



2015 STATE OF LIFE SCIENCES HEALTHCARE COMPLIANCE SURVEY

We all have a keen interest in better understanding the life sciences healthcare compliance environment and gaining insight into how companies handle compliance challenges. To that end, Porzio Life Sciences has created the **2015 State of Life Sciences Healthcare Compliance Survey**.

The following pages detail the responses gathered from compliance professionals across a variety of life sciences companies, throughout all industry sectors and company sizes.

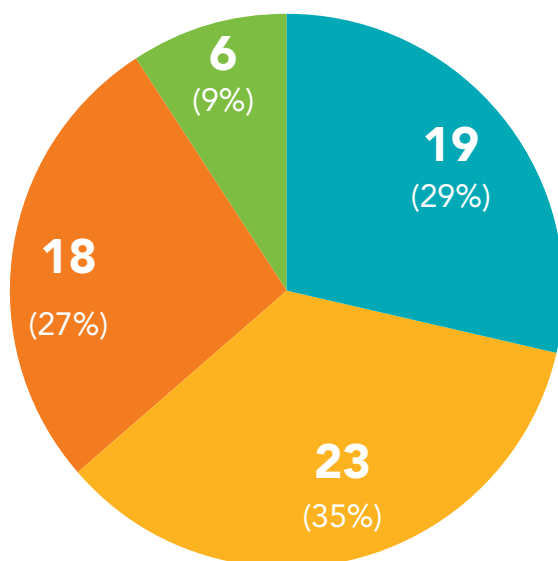
Our hope is that this data will serve as a useful benchmarking tool for you and your compliance program throughout the upcoming year.

- Distributed through various channels – primarily via email to Porzio Life Sciences contacts – from September to December 2015
- 60% of respondents chose to take the survey anonymously
- Sixty-six (66) valid respondents contributed to this research
 - Respondents considered not valid:
 - Those with no healthcare compliance responsibilities
 - Those who did not answer any questions
 - Those who answered only the few opening profile questions, e.g. company size, company annual revenue, product category/-ies, number of employees, etc.
- All 66 valid respondents have *healthcare* compliance responsibilities in life sciences companies
 - 29% of valid respondents have only healthcare compliance responsibilities
 - 35% of valid respondents have mostly healthcare compliance responsibilities
 - 27% of valid respondents have a split of healthcare compliance responsibilities and other responsibilities
 - 9% of valid respondents have few healthcare compliance responsibilities

- Only 23% of valid respondents have been in their current job for less than a year; 40% have been in their current position for at least 3 years
- Respondents work in an array of life sciences industries/markets
- A range of large, medium and small companies (based on the number of employees) are represented
- Approximately 1/3 of the companies represented sell only medical devices; 1/3 sell only pharmaceuticals and the remaining companies sell some combination of biotechnologies/medical devices/pharmaceuticals
- Among the limitations of this study
 - The answers are self-reported and not able to be objectively verified
 - It is possible, though not confirmed, that more than one person from the same company are included in the data; if that did occur, they may have not offered the same answers regarding their company's healthcare compliance system/performance
 - Not every valid respondent completed the entire survey

Complete the following sentence with the statement that best describes your current job.

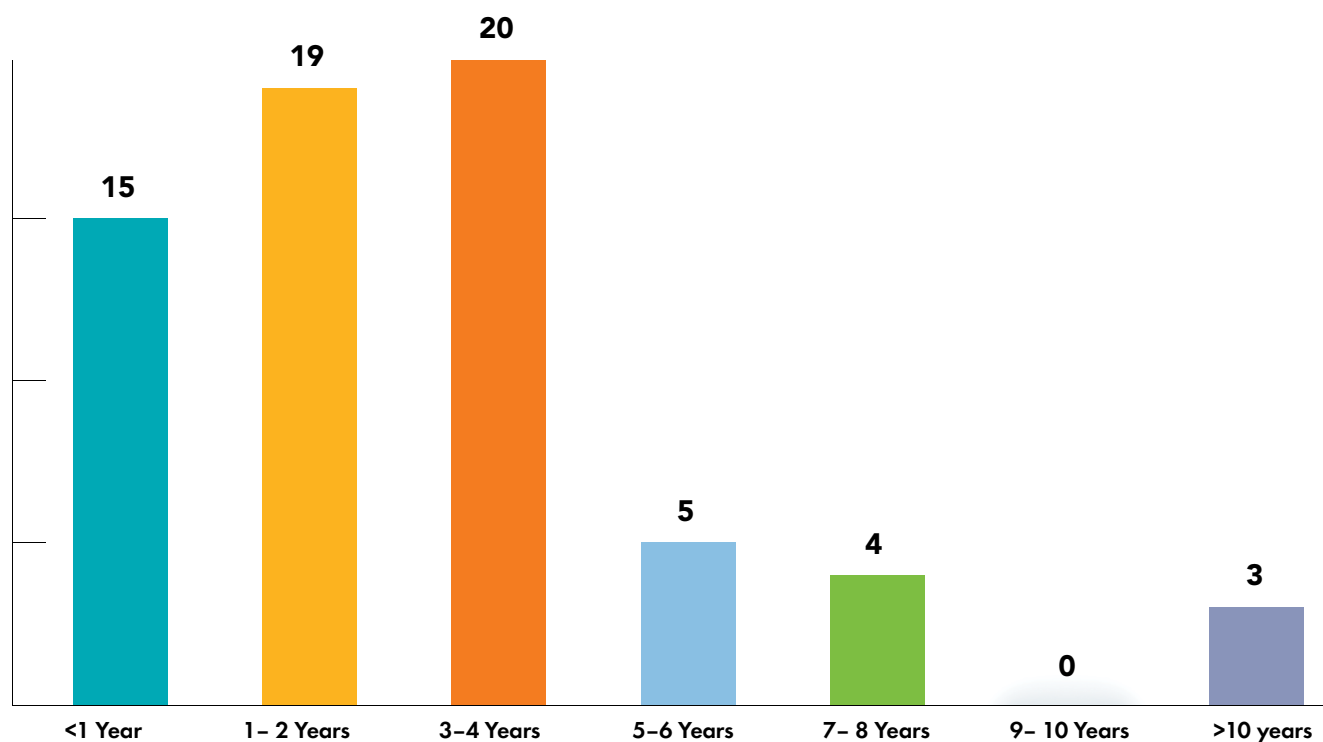
"My current job involves..."



- Only healthcare compliance responsibilities.
- Mostly healthcare compliance responsibilities; some other company responsibilities.
- Some healthcare compliance responsibilities and some other company responsibilities.
- Few healthcare compliance responsibilities; mostly other company responsibilities.
- No healthcare compliance responsibilities. (0%)

