AdvaMed
Advanced Medical Technology Association

AdvaMed Chief Compliance Officers Committee Benchmarking Working Group

2022 Compliance Department Size, Spend & Scope

Benchmarking Survey Results Report

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Questions: 16
Submissions: 27

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AdvaMed Code of Ethics CERTIFIED

Survey Questions

Demographics

1. Which of the below best describes your company?
    a. Medical Device-Specific
    b. Medical Device & Pharmaceutical
    c. More than Medical Device and/or Pharmaceutical

2. 2021 worldwide device-related gross revenue:
    a. Pre-Revenue
    b. < $100M
    c. $100M - $500M
    d. $500M - $1B
    e. $1B - $5B
    f. > $5B

3. How many US-based employees are in your company?
    a. < 1,000
    b. 1,000 – 5,000
    c. 5,001 – 10,000
    d. > 10,000
    e. N/A

4. How many OUS-based employees are in your company?
    a. < 1,000
    b. 1,000 – 5,000
    c. 5,001 – 10,000
    d. > 10,000
    e. N/A

5. Which best describes your compliance department's geographic scope?
    a. US Only
    b. Global

6. Is your compliance department at a corporate or division level?
    a. Corporate
    b. Divisional

Size & Spend

1. How many full-time employees work within your Company's Compliance Department?
    a. 0-5
    b. 5-10
    c. 10-25
    d. 25-50
    e. >50

2. How many consultants (including outside counsel) or temps work for your Company's Compliance Department?
    a. 0-5
    b. 5-10
    c. 10-25
    d. 25-50
    e. >50

3. What is your all-in compliance budget that you manage (internal spend, including employee salary, benefits, external spend for vendors, systems, consultants, outside counsel, etc.) for 2021?

4. What is your 2021 budget for INTERNAL (employee salary, benefits, etc.) Compliance Spend?

5. Relative to 2021, I expect my 2022 INTERNAL (employee salary, benefits, etc.) Compliance Spend to:
    a. Increase
    b. Stay the same
    c. Decrease
    d. Not sure

6. Relative to 2021, I expect my 2022 EXTERNAL (vendors, systems, consultants, outside counsel, etc.) Compliance Spend to:
    a. Increase
    b. Stay the same
    c. Decrease
    d. Not sure

Scope

1. Please indicate which department(s) is responsible for the below: [Compliance/Legal/HR/Finance/IT/ Medical Affairs/Other]
    a. Sales, promotional and other business meetings
    b. Company-conducted product training & education
    c. Consulting arrangements with health care professionals
    d. Grants and charitable donations
    e. Research & development (including investigator-initiated trials)
    f. Evaluation, loaner, consignment, and demonstration products
    g. Payment of royalties
    h. Patient support programs
    i. Provision of coverage, reimbursement, and health economics information
    j. Medical information
    k. Third-party management
    l. Data Privacy
    m. Environment, Social, and Governance (ESG)
    n. Diversity, Equity, and Inclusion (DEI)
    o. Sunshine/Transparency Reporting
    p. Trade Compliance
    q. Antitrust
    r. Employee Training
    s. Social Media Behavior Guidance
    t. Document Retention/Records Management
    u. Other

