AdvaMed Device & Diagnostic Compliance Group

June 2024

Compliance Department Size, Spend & Scope Survey

Distributed: April 9, 2024 – May 1, 2024
Collated: June 28, 2024
Questions: 26
Submissions: 32
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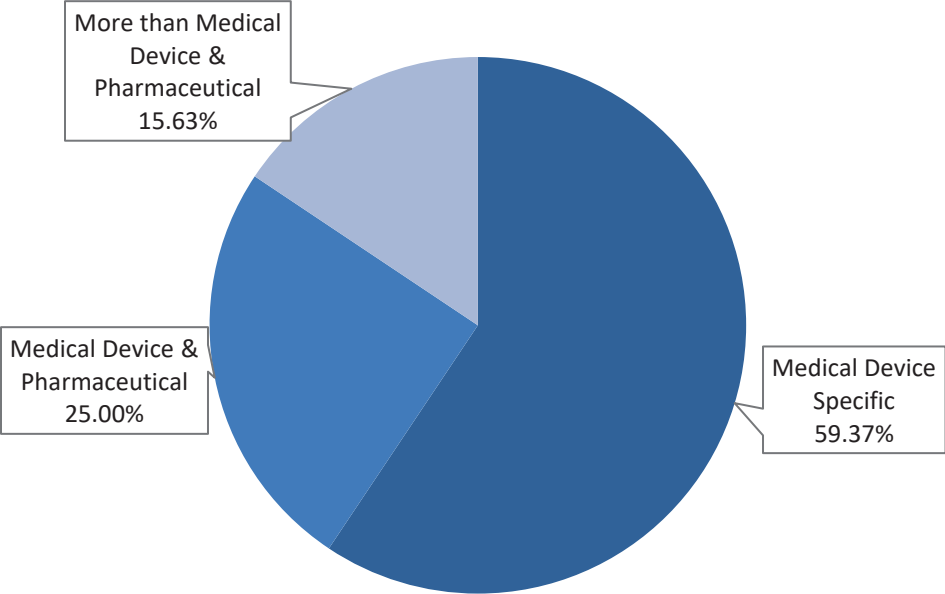
BACKGROUND

AdvaMed surveyed its members regarding their compliance departments. Thirty-two companies completed the survey in April 2024. This document summarizes the survey responses, including additional commentary submitted by some (but not all) companies. The responses reflect a broad cross-section of company policies and are not intended to reflect all medical technology companies.

DEFINITION - Compliance Department: for the purpose of this survey, if your compliance department is responsible for areas other than healthcare compliance, please respond to the survey questions with respect to your department's healthcare compliance functions only. (e.g., if compliance and privacy both report to the Chief Compliance Officer but each function has separate/dedicated staff, respond to the survey based on your compliance function/staff) [If you have any questions about filling out the survey, please reach out to Ida Nassar inassar@advamed.org].
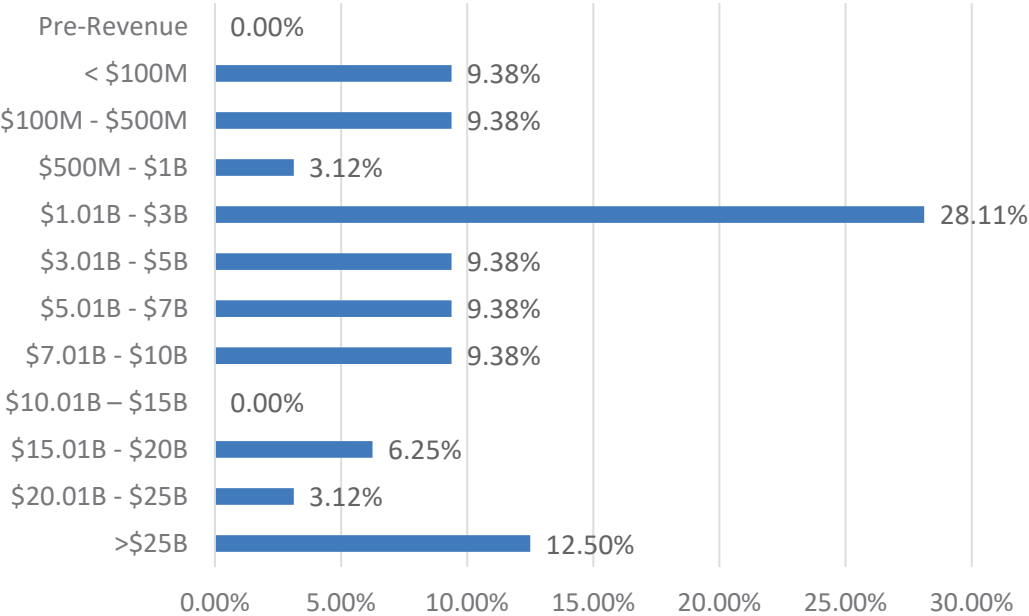
Note: AdvaMed periodically gathers and shares information from Member companies in order to assist companies in understanding industry trends and practices when the information is not competitively sensitive. In all cases, it is understood by AdvaMed and its Members that any company policy or practice that is adopted as a result of this sharing of information is done voluntarily and is a decision by the individual member. The information contained in this report is intended to provide benchmarking data on companies' existing policies only. It is not intended to endorse or mandate any one particular approach for medical technology companies' policies on compliance department size, spend, and scope.
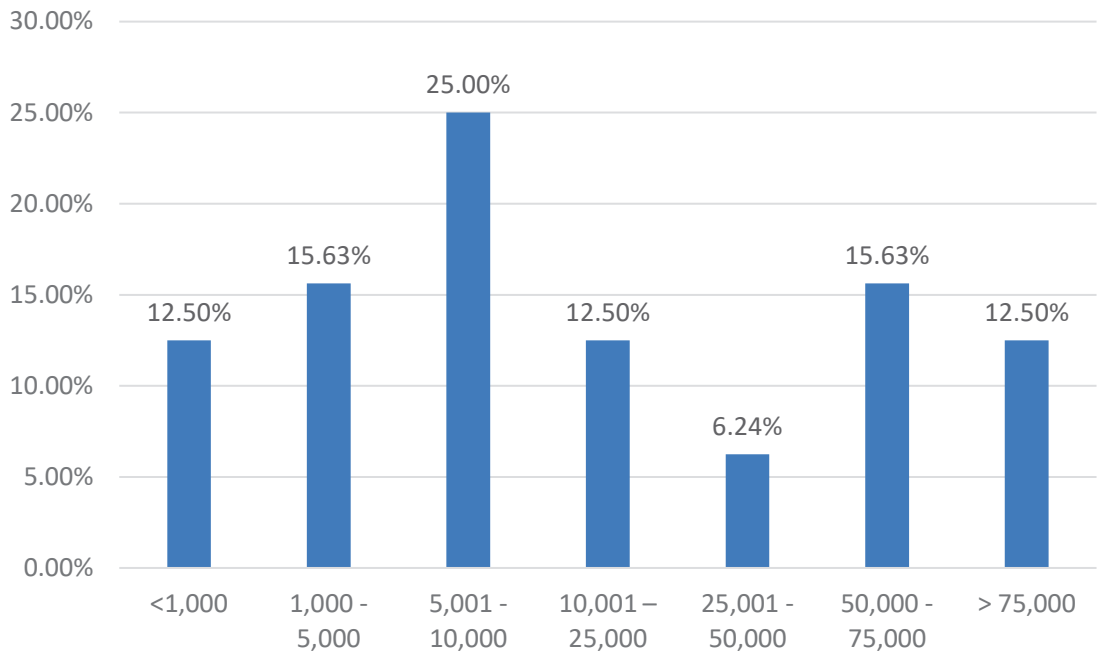
3. Which below best describes your company?

