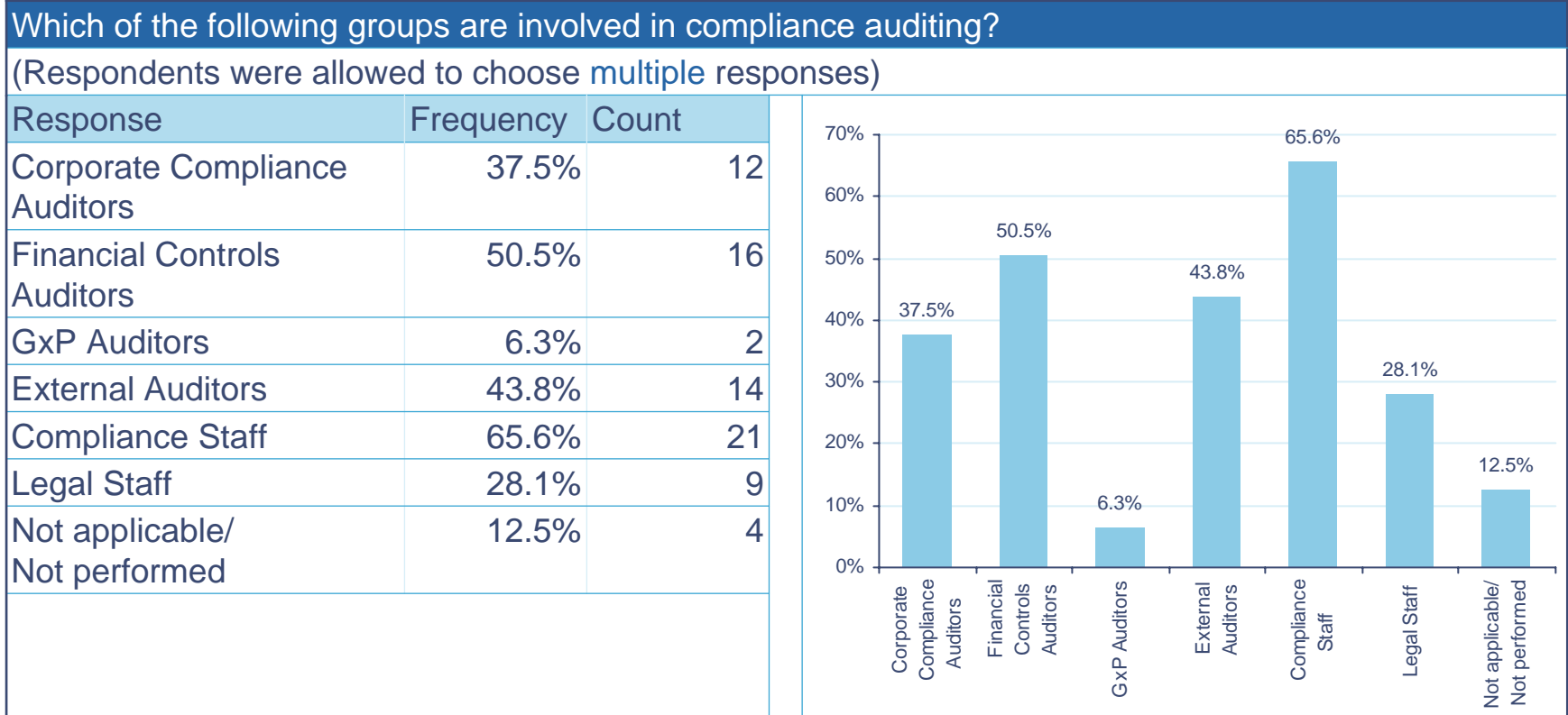
## Challenges to Assessments and Auditing

- “Budget and systems issues”
- Lack of a robust compliance audit function; no infrastructure with time, expertise for compliance
  - “A lack of understanding with how to complete them, the methodology and approach. How to collect right info and roll into a report that is useful.”