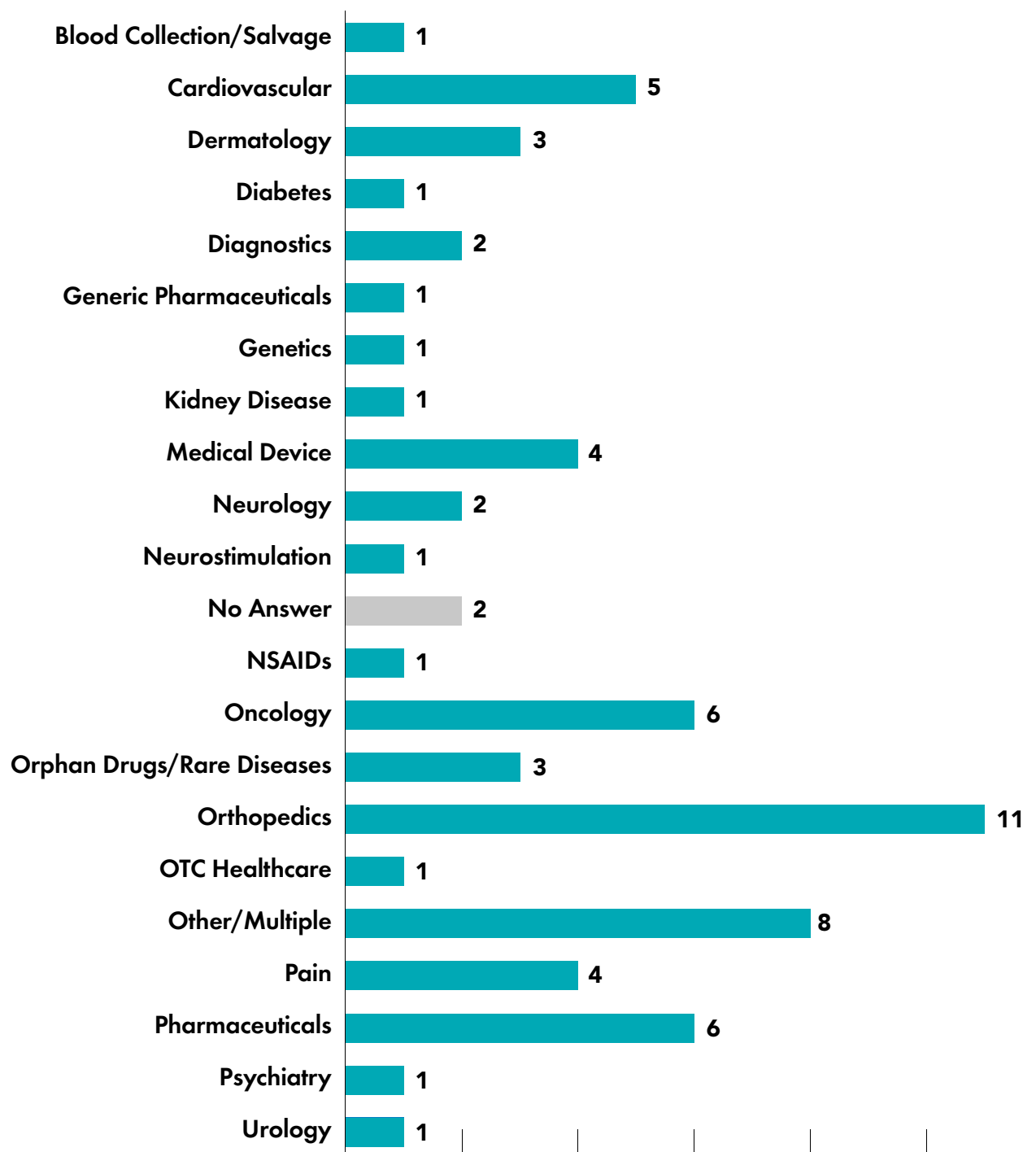
N=66

How many years have you been in your current position?



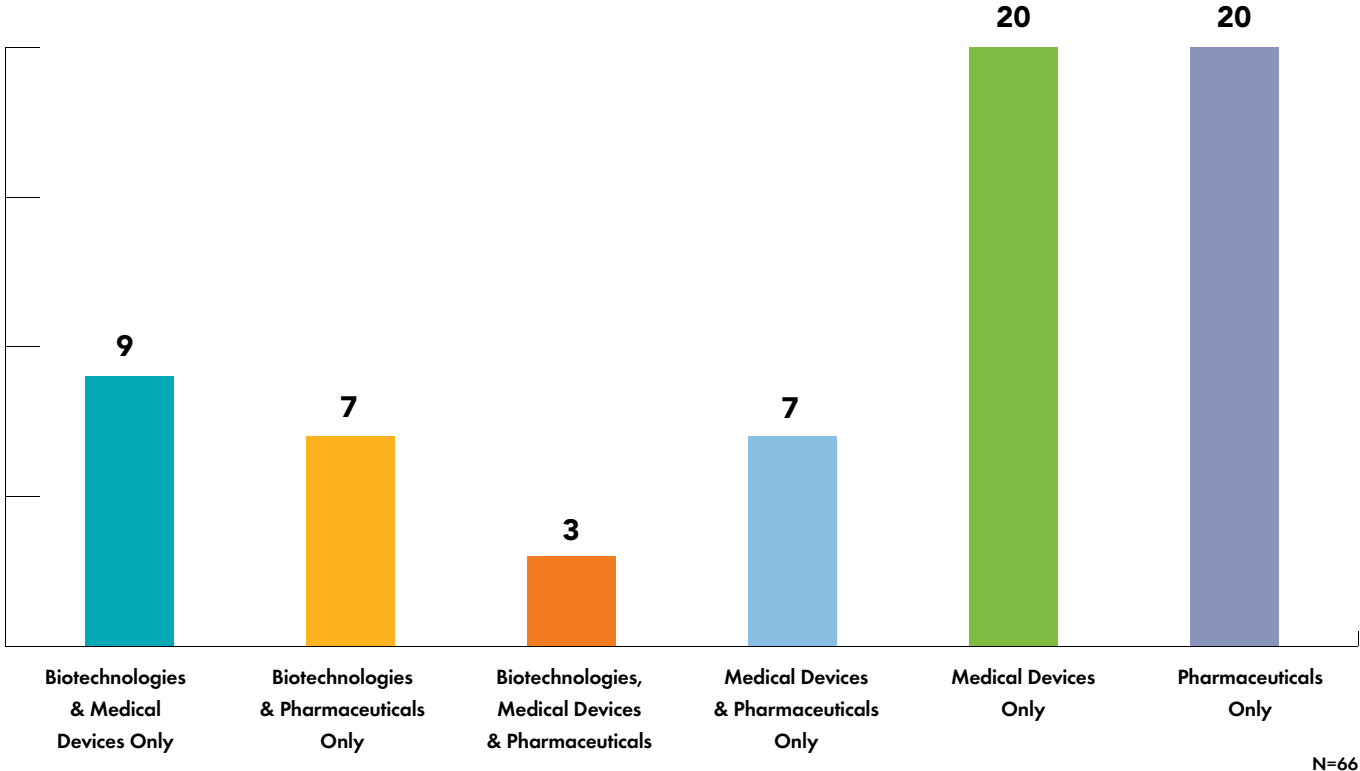
N=66

The name of the industry/market in which your company operates is:

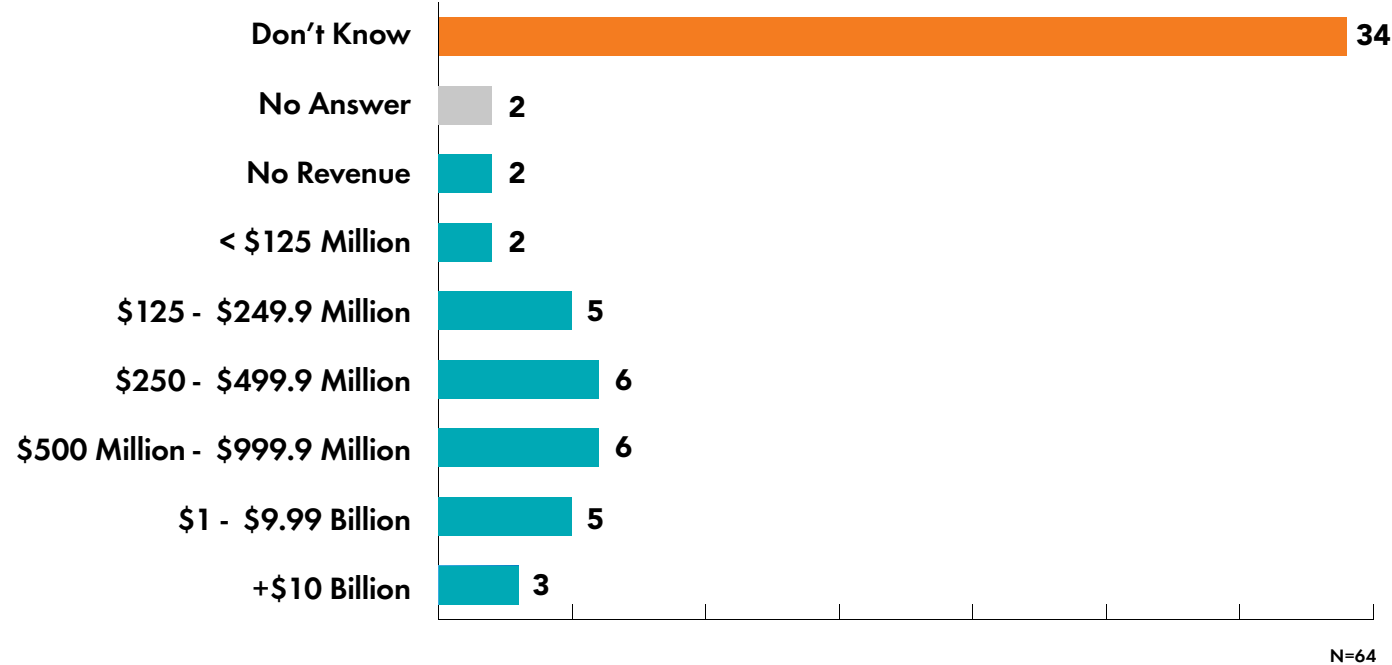


N=64

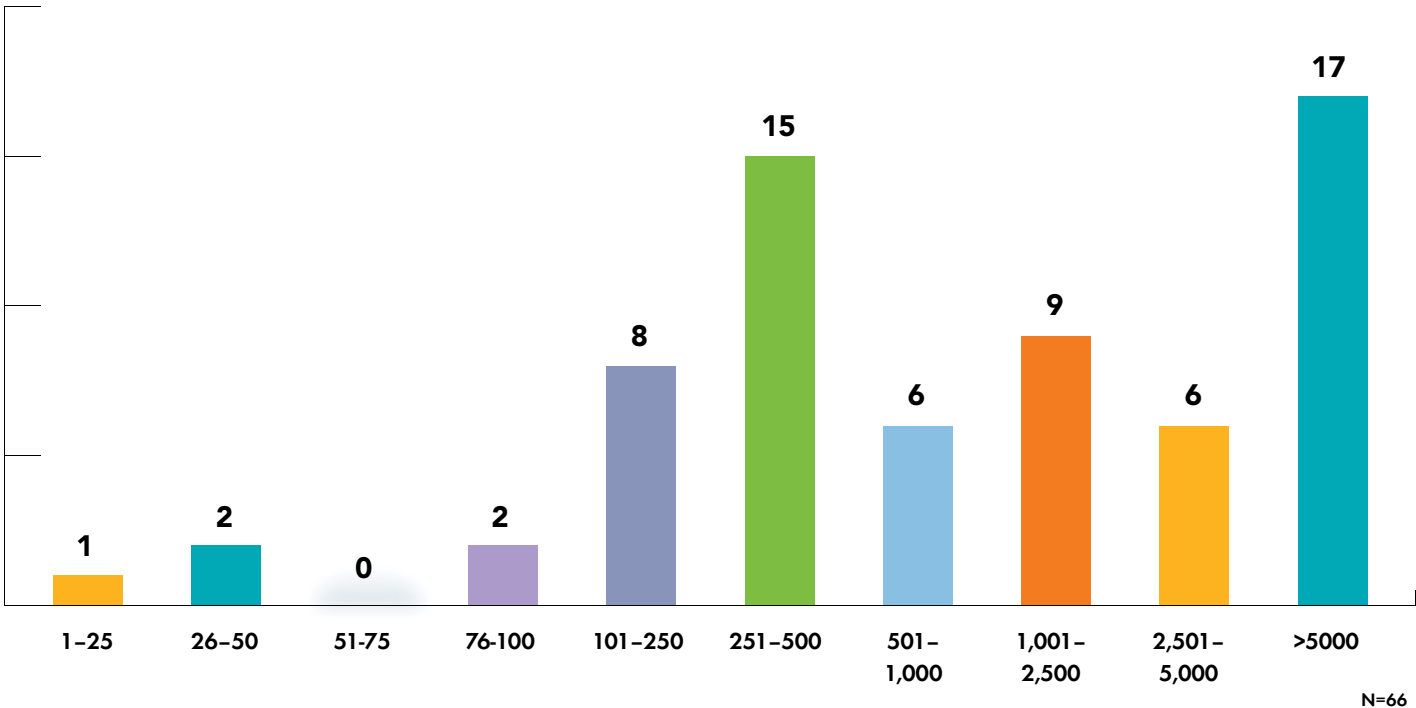
Indicate which of the following categories best describes the products your company sells.



What is your company's annual revenue?

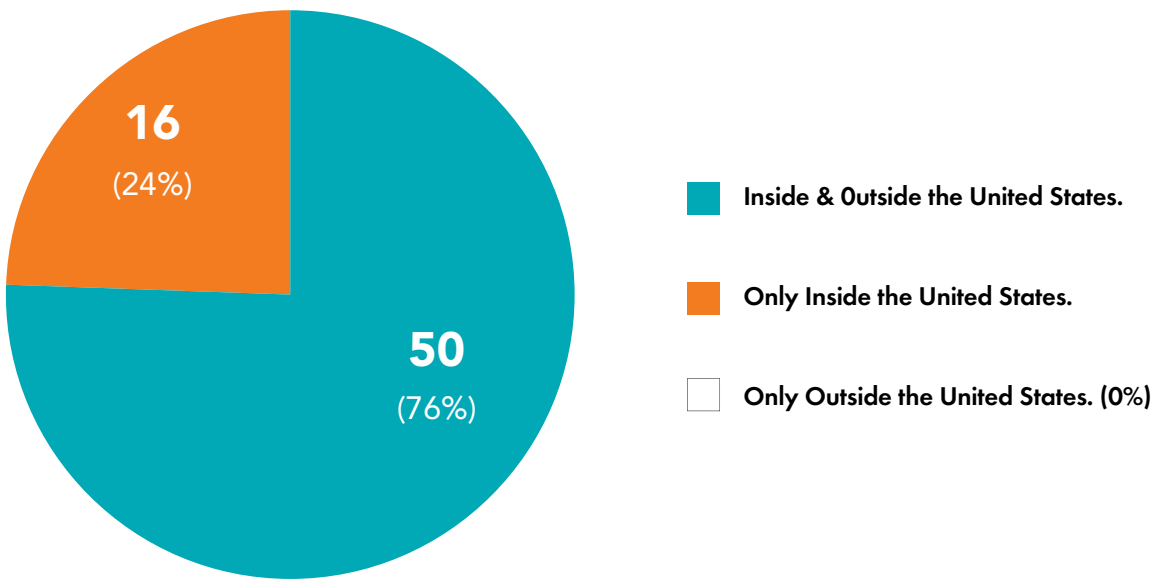


How many employees work at your company?

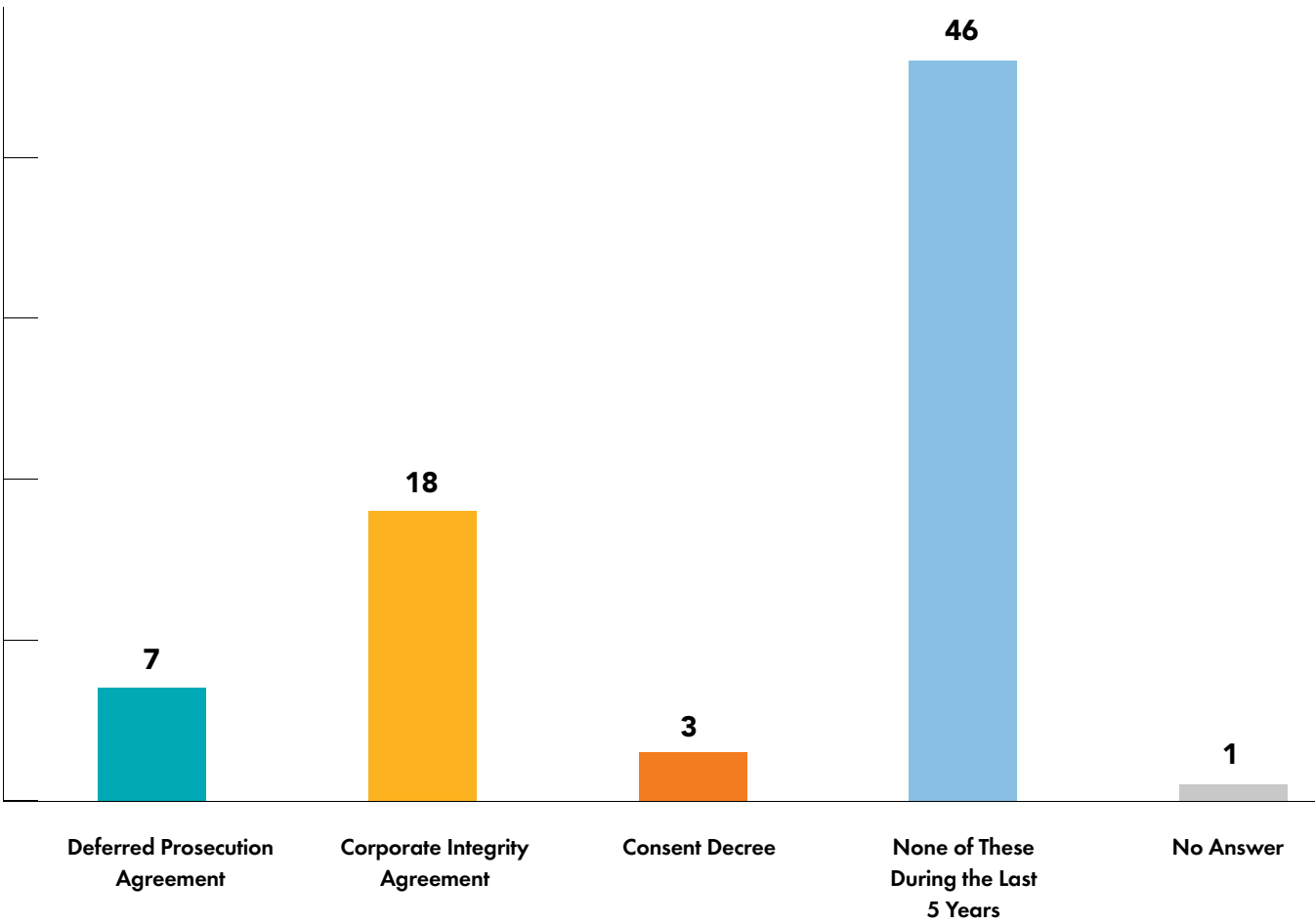


Choose a phrase to complete the following sentence.

"Our company sells products..."