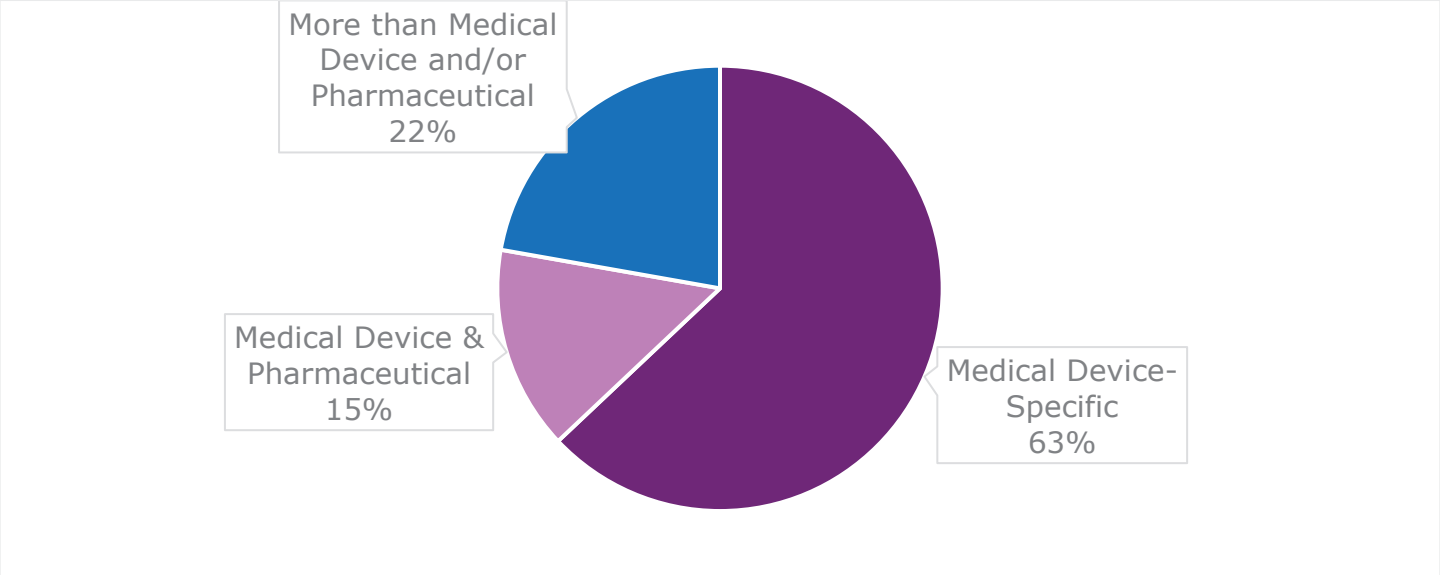
2. Please indicate if your compliance department has (1) primary or (2) supporting responsibility for each of the below:
    a. Sales, promotional and other business meetings
    b. Company-conducted product training & education
    c. Consulting arrangements with health care professionals
    d. Grants and charitable donations
    e. Research & development (including investigator-initiated trials)
    f. Evaluation, loaner, consignment, and demonstration products
    g. Payment of royalties
    h. Patient support programs
    i. Provision of coverage, reimbursement, and health economics information
    j. Medical information
    k. Third-party management
    l. Data Privacy
    m. Environment, Social, and Governance (ESG)
    n. Diversity, Equity, and Inclusion (DEI)

o. Sunshine/Transparency Reporting
p. Trade Compliance
q. Antitrust
r. Employee Training
s. Social Media Behavior Guidance
t. Document Retention/Records Management
u. Other