More than Medical Device & Pharmaceutical
15.63%

Medical Device & Pharmaceutical
25.00%

Medical Device Specific
59.37%

4. What was your Company's 2023 worldwide device-related gross revenue?

Revenue	Percentage
Pre-Revenue	0.00%
< $100M	9.38%
$100M - $500M	9.38%
$500M - $1B	3.12%
$1.01B - $3B	28.11%
$3.01B - $5B	9.38%
$5.01B - $7B	9.38%
$7.01B - $10B	9.38%
$10.01B – $15B	0.00%
$15.01B - $20B	6.25%
$20.01B - $25B	3.12%
>$25B	12.50%

5. What is your organization's total number of full-time employees/headcount?

6. How many total US-based full-time employees are in your company?
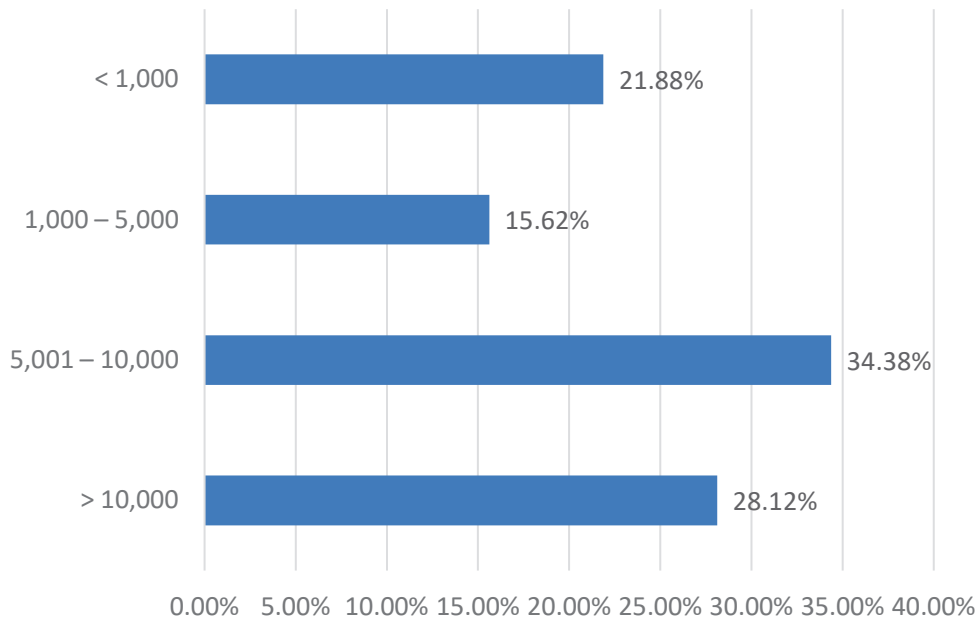
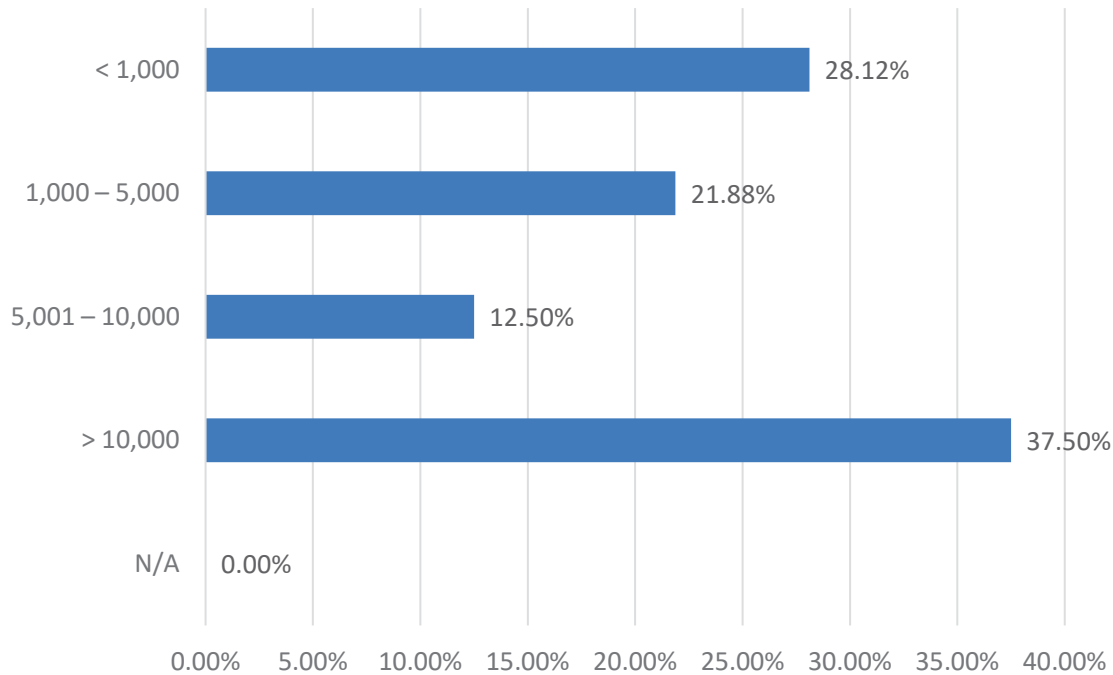Comments:

- o Device-related Revenue **$500M - $1B:**
  - o Probably right around 1,000 FTEs.

7. How many total OUS-based full-time employees are in your company?

Category	Percentage
< 1,000	28.12%
1,000 – 5,000	21.88%
5,001 – 10,000	12.50%
> 10,000	37.50%
N/A	0.00%

Comments:

- o Device-related Revenue **<$100M**
  - o <1,000 in Canada and the US only.

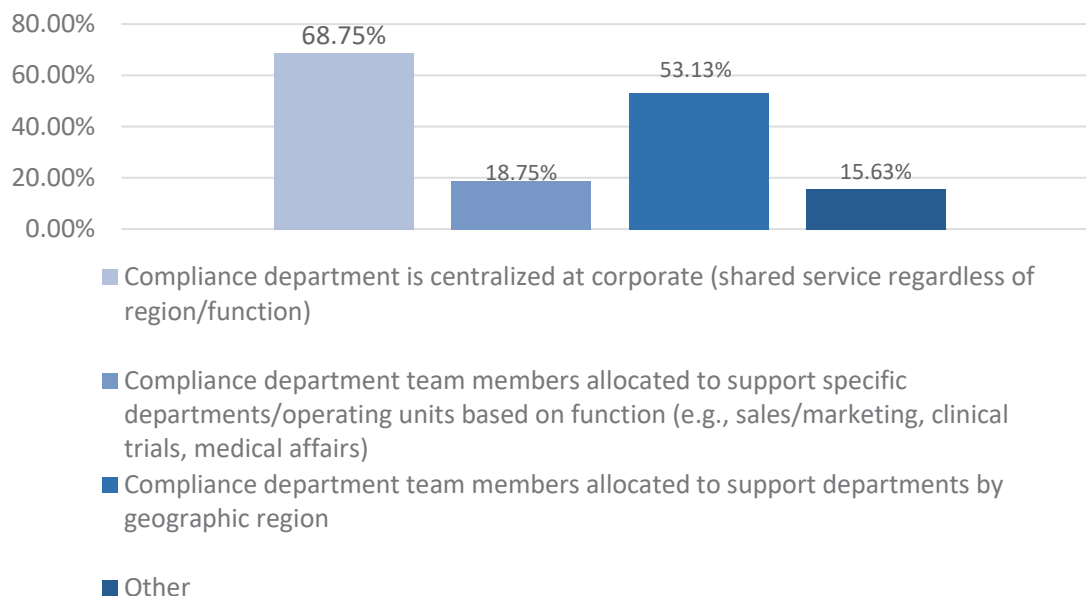## 8. Which best describes your compliance department's geographic scope?

- o **87.50%** - Global
- o **6.25%** - Americas
- o **6.25%** - US Only

Comments:

- o Device-related Revenue **<$100M**
  - o US and Canada - North America only.
- o Device-related Revenue **$1.01B - $3B**
  - o I perform work globally to upskill the Global Compliance Team, so I regularly engage in activities in the EU/UK.