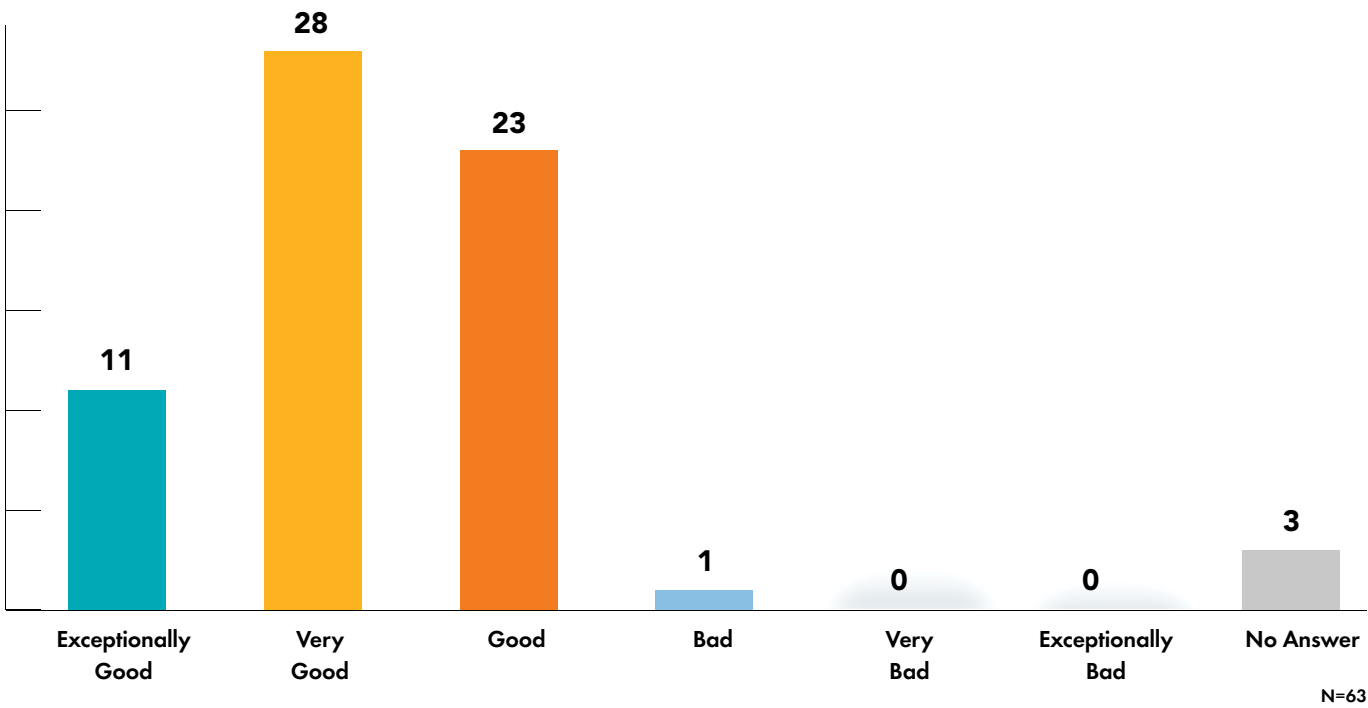


Identify any of the following that your company has operated under at any point during the last 5 years. [check all that apply]



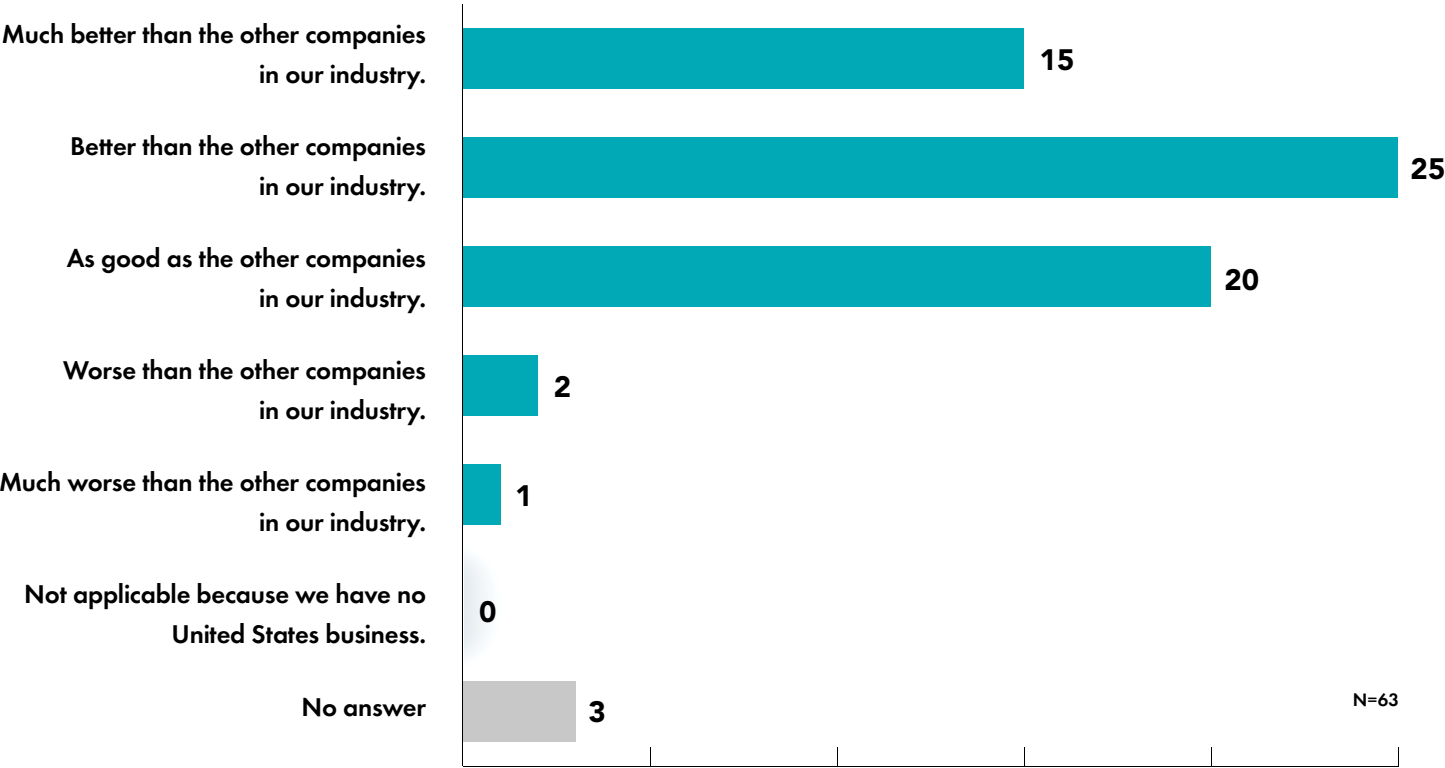
N=65

Choose the statement that best describes the adherence to UNITED STATES healthcare compliance laws, regulations and codes by companies in your industry.

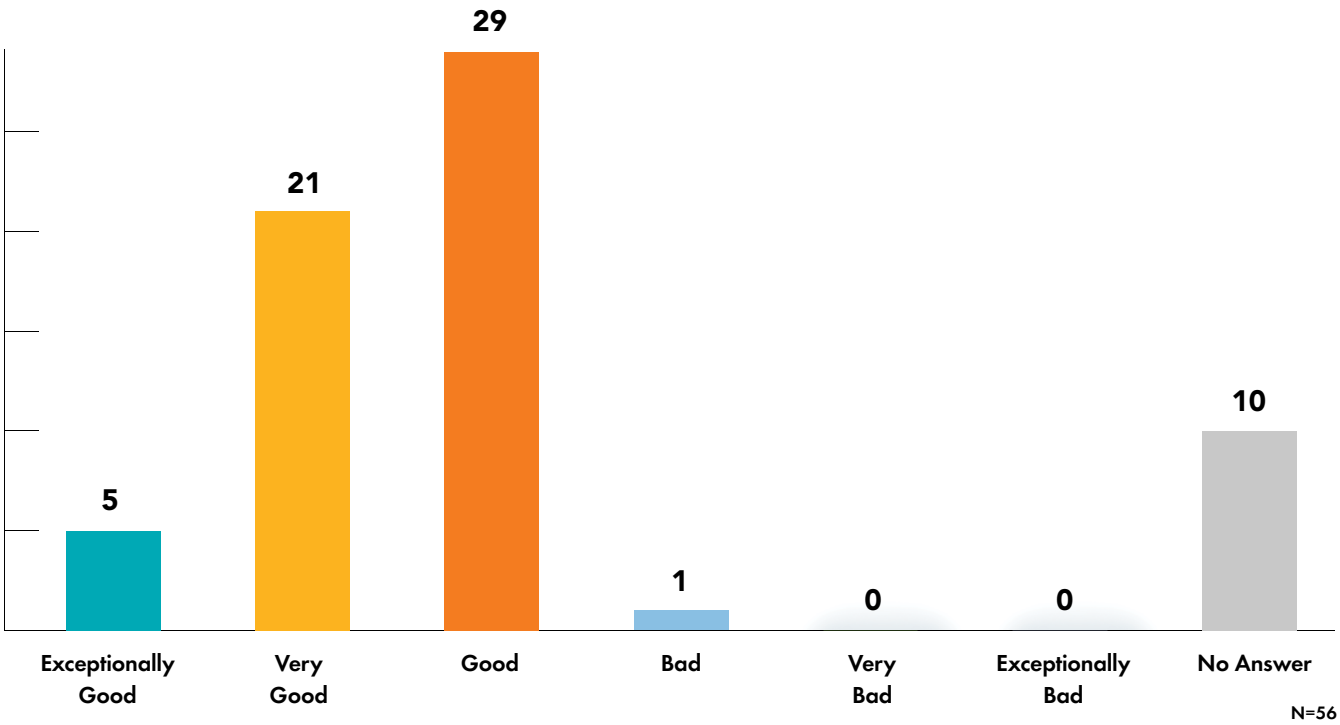


Complete the following sentence with the statement that best describes your view.