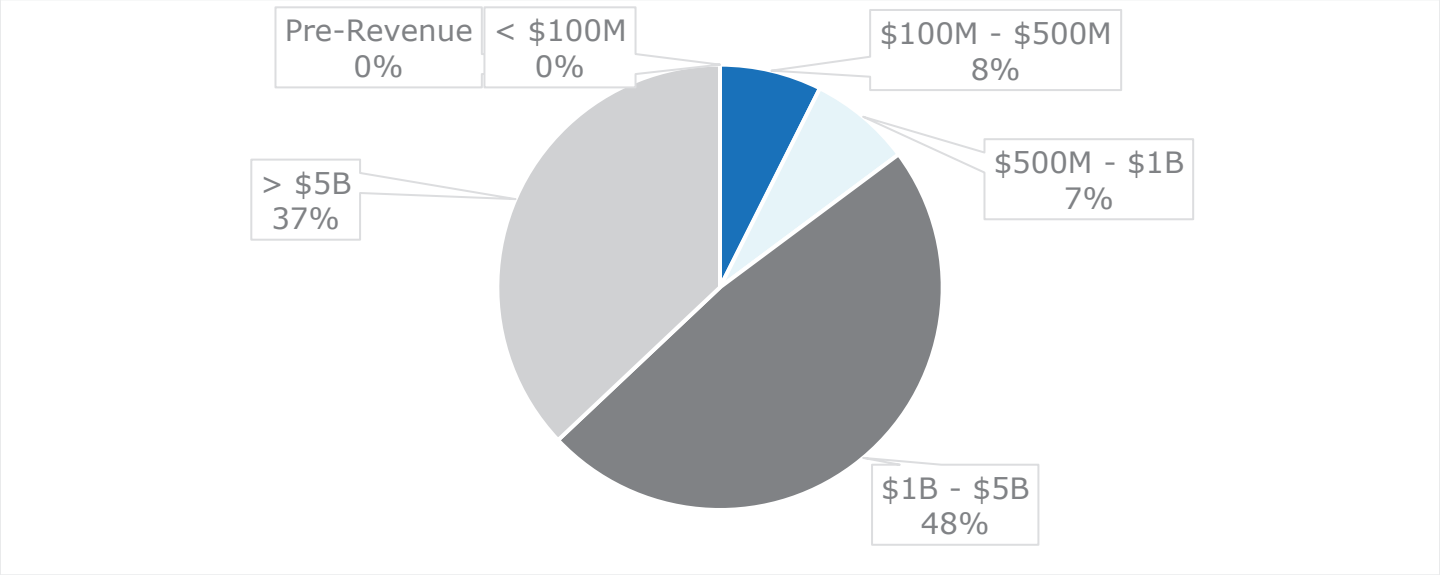
Survey Results

Demographics

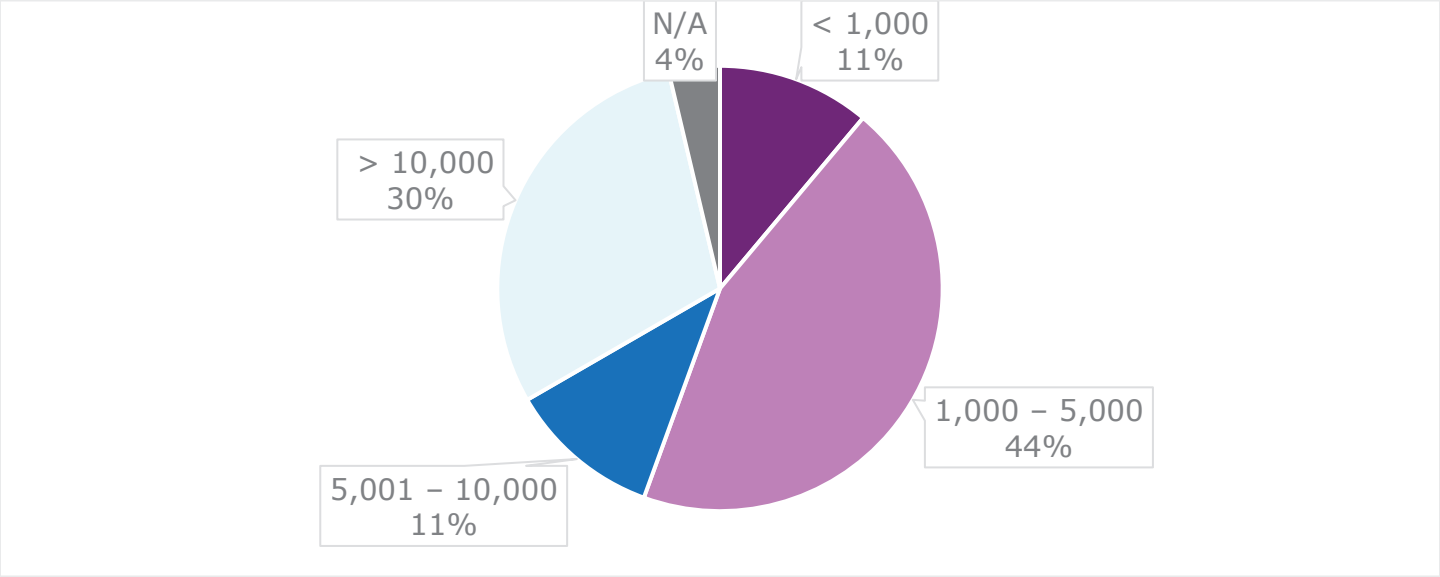
1. Which of the below best describes your company?