9. Is your compliance department/function centralized or does your company have compliance functions allocated to specific groups by subject matter or otherwise? [Please select all that apply].


Bar chart showing:
- Compliance department is centralized at corporate (shared service regardless of region/function): 68.75%
- Compliance department team members allocated to support specific departments/operating units based on function (e.g., sales/marketing, clinical trials, medical affairs): 18.75%
- Compliance department team members allocated to support departments by geographic region: 53.13%
- Other: 15.63%

Comments:

- Device-related Revenue **$500M - $1B**
  - Compliance ops is centralized at corporate with a local person in the region for Legal/Compliance guidance.
- Device-related Revenue **$1.01B - $3B**
  - Compliance department team members are also allocated to different business units.
  - I run all compliance topics including anti-kickback, conflict of interest, anti-trust, investigations, sunshine, etc. (everything – 1 person).
- Device-related Revenue **$3.01B - $5B**
  - Some team members have global responsibilities and others have region-specific responsibilities.
  - We have a corporate function in the US and regional compliance groups that service those regions only. The corporate function supports all regions.
- Device-related Revenue **$5.01B - $7B**
  - Centralized Compliance department at the corporate level with some business partner roles dedicated to supporting specific geographic regions supported by global support/oversight/operations teams.
- Device-related Revenue **$7.01B - $10B**

- Global operations (policy, monitoring, training, communications, helpline) of the compliance function are centralized with business partners, and additional support is allocated across the globe.
  - Device-related Revenue **$7.01B - $10B**
    - All the above.

10. How many full-time employees work within your Company's Compliance Department globally?
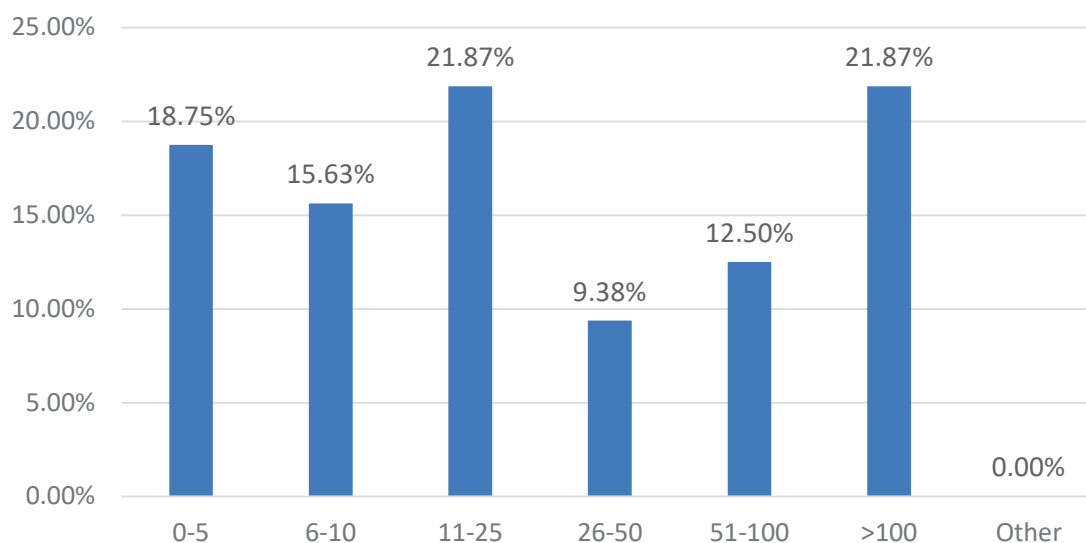
2022 & 2024 Response Comparison

Compliance FTEs	2024 Responses	2022 Responses
<5	18.75%	26%
5-10	15.63%	18%
10-25	21.87%	15%
25-50	9.38%	11%
>50	34.37%	30%

2023 Device Revenue vs. Global Compliance Department FTEs (CFTEs)

Device-Related Revenue	0-5 CFTEs	6-10 CFTEs	11-25 CFTEs	26-50 CFTEs	51-100 CFTEs	>100 CFTEs	Total Respondents	
Pre-Revenue	-	-	-	-	-	-	0%	0
< $100M	100%	-	-	-	-	-	9.38%	3
$100M - $500M	66.67%	33.33%	-	-	-	-	9.38%	3
$500M - $1B	-	100%	-	-	-	-	3.12%	1
$1.01B - $3B	11.11%	33.33%	44.45%	11.11%	-	-	28.13%	9
$3.01B - $5B	-	-	100%	-	-	-	9.38%	3

|								
$5.01B - $7B	-	-	-	66.67%	-	33.33%	9.38%	3
$7.01B - $10B	-	-	-	-	66.67%	33.33 %	9.38%	3
$10.01B – $15B	-	-	-	-	-	-	0%	0
$15.01 - $20B	-	-	-	-	50%	50%	6.23%	2
$20.01B - $25B	-	-	-	-	-	100%	3.12%	1
>$25B	-	-	-	-	25%	75%	12.5%	4
Total	18.75%	15.63%	21.87%	9.38%	12.5%	21.87%	100%	32

Organization's Total FTEs vs. Global Compliance Department FTEs (CFTEs)

Organization's Total FTEs	0-5 CFTEs	6-10 CFTEs	11-25 CFTEs	26-50 CFTEs	51-100 CFTEs	>100 CFTEs	Total Respondents	
<1,000	100%	-	-	-	-	-	12.5%	4
1,000 - 5,000	40%	60%	-	-	-	-	15.63%	5
5,001 - 10,000	-	25%	62.5%	12.5%	-	-	25%	8
10,001 – 25,000	-	-	50%	25%	25%	-	12.5%	4
25,001 - 50,000	-	-	-	-	50%	50%	6.24%	2
50,000 - 75,000	-	-	-	20%	40.%	40%	15.63%	5
>75,000	-	-	-	-	-	100%	12.5%	4
Total	18.75%	15.63%	21.87%	9.38%	12.50%	21.87%	100%	32

Comments:

- o Device-related Revenue **$1.01B - $3B**
  - o Total of 10, including the CCO.
  - o 15.
  - o About 30ish FTEs, 30 part of their responsibility is compliance.
- o Device-related Revenue **$7.01B - $10B**
  - o 75 total; 15 in trade compliance, 26 in regional compliance business partnering roles, and 34 in global compliance function roles (investigations, third party compliance, operations, audit & monitoring).

11. How many full-time employees work within your Company's Compliance Department in the US?
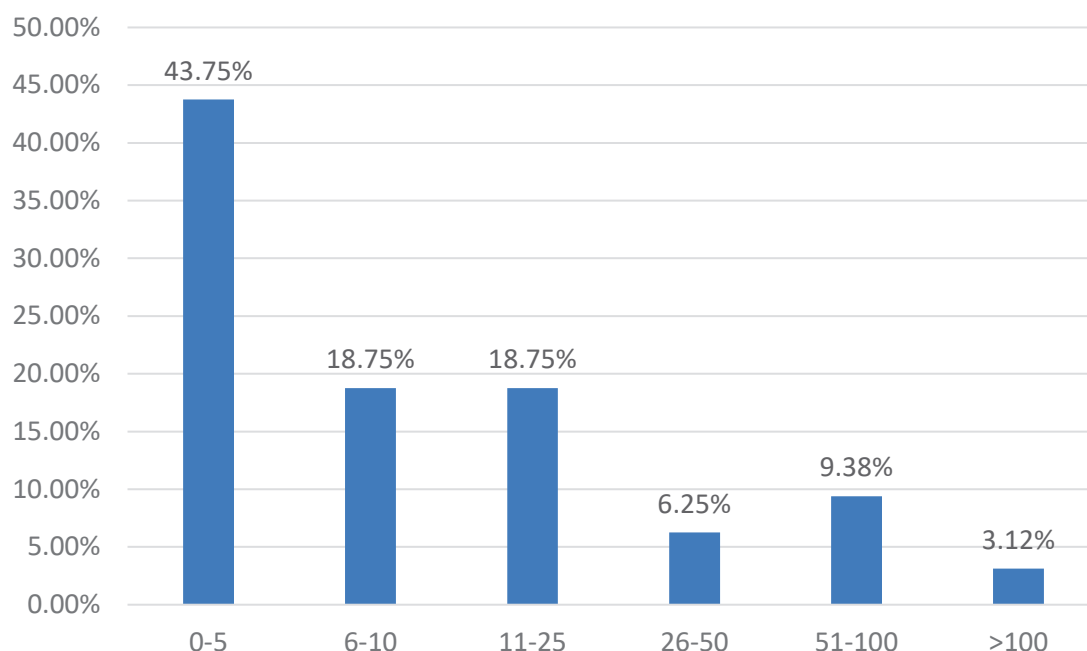
2023 Device Revenue vs. US Compliance Department FTEs (CFTEs)