# Survey, Polling & Interview Findings



# Survey, Polling & Interview Findings

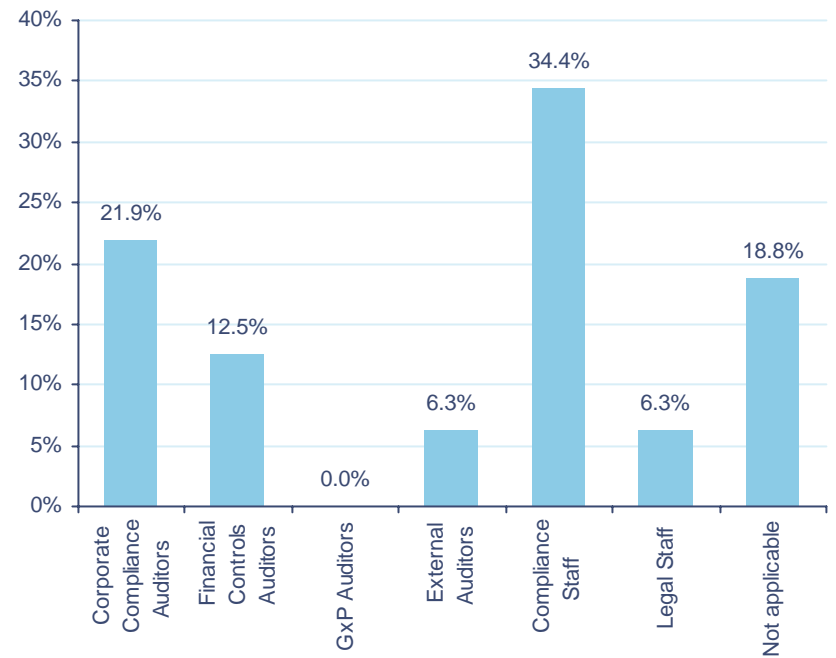


# Survey, Polling & Interview Findings

Specify which of these groups has primary oversight for compliance auditing:

(Respondents could only choose a single response)

Response	Frequency	Count
Corporate Compliance Auditors	21.9%	7
Financial Controls Auditors	12.5%	4
GxP Auditors	0.0%	0
External Auditors	6.3%	2
Compliance Staff	34.4%	11
Legal Staff	6.3%	2
Not applicable	18.8%	6

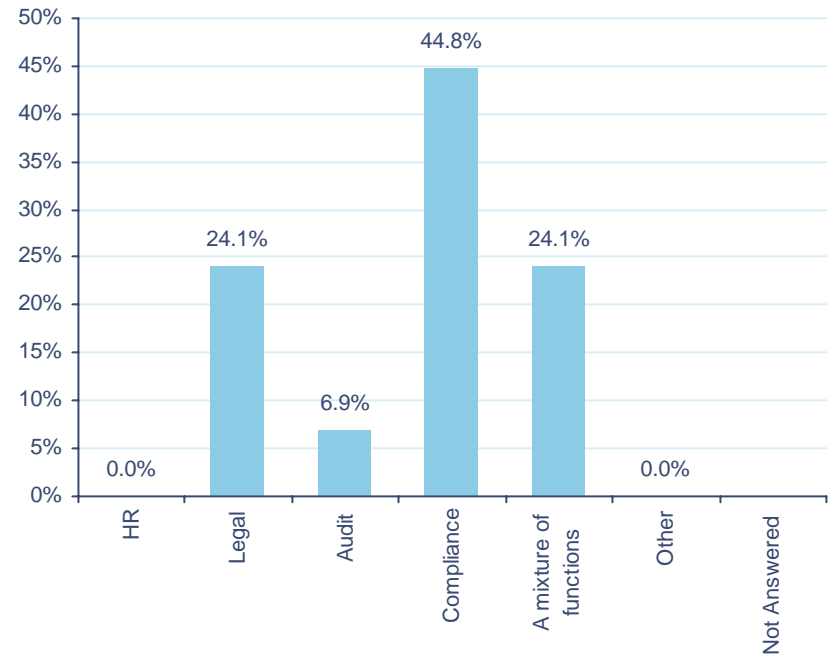


# Survey, Polling & Interview Findings

Typically, which group has primary oversight for internal investigations or review when conduct inconsistent with compliance policies is suspected/detected?