"Our company's performance in meeting UNITED STATES healthcare compliance obligations is..."

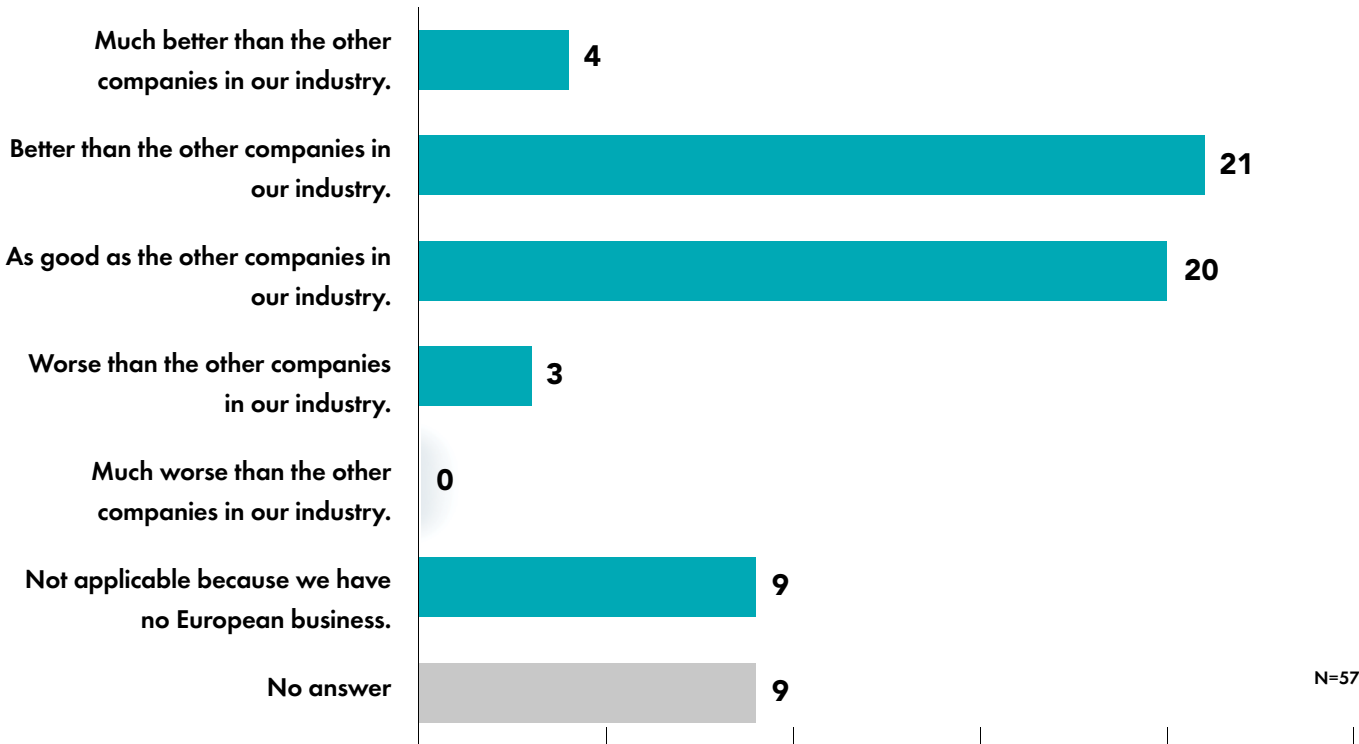


Choose the statement that best describes the adherence to EUROPEAN healthcare compliance laws, regulations and codes by companies in your industry.



Complete the following sentence with the statement that best describes your view.

"Our company's performance in meeting our EUROPEAN healthcare compliance obligations is..."



What is the single most important thing your company has done to successfully implement its compliance program?

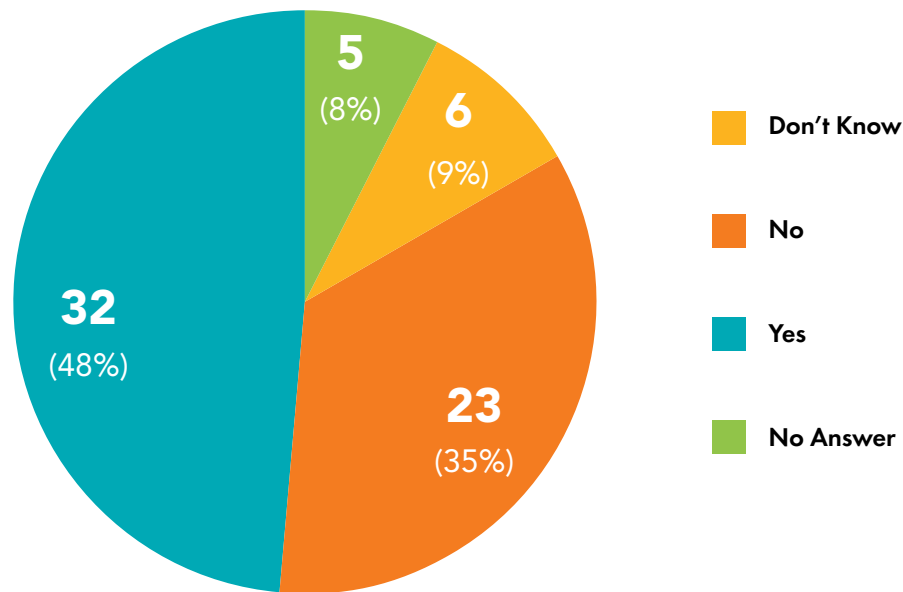
- The categories below represent the intent of the answers given to this open question, though they are not always exact quotes.
- Some respondents listed multiple things instead of the "single most important thing."
- The number on each line is the number of respondents who gave that answer.

AdvaMed Code Adoption	1
Aggregate Spend Compliance Group	1
Applied the 7 Elements	1
Auditing/Monitoring	1
Automation of Tasks	2
Centralized Compliance Tracking System	1
Communication/ Training	1
Compliance Initiatives: Created & Expanded	1
Compliance Officer Appointed/Hired	3
Compliance Staff: New, Experienced	4
Compliance Structure/ Training	1
Don't Know	2
Healthcare Compliance Committee Oversight	1
Hired Me!	1
Hotline	1
Leadership Support/Tone at the Top	4
Needs Assessment	1
Policies, Procedures & Training Implemented	2
Procurement Tracking System*	1
Resources Added	2
Royalty Audits Enhanced	1
Total Program Overhaul & Training	1
Training	12
Training & Strong Culture	1
Training , Communication, Monitoring & Auditing	1
Work in Progress	1
Zero Tolerance Code of Conduct	1
No Answer	16

*This respondent has an HCC job title.

N=50

Is your Compliance Officer a member of the company's management board?



N=66

Complete the following sentence with the statement that best reflects your views.

"In our industry, the department that most frequently has difficulties adhering to healthcare compliance laws and regulations is..."