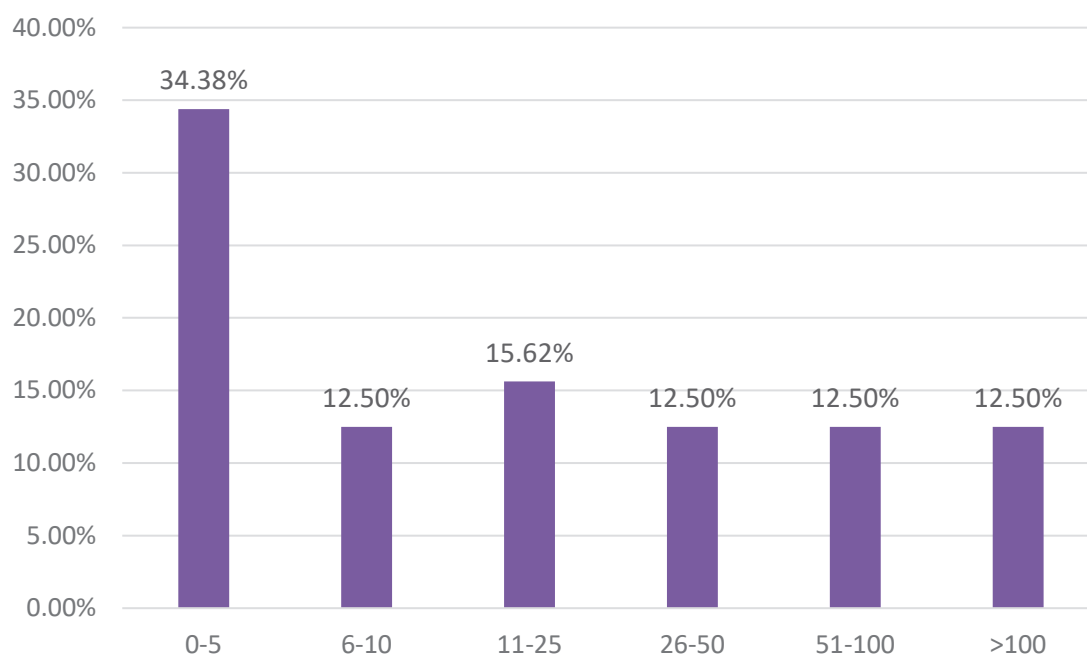| Device-Related Revenue	0-5 CFTEs	6-10 CFTEs	11-25 CFTEs	26-50 CFTEs	51-100 CFTEs	>100 CFTEs	Total Respondents	
Pre-Revenue	-	-	-	-	-	-	0%	0
< $100M	100%	-	-	-	-	-	9.38%	3
$100M - $500M	66.67%	33.33%	-	-	-	-	9.38%	3
$500M - $1B	-	100%	-	-	-	-	3.12%	1
$1.01B - $3B	55.56%	22.22%	22.22%	-	-	-	28.13%	9
$3.01B - $5B	100%	-	-	-	-	-	9.38%	3
$5.01B - $7B	33.33%	33.33%	33.34%	-	-	-	9.38%	3
$7.01B - $10B	-	33.33%	33.33%	-	-	33.34%	9.38%	3
$10.01B – 15B	-	-	-	-	-	-	0%	0
$15.01 - $20B	-	-	50%	50%	-	-	6.23%	2
$20.01B - $25B	-	-	-	100%	-	-	3.12%	1
>$25B	-	-	-	-	75%	25%	12.5%	4
Total	43.75%	18.75%	18.75%	6.25%	9.38%	3.12%	100%	32

Organization's Total FTEs vs. US Compliance Department FTEs (CFTEs)

Organization's Total FTEs	0-5 CFTEs	6-10 CFTEs	11-25 CFTEs	26-50 CFTEs	51-100 CFTEs	>100 CFTEs	Total Respondents	
<1,000	100%	-	-	-	-	-	12.5%	4
1,000 - 5,000	60%	40%	-	-	-	-	15.63%	5
5,001 - 10,000	50%	25%	25%	-	-	-	25%	8
10,001 − 25,000	75%	25%	-	-	-	-	12.5%	4
5,001 - 50,000	-	-	100%	-	-	-	6.24%	2
50,000 - 75,000	-	20%	40%	40%	-	-	15.63%	5
>75,000	-	-	--	-	75%	25%	12.5%	4
Total	43.75%	18.75%	18.75%	6.25%	9.38%	3.12%	100%	32

Comments:

- Total FTEs **5,001 - 10,000**
    - 9/10 are in the US.
    - 7.
- Total FTEs **10,001 − 25,000**
    - 8 FTEs focused on US compliance.
    - Additional support team members located in the US but they are not solely responsible for supporting the US business.
    - Solo compliance officer.
- Total FTEs >**75,000**
    - 61.

12. How many full-time employees work within your Company's Compliance Department OUS?

2023 Device Revenue vs. OUS Compliance Department FTEs (CFTEs)

| Gross-Device Revenue	0-5 CFTEs	6-10 CFTEs	11-25 CFTEs	26-50 CFTEs	51-100 CFTEs	>100 CFTEs	Total Respondents	
Pre-Revenue	-	-	-	-	-	-	0%	0
< $100M	100%	-	-	-	-	-	9.38%	3
$100M - $500M	100%	-	-	-	-	-	9.38%	3
$500M - $1B	100%	-	-	-	-	-	3.12%	1
$1.01B - $3B	44.45%	22.22%	33.33%	-	-	-	28.12%	9
$3.01B - $5B	-	66.67%	33.33%	-	-	-	9.38%	3
$5.01B - $7B	-	-	-	66.67%	-	33.33%	9.38%	3
$7.01B - $10B	-	-	33.33%	-	33.33%	33.34%	9.38%	3
$10.01B – 15B	-	-	-	-	-	-	0%	0
$15.01 - $20B	-	-	-	50%	50%	-	6.24%	2
$20.01B - $25B	-	-	-	-	100%	-	3.12%	1
>$25B	-	-	-	25%	25%	50%	12.5%	4
Total	34.38%	12.5%	15.62%	12.5%	12.5%	12.5%	100%	32

Organization's Total FTEs vs. OUS Compliance Department FTEs (CFTEs)

Organization's Total FTEs	0-5 CFTEs	6-10 CFTEs	11-25 CFTEs	26-50 CFTEs	51-100 CFTEs	>100 CFTEs	Total Respondents	
<1,000	100%	-	-	-	-	-	12.5%	4
1,000 - 5,000	100%	-	-	-	-	-	15.63%	5
5,001 - 10,000	25%	50%	25%	-	-	-	25%	8
10,001 − 25,000	-	-	75%	25%	-	-	12.5%	4
25,001 - 50,000	-	-	-	-	50%	50%	6.24%	2
50,000 - 75,000	-	-	-	60%	40%	-	15.63%	5
>75,000	-	-	-	-	25%	75%	12.5%	4
Total	34.37%	12.5%	15.63%	12.5%	12.5%	12.5%	100%	32

Comments:

- Total FTEs **<1,000**
  - Zero.
- Total FTEs **5,001 - 10,000**
  - 1/10 are OUS.
  - 2 compliance personnel OUS also act as local legal representatives.
  - 8.
- Total FTEs **10,001 − 25,000**
  - 18 FTEs focused on OUS compliance.
- Total FTEs >**75,000**
  - 103.