(Respondents could only choose a single response)

Response	Frequency	Count
HR	0.0%	0
Legal	24.1%	7
Audit	6.9%	2
Compliance	44.8%	13
A mixture of functions	24.1%	7
Other	0.0%	0
Not Answered	-	3

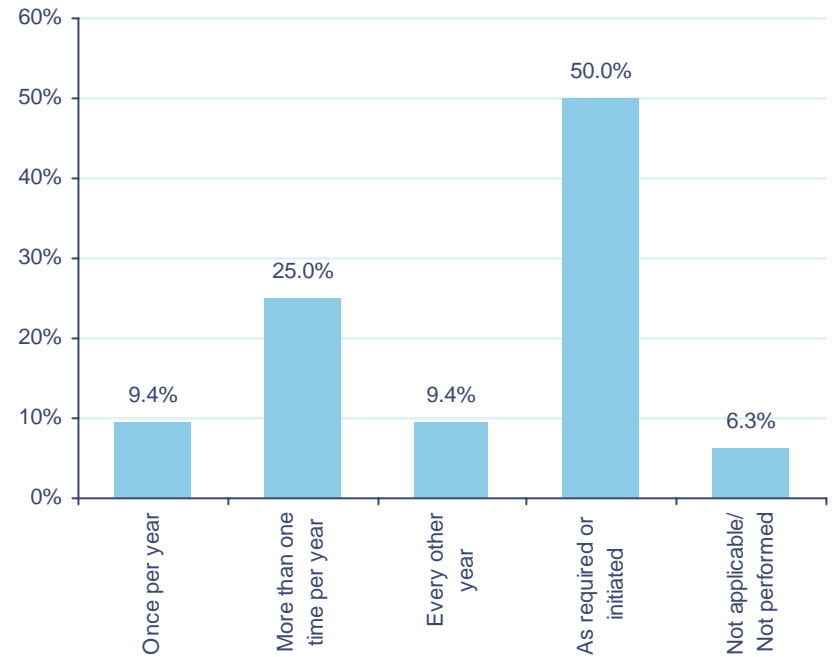


# Survey, Polling & Interview Findings

How frequently are audits conducted on the AdvaMed Code or your company's corresponding compliance policies?

(Respondents could only choose a single response)

Response	Frequency	Count
Once per year	9.4%	3
More than one time per year	25.0%	8
Every other year	9.4%	3
As required or initiated	50.0%	16
Not applicable/Not performed	6.3%	2

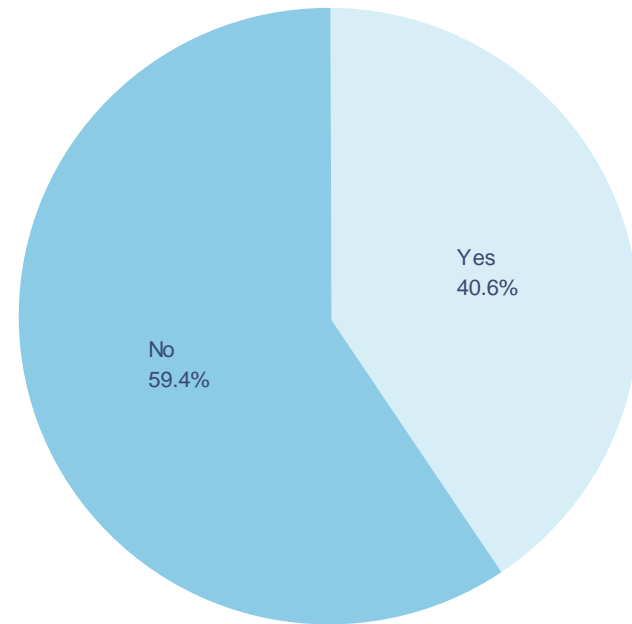


# Survey, Polling & Interview Findings

Do you use compliance risk assessments to determine whether your monitoring program is effective?