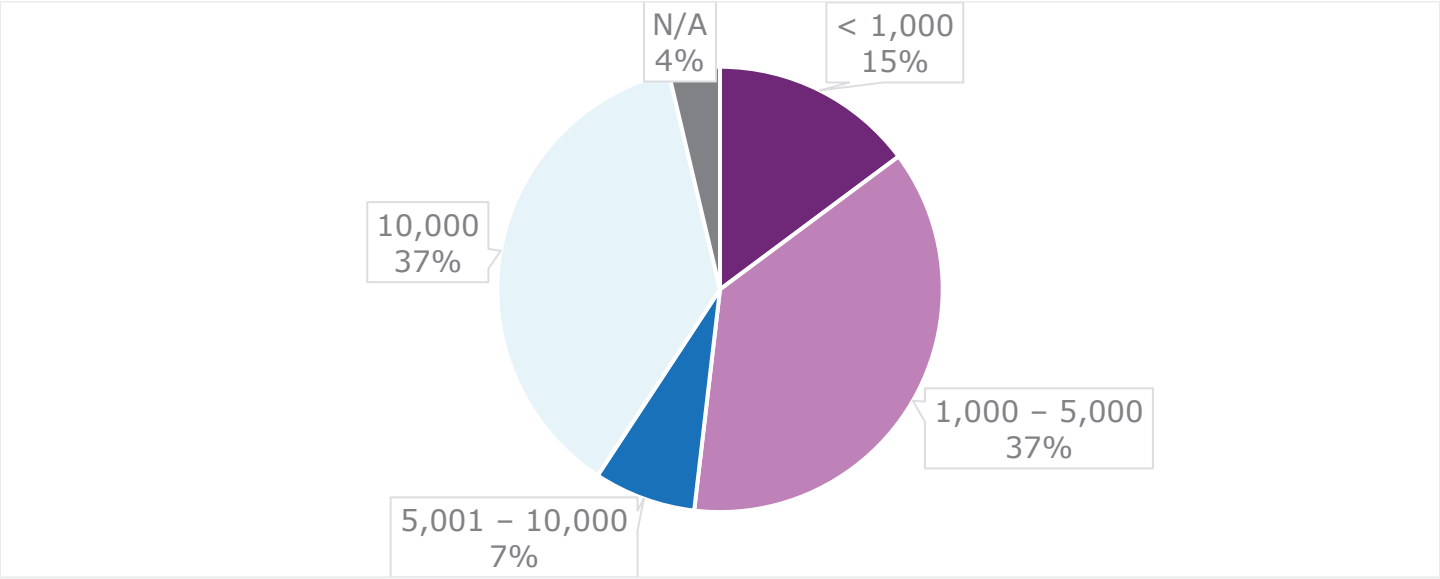
2. 2021 worldwide device-related gross revenue:



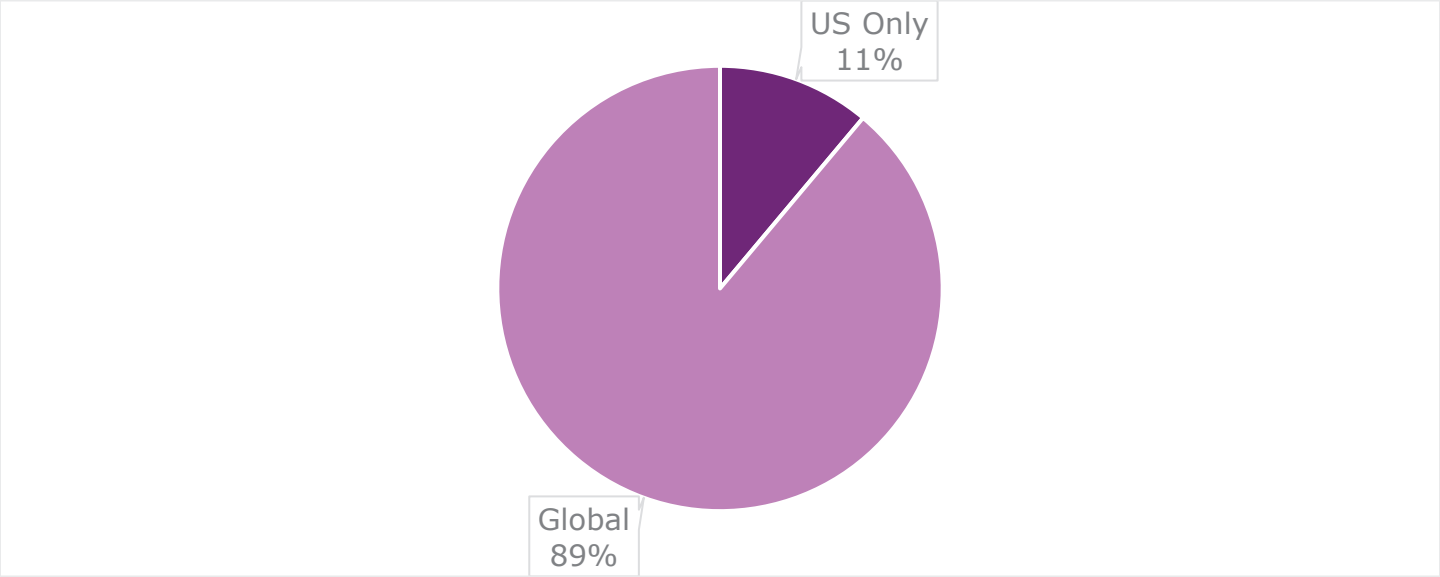
3. How many US-based employees are in your company?