13. **How many consultants (including outside counsel) or temps/contractors routinely work for your Company's Compliance Department globally?**
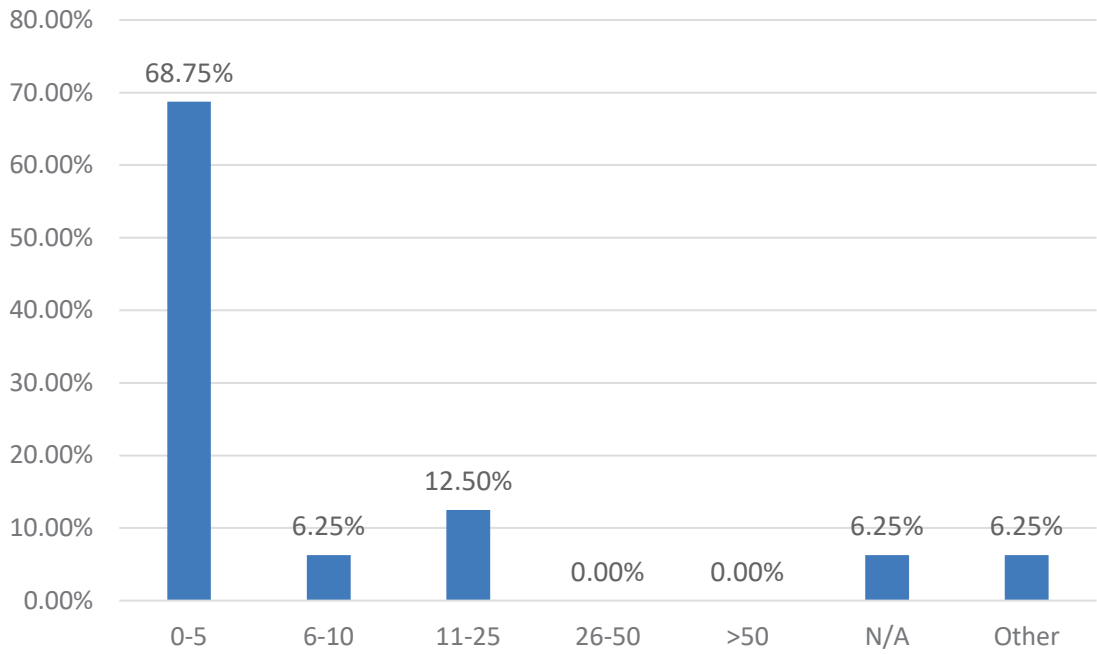
2022 & 2024 Response Comparison

Consultants	2024 Responses	2022 Responses
0-5	68.75%	67%
5-10	6.25%	11%
10-25	12.50%	11%
25-50	0%	7%
>50	0%	4%
NA	6.25%	0%
Other	6.25%	0%

2023 Device-Revenue vs. Global Consultants/Outside Counsel/Temps/Contractor

Gross-Device Revenue	0-5	6-10	11-25	26-50	>50	N/A	Other	Total Respondents	
Pre-Revenue	-	-	-	-	-	-	-	0%	0
<$100M	100%	-	-	-	-	-	-	9.38%	3
$100M - $500M	100%	-	-	-	-	-	-	9.38%	3
$500M - $1B	100%	-	-	-	-	-	-	3.12%	1
$1.01B - $3B	66.67%	-	22.22%	-	-	11.11%	-	28.12%	9
$3.01B - $5B	100%	-	-	-	-	-	-	9.38%	3
$5.01B - $7B	-	33.33%	33.33%	-	-	33.34%	-	9.38%	3
$7.01B - $10B	33.33%	-	33.33%	-	-	-	33.34%	9.38%	3
$10.01B – $15B	-	-	-	-	-	-	-	0%	0
$15.01 - $20B	100%	-	-	-	-	-	-	6.24%	2
$20.01B - $25B	100%	-	-	-	-	-	-	3.12%	1
>$25B	50%	25%	-	-	-	-	25%	12.5%	4
Total	68.75%	6.25%	12.5%	0%	0%	6.25%	6.25%	100%	32

Organization's Total FTEs vs. Global Consultants/Outside Counsel/Temps/Contractors

Organization's Total FTEs	Global Consultants:0-5	6-10	11-25	26-50	>50	N/A	Other	Total Respondents	
<1,000	100%	-	-	-	-	-	-	12.5%	4
1,000 - 5,000	100%	-	-	-	-	-	-	15.63%	5
5,001 - 10,000	75%	-	12.5%	-	-	12.5%	-	25%	8
10,001 – 25,000	50%	-	25%	-	-	25%	-	12.5%	4
25,001 - 50,000	-	50%	50%	-	-	-	-	6.24%	2
50,000 - 75,000	80%	-	20%	-	-	-	-	15.63%	5
>75,000	25%	25%	-	-	-	-	50%	12.5%	4
Total	68.75%	6.25%	12.5%	0%	0%	6.25%	6.25%	100%	32

Comments:
- Device-related Revenue **$100M - $500M**
  - Zero
- Device-related Revenue **$1.01B - $3B**
  - Zero.
- Device-related Revenue **$7.01B - $10B**
  - Do not have this information.

14. What is your all-in 2024 compliance budget that you manage (internal spending, including employee salary, benefits, external spending for vendors, systems, consultants, outside counsel, etc.) globally?

2023 Device Revenue vs. 2024 All-In Compliance Budget

All-in 2024 Compliance Budget for Revenue <$100M	Revenue $100M - $500M	Revenue $500M - $3B	Revenue $3.01B - $5B	Revenue $5.01B - $7B	Revenue $7.01B - $15B	Revenue $15B - $25B	Revenue >$25B
$242,500	$1.1M	$1.13M	$3M	$3 - $4M The all-in annual budget for the US only.	$28M	~$10M	$23.25M
$500K	~$500K	$2.6M	N/A	$4.31M Americas Region	~$18.5M	$15M	>$50M
$1M	$1.9M	$4.8M	$3.8M	$8.3M Does not include external counsel spend which is held in the Legal budget.	$6.7M	~$34.5M	Not sure at this time.
		Don't have exact numbers.					N/A
		~$2M					
		$8M for the US (don't have access to Global Compliance or other regions, but theirs is less)					
		N/A not responsible for global					
		N/A					
		$2.6M					

2023 Device Revenue vs. All-In Compliance Budget **Range**

Revenue <$100M	$100M - $500M	$500.1M - $3B	$3.01B - $7B	$7.01B - $15B	$15.1B - $25B	>$25B
Budget $242.5K – $1M	$1.1M - $1.9M	$1.13M - $8M	$3M - $8.3M	$6.7M - $28M	$10M - $34.5M	$23.24M - >$50M
0.24% - 1.00%	0.37% - 0.63%	0.065% - 0.457%	0.06% - 0.166%	0.06% - 0.26%	0.05% - 0.17%	0.10% - 0.20%

Total FTEs vs. 2024 All-In Compliance Budget

All-In Compliance Budget for Organization's FTEs <1,000	FTEs 1,000 - 5,000	FTEs 5,001 - 10,000
$242.5K	$1.1M	~ $1.13M
<$500K Combined with Legal Budget.	$1.9M	$2.6M
$500K	N/A	$4.8M
$1M	N/A	$3M
		<$2M Outside counsel expenses are covered by the Legal department.
		$8M For the US.
		$3.8M

All-In Compliance Budget for Organization's FTEs 10,001 – 50,000	FTEs 50,000 - 75,000	FTEs > 75,000
$28M	$3-4M All-in annual budget for US only.	N/A
$8.3M Does not include external counsel spend which is held in the Legal budget.	~$34.5M	>$50,000,000
N/A	~ $10M Global	6.7M
N/A Not responsible for global	$15M	$23.25M
$4.31M Americas Region.	N/A	
~$18.5M		