(Respondents could only choose a single response)

Response	Frequency	Count
Yes	40.6%	13
No	59.4%	19

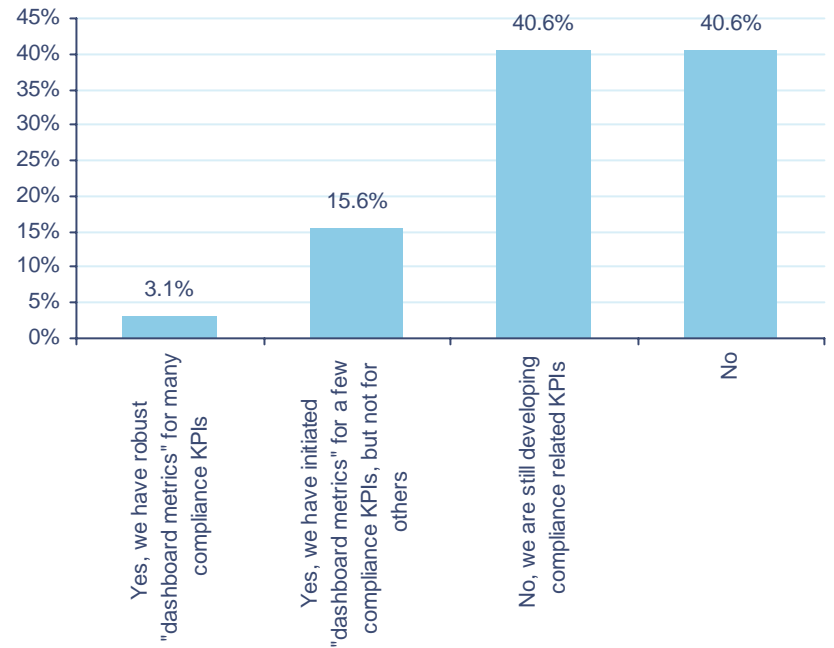


# Survey, Polling & Interview Findings

## Are KPIs used to assess the effectiveness of your compliance program?

(Respondents could only choose a single response)

Response	Frequency	Count
Yes — robust "dashboard metrics" for many KPIs	3.1%	1
Yes — initiated "dashboard metrics" for a few KPIs	15.6%	5
No — still developing	40.6%	13
No	40.6%	13



## KPIs

- Challenge (multiple comments)
  - “It is difficult to define measurable items for a compliance program ... and how to get [agreement] on what defines the program.”
- Examples
  - Training metrics
  - Expense reporting violations
  - Number/type of investigations, hotline calls
  - Metrics for committee activities
  - Measurement of action plans developed, completed
  - Metrics for diligence on vendors
  - Tracking of patient complaints handled and resolved
  - Database to report on compliance incidents
  - Track number of contracts reviewed
  - Self assessments by business units

# Section 3

## Analysis and Discussion

# Analysis and Discussion

## Top 9 Compliance Challenges in 2009

- Increased investigations building off of the success of US Attorneys/DOJ/OIG in the Pharma and Healthcare industries
- Financial relationships with HCPs a growing concern for the OIG
- Increased activity around the Federal Anti-kickback Statute and FCPA
- Increase in the number of state marketing and disclosure laws (e.g. CA, NV, VT and MA) & pending Sunshine Act legislation
- Implementing an international compliance program with focus on international customizations/accommodations
- Investigations, settlements and CIAs attract negative publicity and harm company reputation
- Increased scrutiny for off label promotion (e.g. spine, cardiac and biologics)
- Product quality incidents and regulatory enforcement
- No charge products, trial and demonstration units

# Analysis and Discussion

Compliance program structures and reporting systems are reasonably high-level and robust

- Senior compliance officers generally have access to senior management, Board of Directors
- Systems for periodic reporting are in place

There is still work to be accomplished for strengthening Auditing and Monitoring Programs – ie. Key Performance Indicators (KPIs).