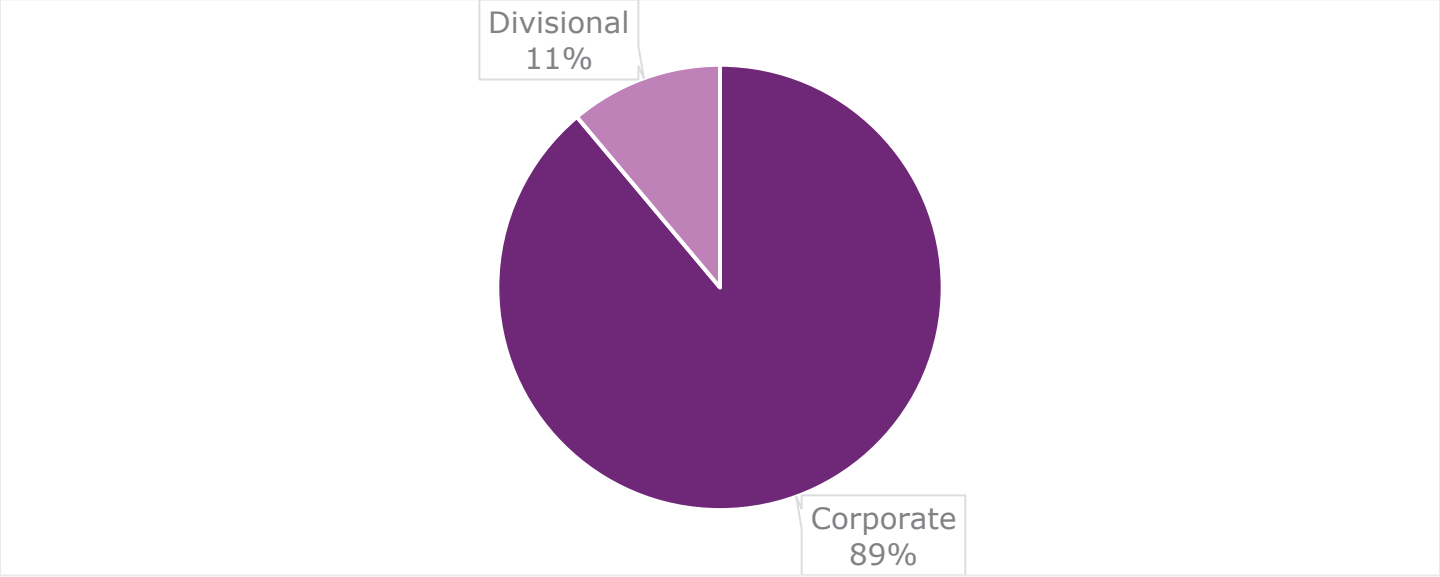
4. How many OUS-based employees are in your company?