Global Compliance Department FTEs (CFTEs) vs. 2024 All-in Compliance Budget

All-in Compliance Budget for Compliance Dept of 0-5 CFTEs	6-10 CFTEs	11-25 CFTEs
$242.5K	$2.6M	~$1.13M
$1.1M	$2.6M	$4.8MM
<$500K Combined with Legal Budget. This is the approximate Compliance portion.	Don't have the exact numbers.	N/A
$500K	$1.9M	$3 million
$1M		~$2 million. Outside counsel expenses are covered by the Legal department.
N/A		N/A not responsible for global
		$3.8M

26-50 CFTEs	51-100 CFTEs	>100 CFTEs
$3M-4M all-in annual budget for US only	$10M Global approx.	$4.31M Americas Region
$8.3M does not include external counsel spend which is held in the Legal budget	$28M	~$34.5M
$8M for US (don't have access to Global Compliance or other regions, but theirs is less)	Not sure at this time.	N/A
	~$18.5M	>$50M
		$6.7M
		$23.25M
		$15M

15. **What is your 2024 budget for INTERNAL (employee salary, benefits, etc.) Compliance Spending globally?**

2023 Device Revenue vs. 2024 Internal Budget

Internal Compliance Budget for Revenue < $100M	Revenue $100M - $500M	Revenue $500.1M - $3B	Revenue $3.01B - $5B	Revenue $5.01B - $7B	Revenue $7.01B - $15B	Revenue $15.1B - $25B	Revenue >$25B
$188.5K	$580k	~$8M	N/A	$4.16M Americas Region	$4.6M	~$4M US only	N/A
$400K	<$300K	~$1.6M wages (no benefits)	$2.3M	$1-2M The internal annual budget for the US only	$23M	$12.5M	$43M
$2M	$1.4M	$3.2M	$2.2M	$7.4M	~$12M	~27.5M	N/A
		<$2M					$21.68M
		~$500K					
		$2.2M					
		Don't have the exact numbers					
		N/A					
		N/A not responsible for global					

*2023 Device Revenue vs. 2024 Internal Budget **Range***

Internal Compliance Budget Range for Revenue <$100M	Revenue $100M - $500M	Revenue $500.1M - $3B	Revenue $3.01B - $5B	Revenue $7.01B - $15B	Revenue $15.1B - $25B	Revenue >$25B
$188.5K – $2M	$300K - $1.4M	$500K - $8M	$2.2M - $2.3M	$4.6M - $23M	$12.5M - $27.5M	$21.68M - $43M
0.19% - 2.00%	0.1% - 0.47%	0.03% - 0.46%	0.06% - 0.06%	0.04% - 0.21%	0.06% - 0.14%	0.09% - 0.17%

Organization's Total FTEs vs. 2024 Internal Budget

Internal Compliance Budget for FTEs <1,000	FTEs 1,001 - 5,000	FTEs 5,001 - 10,000	FTEs 10,001 – 25,000
$188,500	Don't have exact numbers	~$8M	N/A
<$300K	$580k	~$1.6M wages (no benefits)	$23M
$400K	$1.4 million	$3.2M	$7.4M
$2M	~$500K	N/A	N/A not responsible for global
		$2.3M	
		<$2M	
		$2.2M	
		$2.2M	

Internal Compliance Budget for FTEs 25,001– 50,000 FTEs	FTEs 50,000 - 75,000	FTEs > 75,000
$4.16M Americas Region Only	$1-2 million internal annual budget for US only	N/A
~$12M	~$27.5M	$43M
	~$4M US only	$4.6M
	Not sure at this time.	$21.68M
	$12.5M	

Compliance Department FTEs (CFTEs) vs. 2024 Internal Budget

Internal Compliance Budget for Compliance Dept of 0-5 CFTEs	6-10 CFTEs	11-25 CFTEs
$188.5K	$1.9M	~$8M
$580k	~$1.6M wages (no benefits)	$3.2M
<$300K	Don't have the exact numbers	N/A
$400K	N/A	$2.3M
$2M	$1.4M	<$2M
~$500K		N/A not responsible for global
		$2.2M

Internal Compliance Budget for Compliance Dept of 26-50 CFTEs	51-100 CFTEs	>100 CFTEs
$1-2M internal annual budget for US only	~$4M US	$4.16M Americas Region
$7.4M	$23M	~$27.5M
$2.2M	Not sure at this time.	N/A
	~$12M	$43M
		$4.6M
		$21.68M
		$12.5M

16. **Relative to 2024, I expect my 2025 INTERNAL (employee salary, benefits, etc.) Compliance Spend to:**
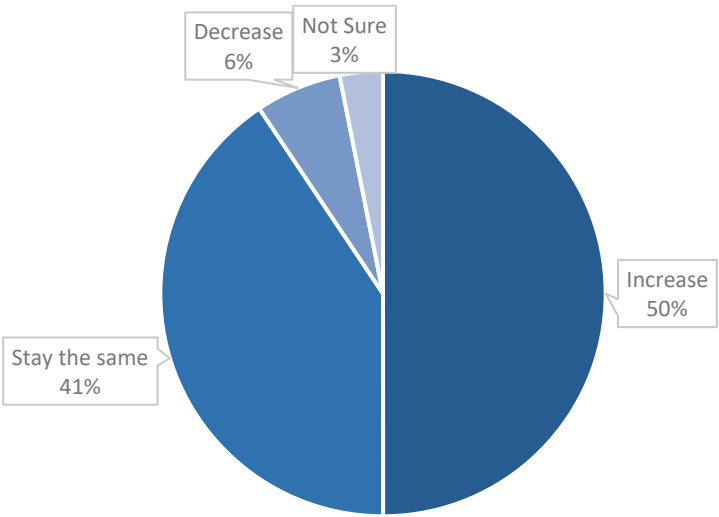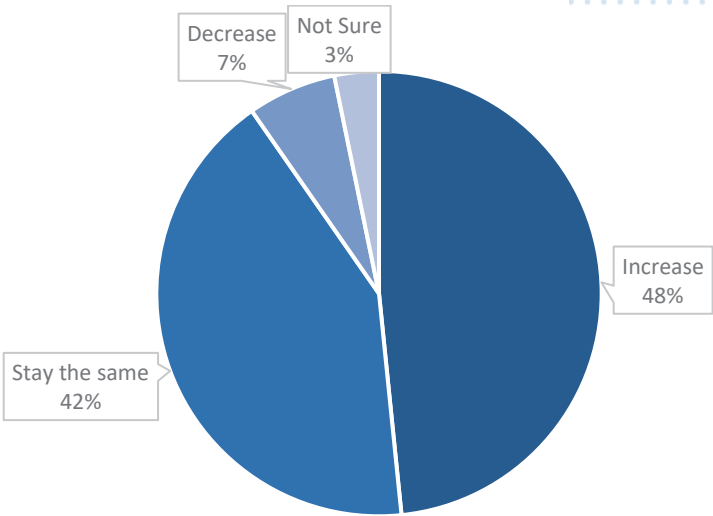

2022 & 2024 Response Comparison

Expected Internal Spend	2024 Responses	2022 Responses
Increase	50%	67%
Stay the Same	41%	29%
Decrease	6%	4%
Not Sure	3%	0%

Comments:

o Increase (related to continued building of compliance program).

o Decrease due to Company targets/reductions; applied various savings due to associate departures and/or reduction in discretionary spend items.

o Looking to add headcount OUS.

o Spend will increase due to cost-of-living increases.

17. **Relative to 2024, I expect my 2025 External (vendors, systems, consultants, outside counsel, etc.) Compliance Spend to:**

2022 & 2024 Response Comparison

Expected External Spend	2024 Responses	2022 Responses
Increase	48%	56%
Stay the Same	42%	44%
Decrease	7%	0%
Not Sure	3%	0%

Comments:

- o Increase (related to continued building of compliance program).
- o Possibly will decrease.