- Some companies have struggled with developing them
- Others appear to question whether they measure the right thing
- Few compliance officers had confidence that the KPIs were viewed by senior management as validating the time/money being invested in compliance.

# Analysis and Discussion

Companies have struggled with policies/procedures to ensure compliance with off-label laws and regulations. Some factors:

- Lack of clear guidance, particularly for device companies
- Paucity of auditing and monitoring tools
- Perceived inapplicability, low-risk for some companies because of product portfolio

Companies continue to struggle with compliance controls around the “drivers” of behavior

- Lack of visibility into, or role in, call plan development, incentive compensation, performance evaluations
- Many recognized that effective means of controlling the drivers of behavior is critical — but industry better practices have not been identified.

# Analysis and Discussion

## 2009 Top Compliance Program Priorities

- Sales and Marketing compliance review (and re-alignment) because of continual pressure from OIG and DOJ to focus activities and questioning whether CIAs/DPAs are working
- Manage impact of revised industry codes, their implementation and affect on promotional tactics
- Foreign Corrupt Practices Act & similar Anti-bribery/Anti-corruption laws. There is increasing enforcement and coordination of local country law enforcement with US DOJ and SEC
- Using compliance as a driver of operational excellence and transparency, combined with cost pressures, how do companies use this as an opportunity for concurrent process improvement to also increase speed and agility

# Analysis and Discussion

## 2009 Top Compliance Program Priorities

- Align risk management roles and responsibilities, ensuring that Compliance, QA, IA, Regulatory and other R&D Risk Management functions are collectively addressing R&D risk
- Data Privacy is becoming an ever-increasing issue with the multiplication of state laws; EU Privacy Directive limitations on x-border transfers and how this may impact ex-US compliance program reporting/tracking

# Analysis and Discussion

## Survey Team Members

PwC Team	
Doug Mowen, Pharmaceutical and Life Sciences	
Managing Director	
T	610.304.4751
E	Doug.Mowen@us.pwc.com

PwC Team	
Jean Sands, Pharmaceutical and Life Sciences	
Senior Associate	
T	312.298.3026
E	Jean.Sands@us.pwc.com

King & Spalding	
Seth H. Lundy, Pharmaceutical and Life Sciences	
Partner	
T	202.626.2924
E	Slundy@kslaw.com