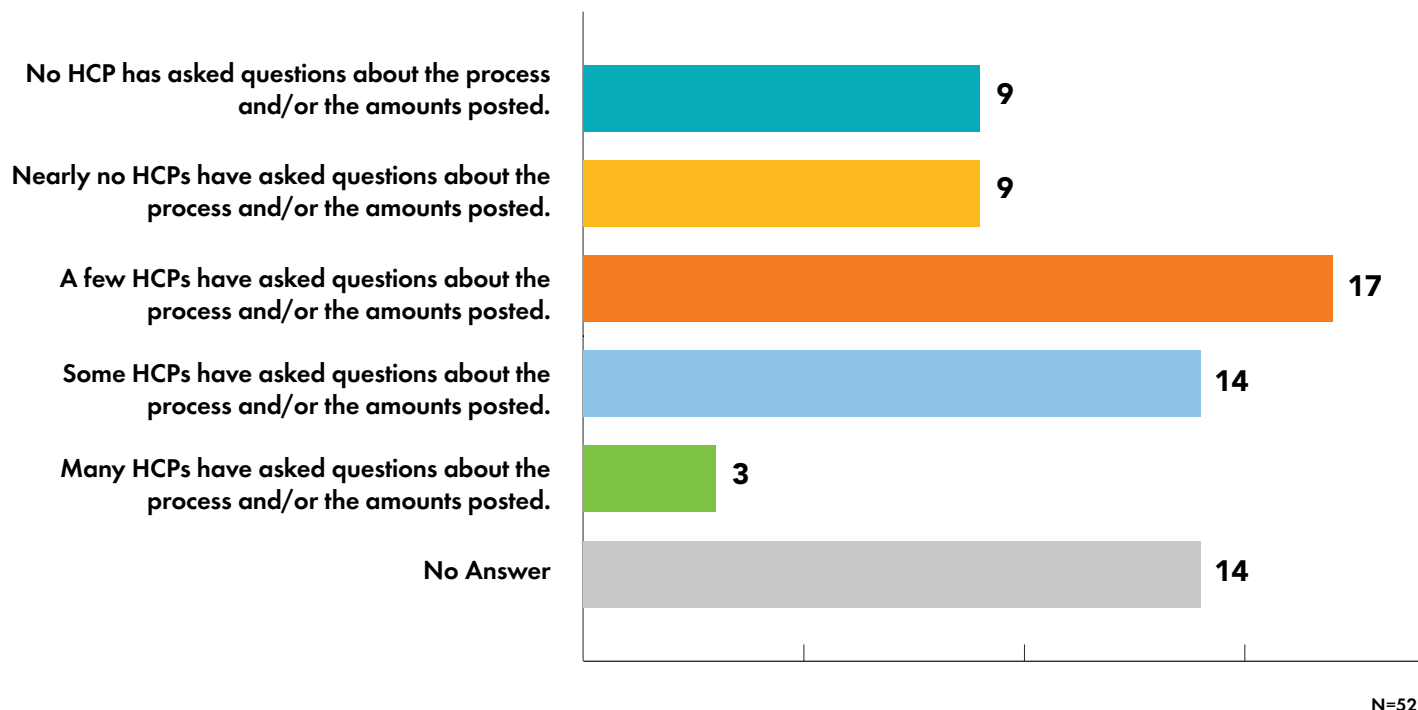
Clinical Affairs/Research	1
CMC-manufacturing	1
Marketing	12
Marketing and Sales	1
Medical Affairs	2
Other	1
Quality Assurance	1
R&D	2
Sales	38
No Answer	7

N=66

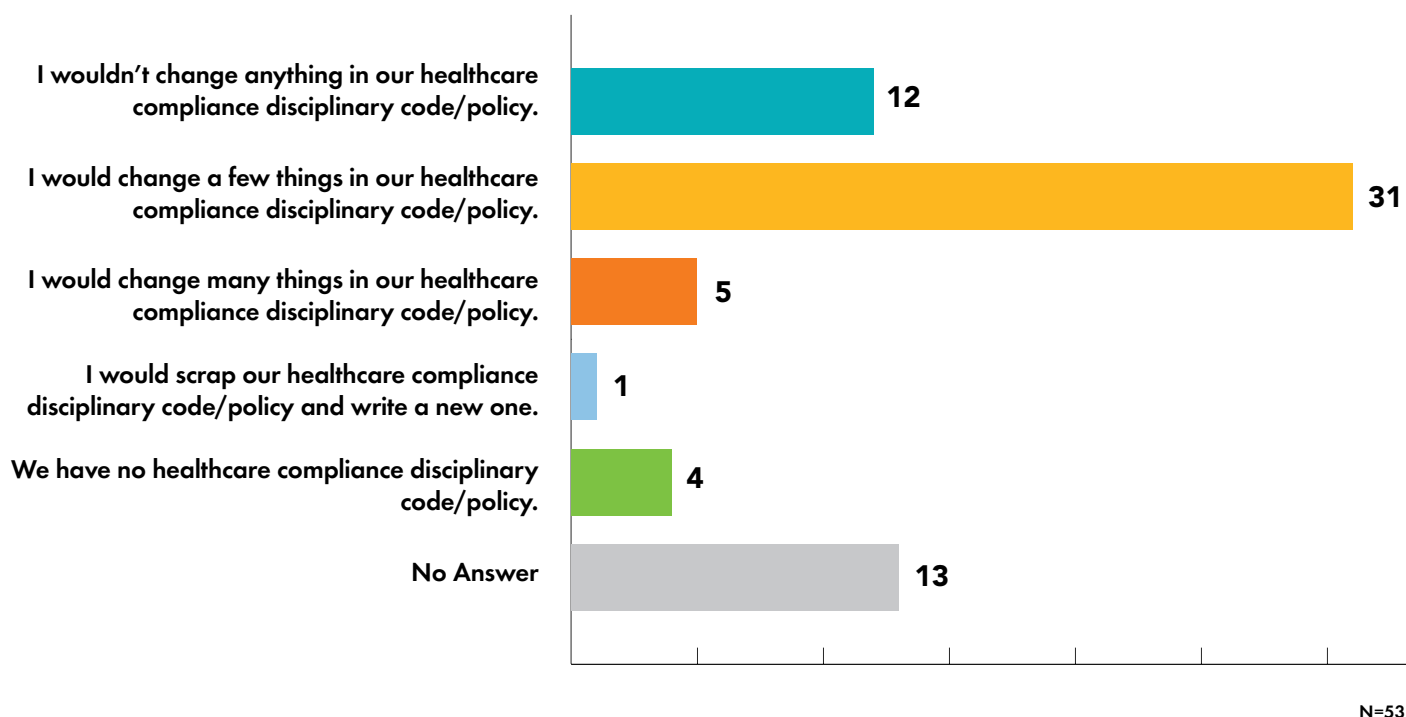
Additional Quotes Offered by Respondents: “ Good question. One assumes promotional but in fact the actual amount per payment is low. R&D and Medical Affairs carries a higher risk. ”

“ It depends on the organization and the associate(s) within the organization. It changes constantly. ”

Which statement best describes how your HCP customers/consultants have reacted this year to your collection/submission of HCP financial data to comply with the Sunshine Act/Open Payments?

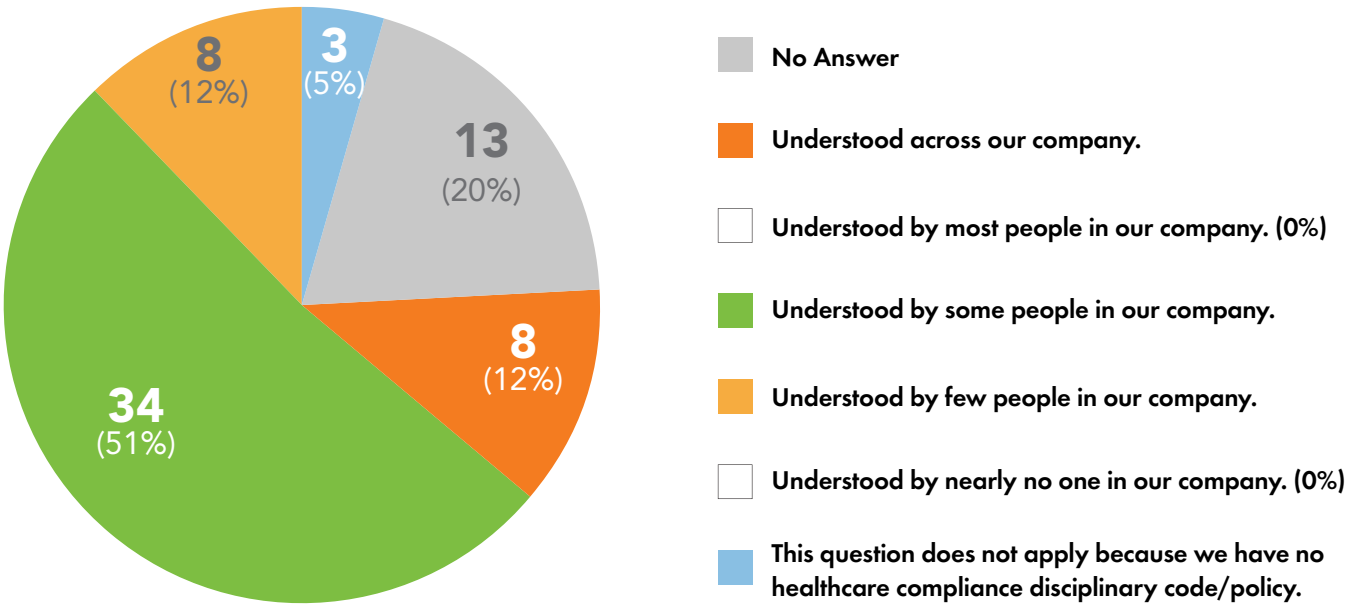


Choose the statement that best reflects your view of your company's healthcare compliance disciplinary code/policy.