18. As it relates to budget and resourcing, what subject areas fall within your compliance program? [Select all that apply]

Answer Choices	Responses %
Sunshine/Transparency Reporting	90.63%
Consulting arrangements with health care professionals	87.50%
Employee Training	84.38%
Grants and charitable donations	81.25%
Sales, promotional and other business meetings	71.88%
Company-conducted product training & education	71.88%
Third-party management	71.88%
Evaluation, loaner, consignment, and demonstration products	68.75%
Research & development (including investigator-initiated trials)	59.38%
Data Privacy	59.38%
Payment of royalties	43.75%
Patient support programs	37.50%
Provision of coverage, reimbursement, and health economics information	37.50%
Social Media Behavior Guidance	37.50%
Medical information	34.38%
Antitrust	34.38%
Environment, Social, and Governance (ESG)	28.13%
Trade Compliance	25.00%
Other	25.00%
Document Retention/Records Management	21.88%
Diversity, Equity, and Inclusion (DEI)	9.38%

Comments:
- o Direct billing to Federal and State programs.
- o Risk Assessment, Compliance Governance, Interactions with HCPs/HCOs, Ethical Culture/Communications/Tone at the Top, Global Policy Governance & Management, Ethics Office & Investigations, Conflicts of Interest, Code of Conduct, M&A Compliance Due diligence, Monitoring/Analytics.
- o Enterprise Risk Management.
- o Compliance function is part of a larger Governance, Risk, Compliance (GRC) function with responsibility for Governance, Risk & Controls, Compliance, Privacy, and Information, Product, and Cyber Security.
- o Other include Conflicts of Interest.
- o Ethical Culture.

19. What other risk areas does your compliance department provide support for (e.g., advisory, guidance)? [Select all that apply]

Answer Choices	Response %
Company-conducted product training & education	59.38%
Sales, promotional and other business meetings	56.25%
Social Media Behavior Guidance	56.25%
Research & development (including investigator-initiated trials)	53.13%
Consulting arrangements with health care professionals	46.88%
Evaluation, loaner, consignment, and demonstration products	46.88%
Employee Training	46.88%
Grants and charitable donations	43.75%
Third-party management	43.75%
Patient support programs	40.63%
Provision of coverage, reimbursement, and health economics information	40.63%
Sunshine/Transparency Reporting	40.63%
Data Privacy	37.5%
Environment, Social, and Governance (ESG)	37.5%
Document Retention/Records Management	37.5%
Antitrust	34.38%
Payment of royalties	31.25%
Medical information	31.25%
Trade Compliance	31.25%
Diversity, Equity, and Inclusion (DEI)	28.13%
Other	12.5%

Comments:

- Same as answers to #19 - also Cyber Security.
- Cybersecurity compliance.
- As things arise.

20. Please describe any recent challenges your Compliance Department may have had (e.g., funding/resources, technology resource systems):

Comments:

- **Resources:**
  - Funding, expanding the department to keep pace with acquisitions.
  - Budget and resources are perennially a challenge.
  - Funding/resources; lack of consolidation among systems of record.
  - Resource challenges.
  - Finding the right balance of internal/external resources and technology resource systems to support a rapidly growing business is challenging, particularly as the company enters new markets.
  - Budgetary pressures.
  - Funding, resource dedication, risk management.
  - Funding, bandwidth to handle the amount of work, finding talent at the right level (junior talent available but needs more senior talent).
  - Funding/resources; technology systems.
  - Employee understanding, pace of work, and expectations.
  - Financial targets, double hatted responsibilities, occasional hiring freezes.
  - Funding/resources; new and changing laws and regulations.
  - Maintaining coverage in a resource-constrained environment.

- **Technology:**
  - Added technology solutions in CD&G, Risk, Conflict of Interest, and ESG. Reconsolidated the global E&C Program and included 3P Distributor Mgt and ESG.
  - Making sure technology platforms are optimized for efficient management of the program.
  - Tool updates and a limited budget for these updates.
  - Technology resources, AI, training time/cost.
  - Technology resource systems.
  - (1) Technology debt, and no industry-leading global IT products available (2) Constrained resources, leading to creative solutions.
  - Technology & IT resources.

- **Specific Program Needs:**
  - Investments in long-term funding projects: risk management system, Policy system, HCP interactions, and grants platforms.
  - We are a small, global company with one Compliance resource who covers several regions. It is challenging to have policies/procedures set up that make it more efficient for one person to manage yet also take into consideration the nuanced differences/industry standards/laws and

- regulations for each country.
  - o As we grow, balancing resources to support compliance and open payment reporting.
- o **4 respondents responded N/A**

21. **Please describe any recent changes that may have provided significant benefit to your Compliance Department:**
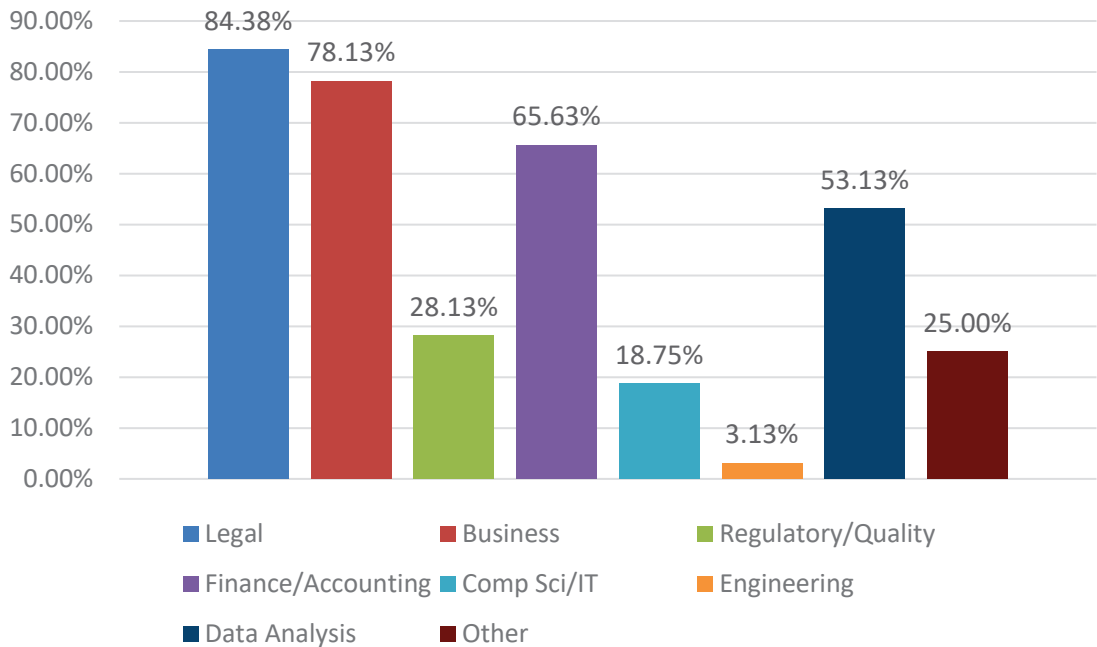
Comments:

- o **Program Enhancements:**
  - o Consolidation of the programs under a single E&C Function.
  - o Switching HCP engagement systems are expected to increase efficiencies.
  - o Increased resources, advances in compliance leadership personnel, improved global compliance coordination new systems.
  - o Build out of analytics function. Dedicated focus and hiring on professional development, change management, enterprise risk management, PMO, and strategy and governance.
  - o Systems have allowed us to become more efficient and the data collected is more conducive to analysis; improvement in data analytics had produced significant benefits.
  - o Increased use of data analytics.
  - o Despite being a small company, moving away from emailed requests and utilizing CRM tools for requests and process flow has been very helpful. The business sometimes complains about the extra steps but maintaining control and accurate records via email was proving not efficient.
  - o Use of new tech platform to compile and analyze compliance program metrics; further automation of processes.
  - o Additional resources/headcount as needed to support growth.
  - o Process improvement/driving consistent processes; strong ethical culture-focused work.
  - o Leadership advances in compliance culture.
  - o Structural changes to move monitoring and investigation into shared global function, transition responsibility for HCP engagements to Med Ed so Compliance provides an oversight role rather than being approvers of individual activities.
  - o Business restructuring that allowed for better Compliance team alignment in support of the business.
  - o The OIG's recent General Compliance Program Guidance has helped focus internal discussions regarding compliance and the importance of compliance.
  - o Hiring a dedicated compliance officer.
  - o Integration into one US entity will ultimately help.
  - o ESG reporting and compliance will be part of the compliance department mandate.
- o **14** Respondents did not comment or responded N/A