5. Which best describes your Compliance Department's geographic scope?

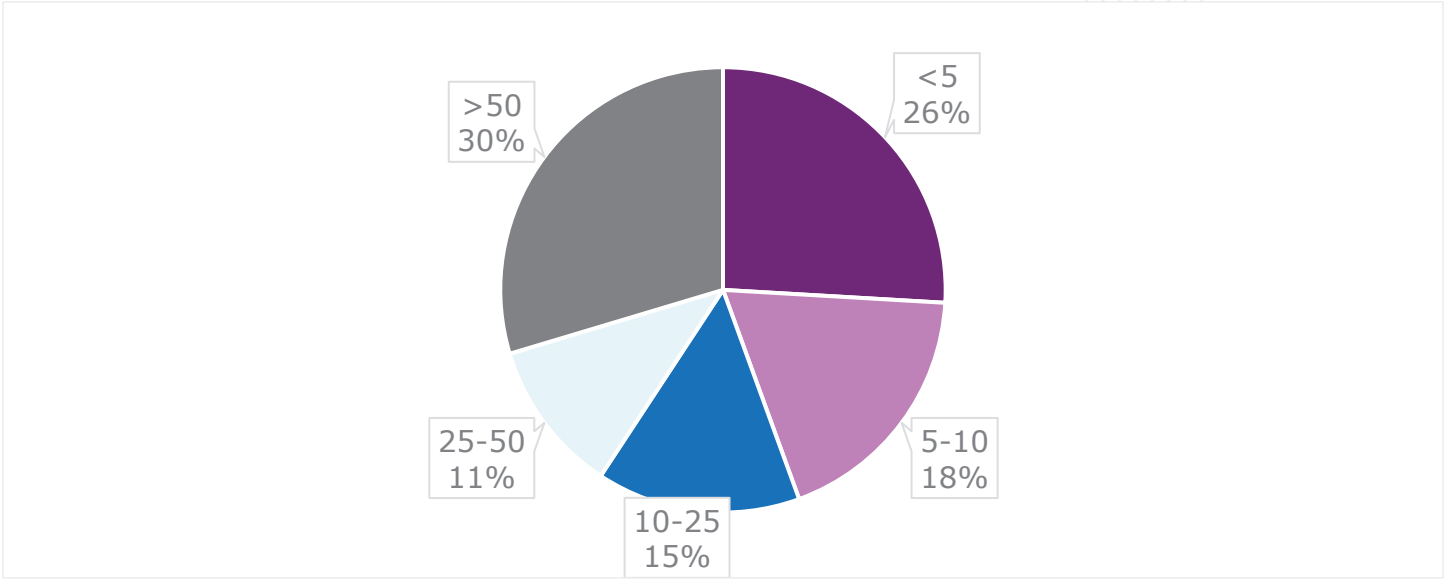


6. Is your Compliance Department at a corporate or division level?

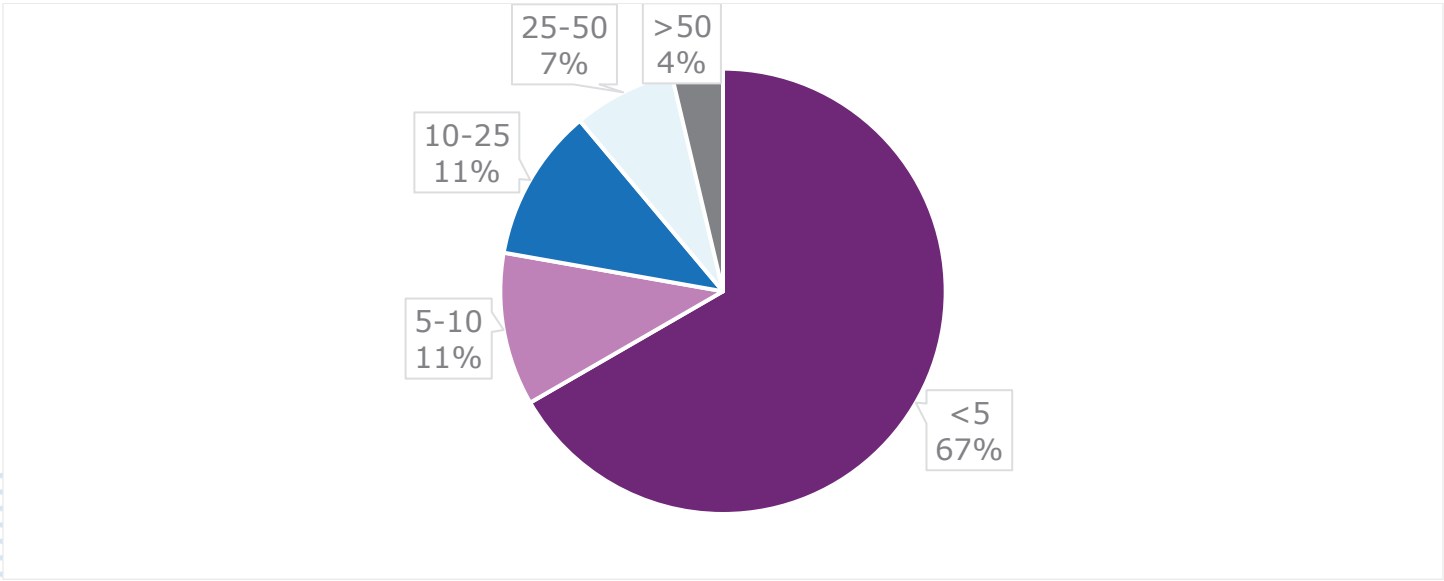


Size & Spend

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



2. How many consultants (including outside counsel) or temps work for your Company's Compliance Department?



3. What is your all-in compliance budget that you manage (internal spend, including employee salary, benefits, external spend for vendors, systems, consultants, outside counsel, etc.) for 2022?