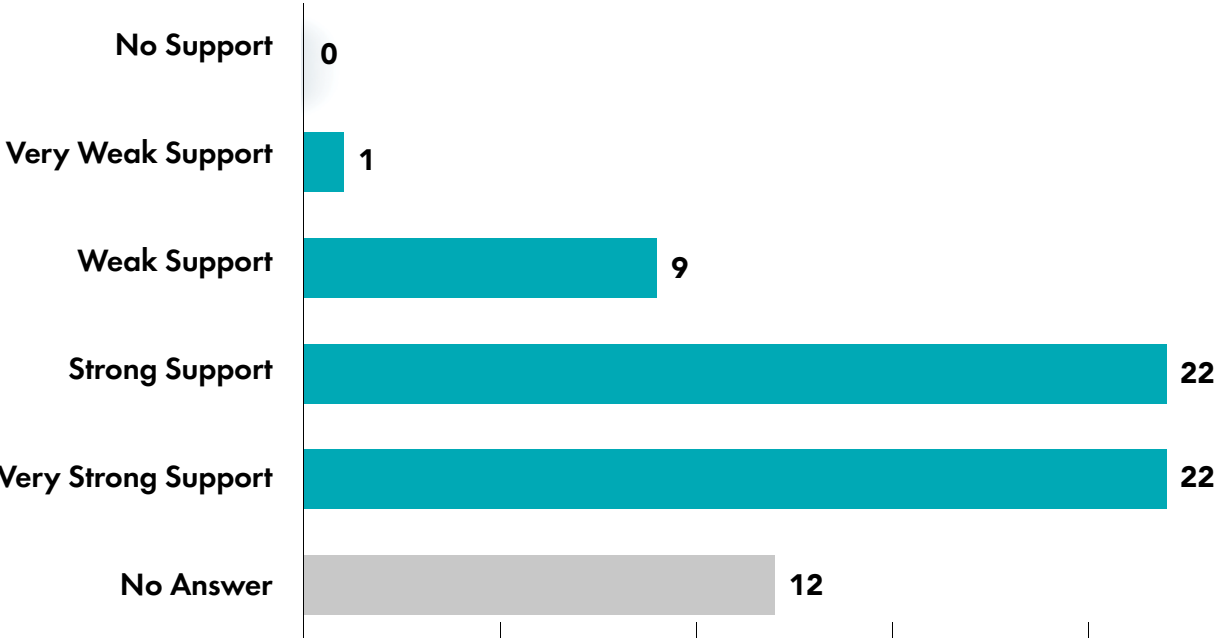
Complete the following sentence with the statement that best describes your view of your colleagues' understanding of your company's healthcare compliance disciplinary code.

"We have a healthcare compliance disciplinary code/policy that is..."



N=53

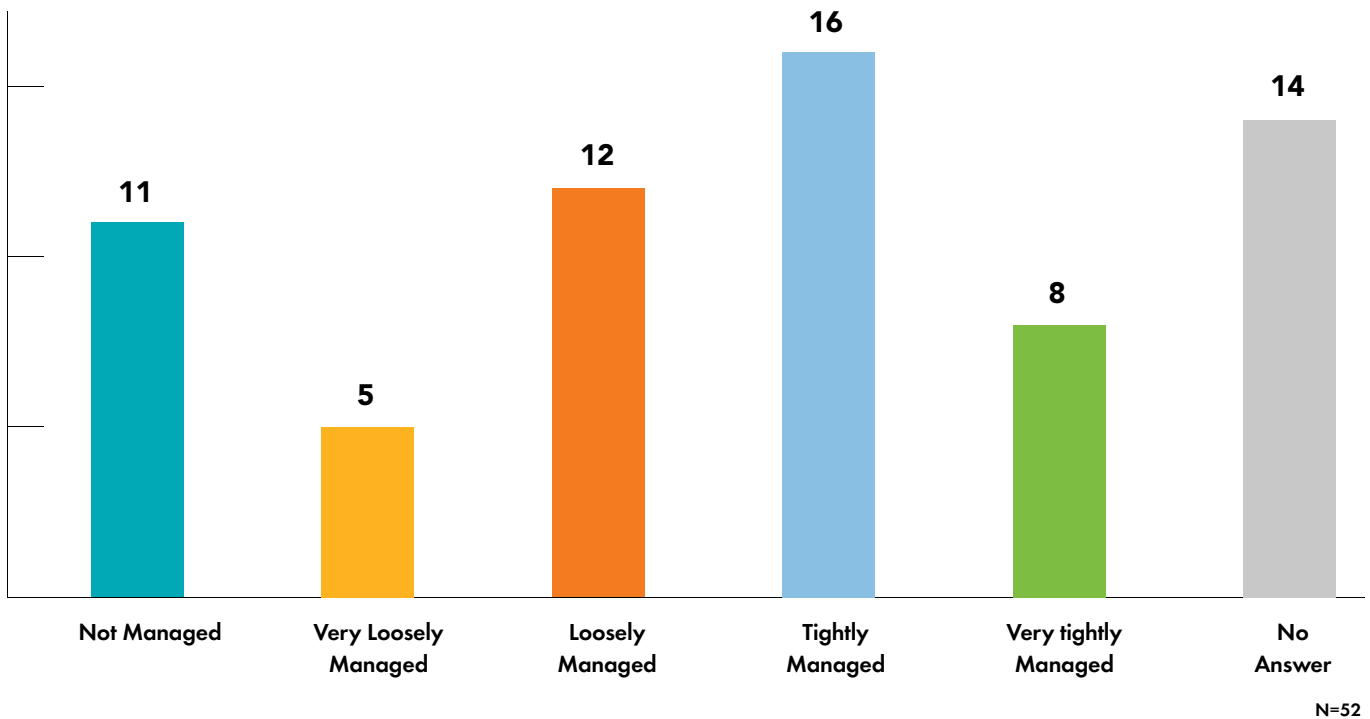
Choose the statement that best describes the support your company's healthcare compliance efforts receives from your company's CEO/Board.



N=54

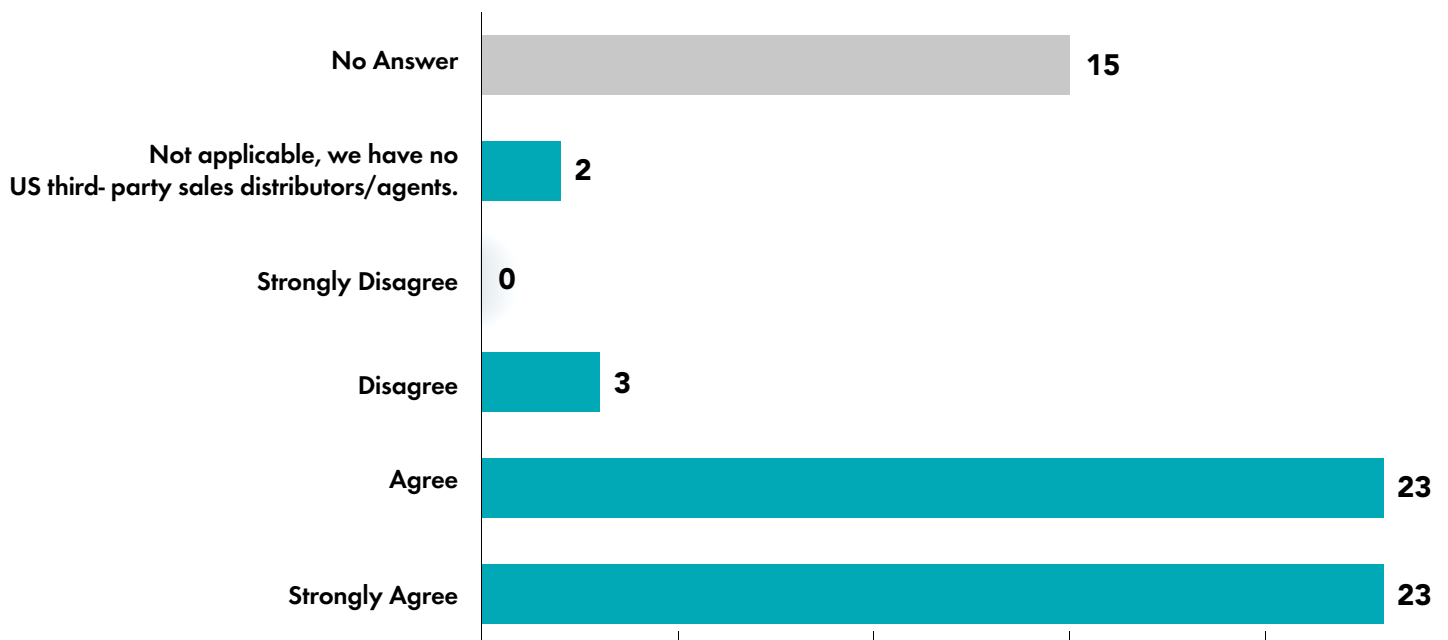
Which phrase below most accurately completes the following sentence?