22. What is the education/background of the professionals in your compliance department?
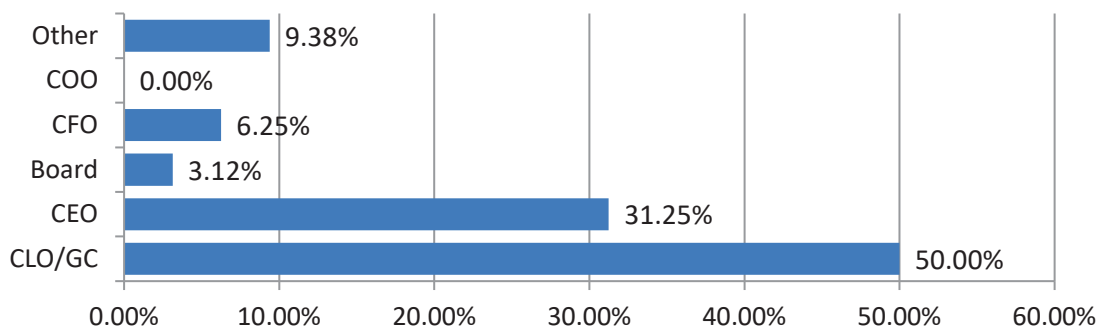

Comments:

- o Prof Ed, Project Management.
- o Audit, Training & Education, Sales and Marketing, Information Technology and Security, and Fraud Examination.
- o Compliance.
- o Other academic backgrounds in the team: Life Sciences, languages, nursing.
- o Sales/marketing/commercial.
- o All of the above.

23. To whom does the head of your compliance department/function directly report to?

Other — 9.38%
COO — 0.00%
CFO — 6.25%
Board — 3.12%
CEO — 31.25%
CLO/GC — 50.00%

(x-axis: 0.00%, 10.00%, 20.00%, 30.00%, 40.00%, 50.00%, 60.00%)

Comments:

o The global head of compliance reports into the global CEO. The regional heads of compliance have a dotted line reporting to the regional CEOs, sit on the regional Executive Committees, and solid line reporting to the global head of Compliance.

o Executive Vice President and Board.

o Chief Risk Officer.

o Direct reporting line to CLO. Dotted line reporting to sub-committee of Board of Directors.

o Chief Compliance Officer reports to the President of the US entity and to the Executive Vice President of Legal, Compliance, and Regulatory for the entire company.

24. Does your company have an established Compliance Committee that meets routinely?

No — 6.25%
Yes — 93.75%

(x-axis: 0.00%, 20.00%, 40.00%, 60.00%, 80.00%, 100.00%)
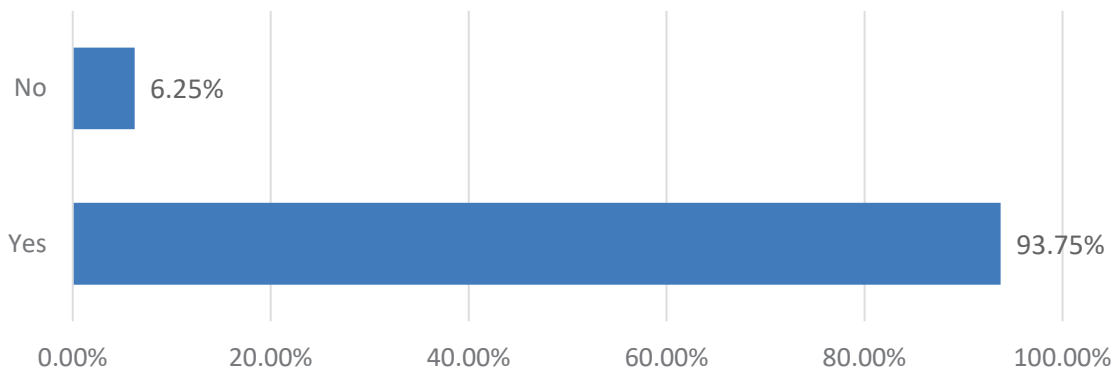
Comments:

o We have one at Board level and management level.

o The Committee's scope is broader than Compliance and also includes Risk & Controls, Privacy, and Information, Product, and Cyber Security.

- o Board Oversight Committee but not a Compliance Committee.
- o Two committees on internal chaired by the CEO and run by CECO with members of the executive committee and Internal Audit. One Board sub-committee that has oversight responsibility for Compliance. In addition, every region and country has a compliance committee run by compliance officer with country/region leadership on the committee.
- o Quarterly Compliance Committee meetings.
- o Quarterly Meetings.
- o Quarterly.

25. What functions outside of compliance sit on your Compliance Committee?

Answer Choices	Responses
Legal	87.50%
Finance	84.38%
Business	78.13%
HR	71.88%
Sales	59.38%
Operations	56.25%
Regulatory	56.25%
Marketing	53.13%
Quality	53.13%
Med Ed/Med Affairs	43.75%
R&D/Research	40.63%
Internal Audit	40.63%
IT	37.50%
Risk	25.00%
Other	12.50%
Not Applicable	9.38%
Process Improvement	6.25%

Comments:

- o The Board Oversight Committee is the Compliance Committee.
- o This is an executive leadership compliance committee so includes the CEO and his staff, other leaders attend as needed based on the agenda.
- o We have multiple levels of compliance committees throughout the organization with different representation.
- o CEO and Regional Leaders.
- o CEO.
- o Data Privacy.

- o The whole Executive Committee sits on the global Compliance Committee.
- o US & Canadian CEO.

26. How does your Board receive reports from the Compliance Committee?

Comments

- o **Board Reporting Frequency:**

  16 Respondents noted quarterly reporting – additional details as follows:

  - o 3 respondents noted quarterly meetings and reports.
  - o Quarterly reports to the Audit Committee, bi-annual reports to the full Board by the CCO.
  - o Quarterly presentations to a sub-committee of the Board (separate from the Compliance Committee); regular and ad hoc meetings with the Chair of that sub-committee.
  - o Quarterly updates to the Board Oversight Committee.
  - o Quarterly updates to the Audit Committee.
  - o Quarterly reports via legal compliance.
  - o Quarterly reports from the CCO to the Board Audit Committee.
  - o The CCO reports to the Board Compliance Committee on a quarterly basis.
  - o We have standing board committee called the Compliance Oversight Committee that meets quarterly.
  - o Yes - the audit committee is a sub-committee of the Board and receives quarterly updates from Compliance.
  - o Quarterly updates to the Executive Management Team.
  - o The committee is a sub-committee of the board, and the Chief Compliance Officer provides quarterly updates to the Board regarding the activities of the committee.
  - o Compliance officer reports directly to the board quarterly.
  - o At least quarterly.

  3 Respondents noted at least annual reporting.

  1 Respondent noted reporting through the CCO semiannually.

  1 Respondent noted reporting 5 times/year through the Audit Committee of the Board and annual update to the full Board of Directors.

  1 Respondent noted periodic reports from the CECO.

- o **Board Reporting Mechanism:**

  - o Compliance committee is a sub-committee of the Board.
  - o CECO reports to meets with and reports out directly to the internal executive compliance committee. Board sub-committee and the full Board.
  - o Updates are provided to the Board from the Compliance Committee.

- o Compliance committee is a sub-committee of the Board.

- o We are a wholly-owned independent subsidiary. We roll up our compliance reporting to our parent's board. The Chief Compliance Officer for our parent provides reports to that board. We do have an independent board that is currently going through restructuring. Once it is established, we will have annual reporting to them.

- o From the GC (General Counsel).