# Section 4 Questions?

# Appendix

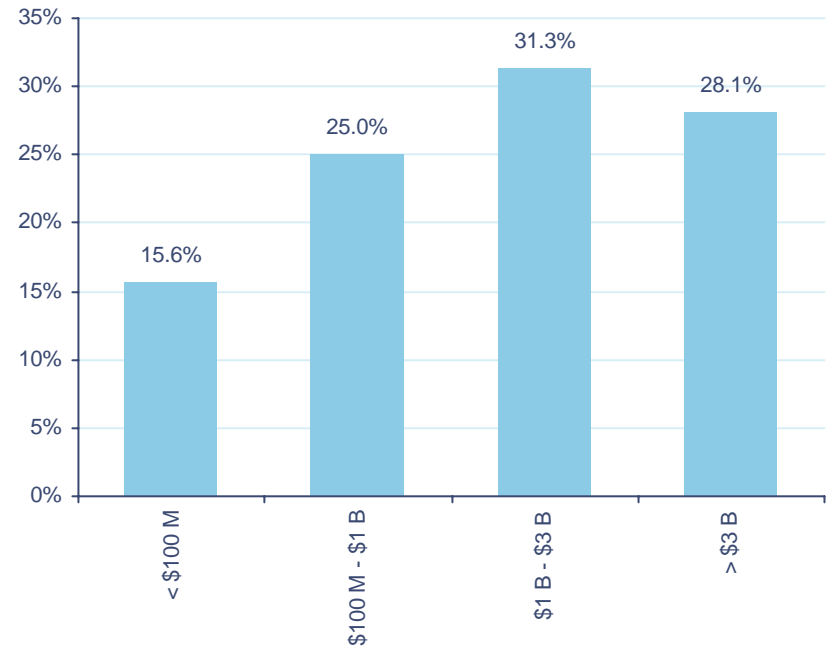
## Company Demographics

# Appendix – Company Demographics

What were your company's 2007 gross sales?

(Respondents could only choose a single response)

Response	Frequency	Count
< \$100 M	15.6%	5
\$100 M - \$1 B	25.0%	8
\$1 B - \$3 B	31.3%	10
> \$3 B	28.1%	9

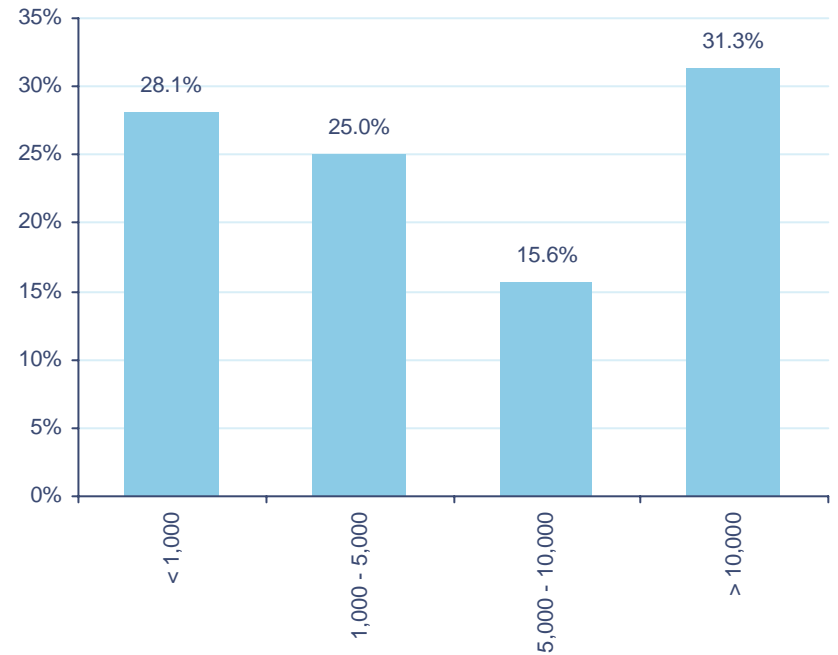


# Appendix – Company Demographics

How many employees are in your company?

(Respondents could only choose a single response)

Response	Frequency	Count
< 1,000	28.1%	9
1,000 - 5,000	25.0%	8
5,000 - 10,000	15.6%	5
> 10,000	31.3%	10