"Social Media postings by our employees regarding the company's products are..."

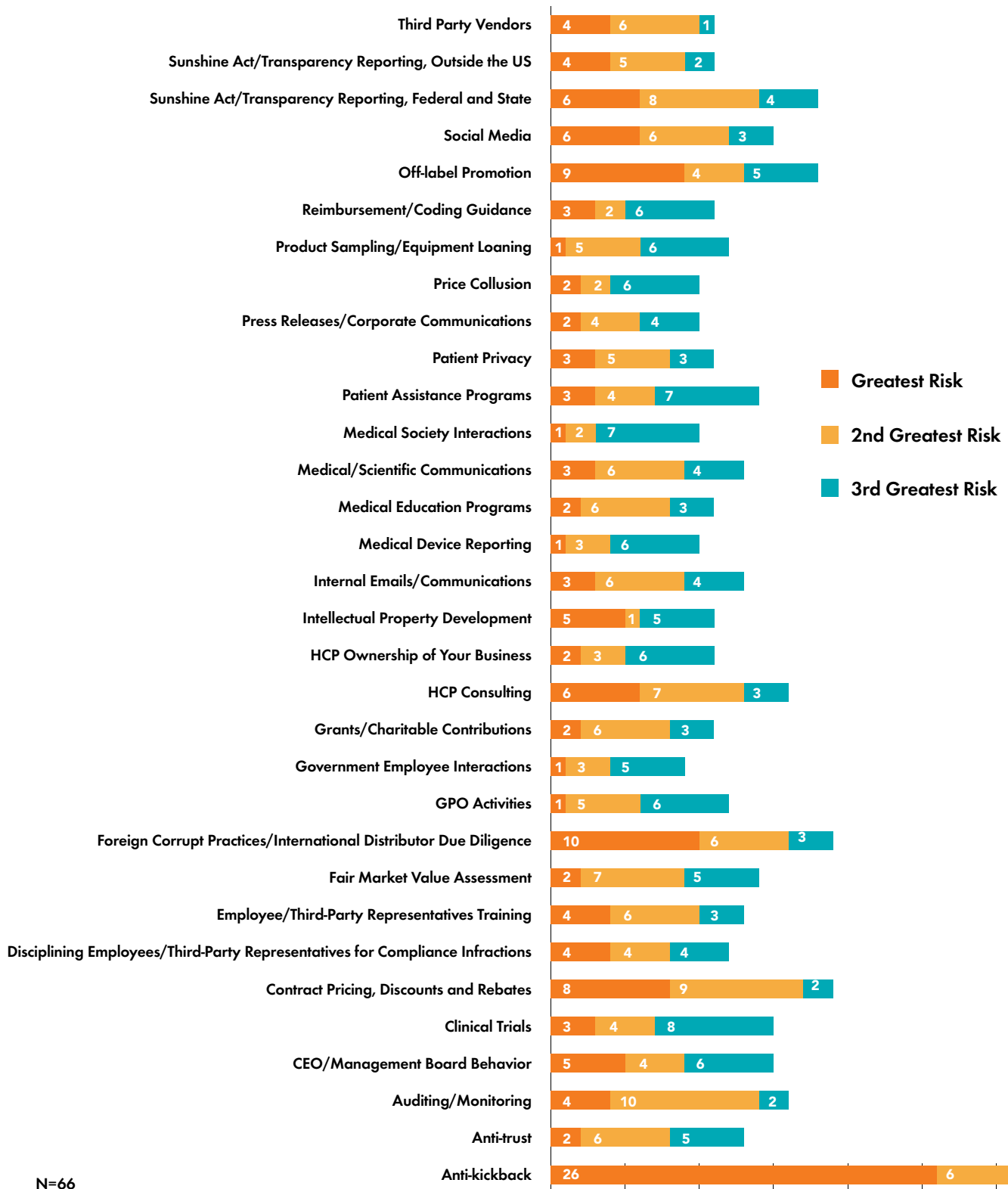


Choose the statement below that reflects the degree to which you agree/disagree with the following statement.

"Our company's United States third-party sales distributors/agents must meet the same healthcare compliance standards that the company has set for direct employees."



From the following list, rank the top 3 healthcare compliance risks faced by companies in your industry.



NOTES

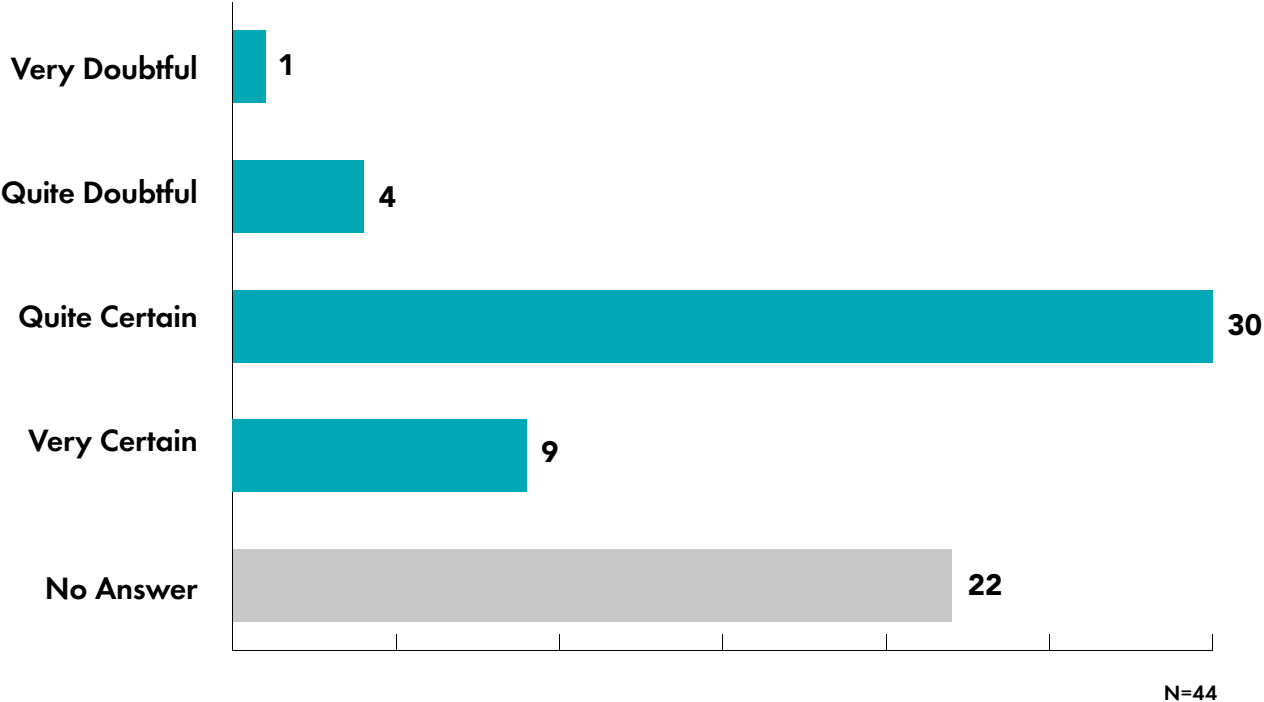
Several respondents identified more than 3 risks. All identified risks are included in this chart.

Two risks were identified in the "other" category; one mention for each risk:

- Distributors
- Value added services and co-marketing with HCPs

Complete the following sentence with the phrase that best reflects your views.

"Regarding the future, I am _____ that healthcare compliance will have a positive impact on the behavior of the United States life sciences industry."





Porzio Life Sciences is dedicated to helping pharmaceutical, medical device and biotechnology organizations master the evolving regulatory environment.

We enhance the marketing and sales programs of a range of companies:

- Pharmaceutical and Medical Device Manufacturers and Distributors
- Virtual Pharmaceutical Companies
- Contract Sales Organizations
- Vendors to Life Sciences Industry
- Wholesale Distributors and Labelers

We strive to improve the efficiency of life sciences departments, including sample compliance, legal, regulatory, governmental affairs and marketing and sales.

We provide compliance tools, such as Porzio Compliance Digest, Porzio GST™ and Porzio AggregateSpendID®, that enable companies to comply with global, federal and state marketing and sales regulations.

Porzio Life Sciences is a wholly owned subsidiary of Porzio, Bromberg & Newman P.C., a law firm nationally recognized for its litigation and regulatory compliance work for the life sciences industry.

Together, the companies provide regulatory compliance and legal and business services related to product development, the Prescription Drug Marketing Act, anti-kickback statutes, the Sunshine Act, Food and Drug Administration regulations, false claims act, ex-US industry codes and Office of Inspector General guidances.

Questions? To request more information, call 973-538-1690.