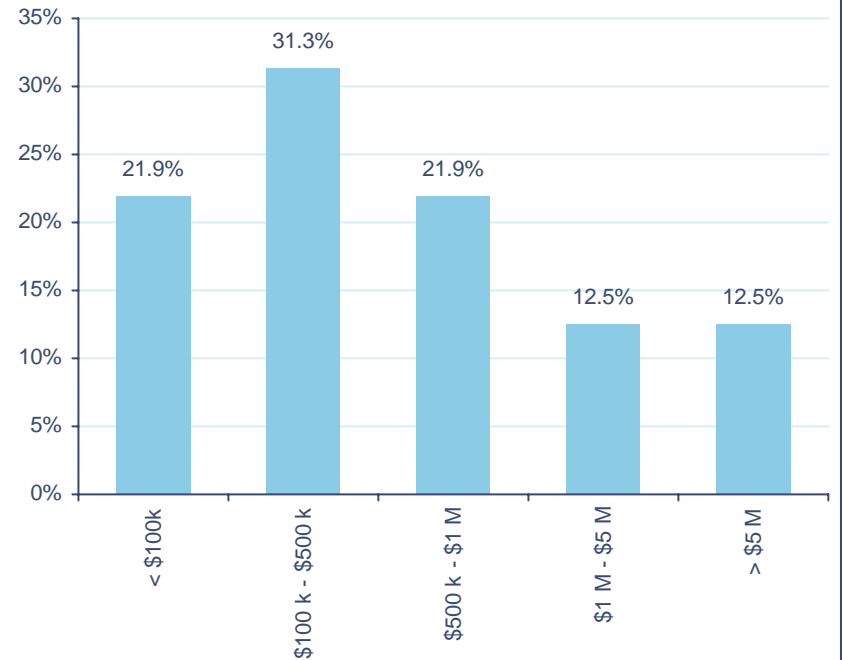


# Appendix – Company Demographics

What is the annual compliance budget for your company (excluding salaries)?

(Respondents could only choose a single response)

Response	Frequency	Count
< \$100 k	21.9%	7
\$100 k - \$500 k	31.3%	10
\$500 k - \$1 M	21.9%	7
\$1 M - \$5 M	12.5%	4
> \$5 M	12.5%	4

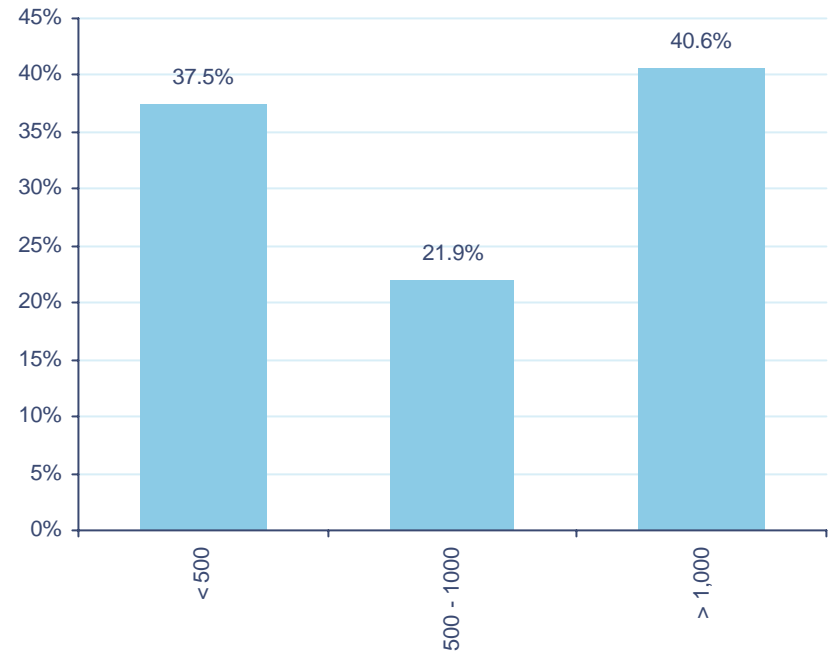


# Appendix – Company Demographics

How many people are in your company's sales force, including contracted sales representatives?

(Respondents could only choose a single response)

Response	Frequency	Count
< 500	37.5%	12
500 – 1000	21.9%	7
> 1,000	40.6%	13



© 2009 PricewaterhouseCoopers LLP. All rights reserved. "PricewaterhouseCoopers" refers to PricewaterhouseCoopers LLP (a Delaware limited liability partnership) or, as the context requires, the PricewaterhouseCoopers global network or other member firms of the network, each of which is a separate and independent legal entity.

PRICEWATERHOUSECOOPERS 