2021 Worldwide Device-related Gross Revenue	Mean	25%	Median	75%
$100M - $500M (2)	$125,000	$50,000	N/A	$200,000
$500M - $1B (2)	$2,675,000	$1,600,000	N/A	$3,750,000
$1B - $5B (4)	$2,806,250	$1,362,000	$2,500,000	$4,250,000
> $5B (5)	$20,000,000	$9,000,000	$28,200,000	$29,300,000

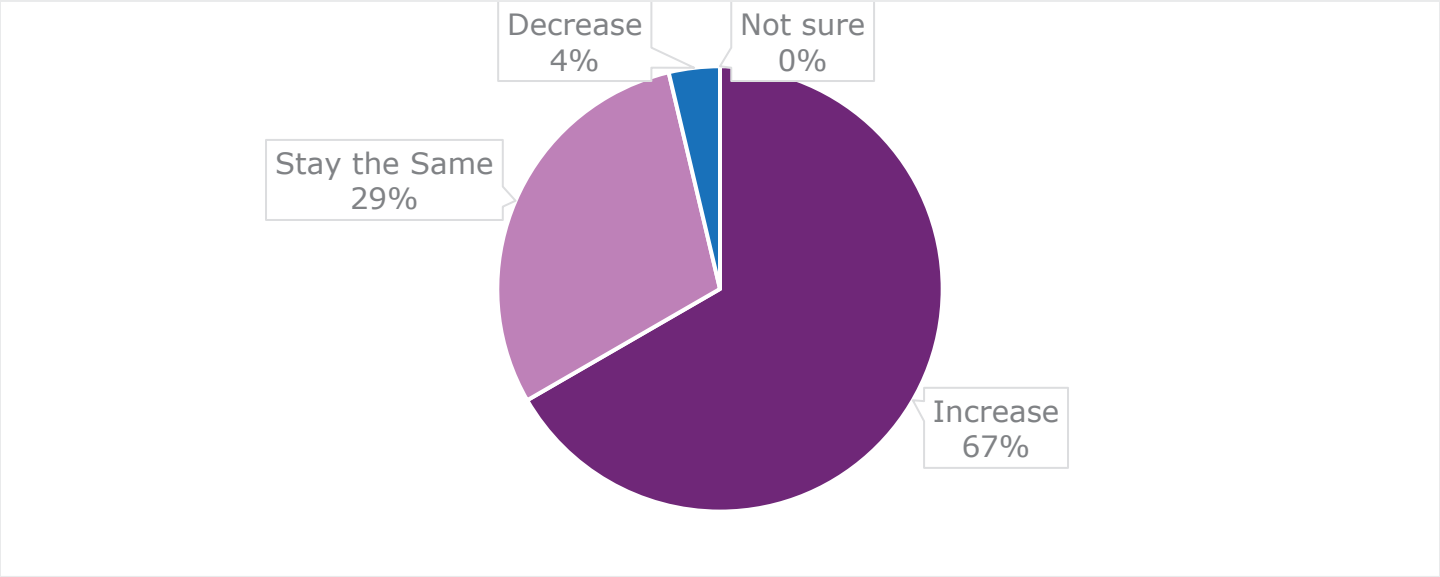
**14 answered "Prefer not to Answer"*

4. What is your 2022 budget for INTERNAL (employee salary, benefits, etc.) Compliance Spend?

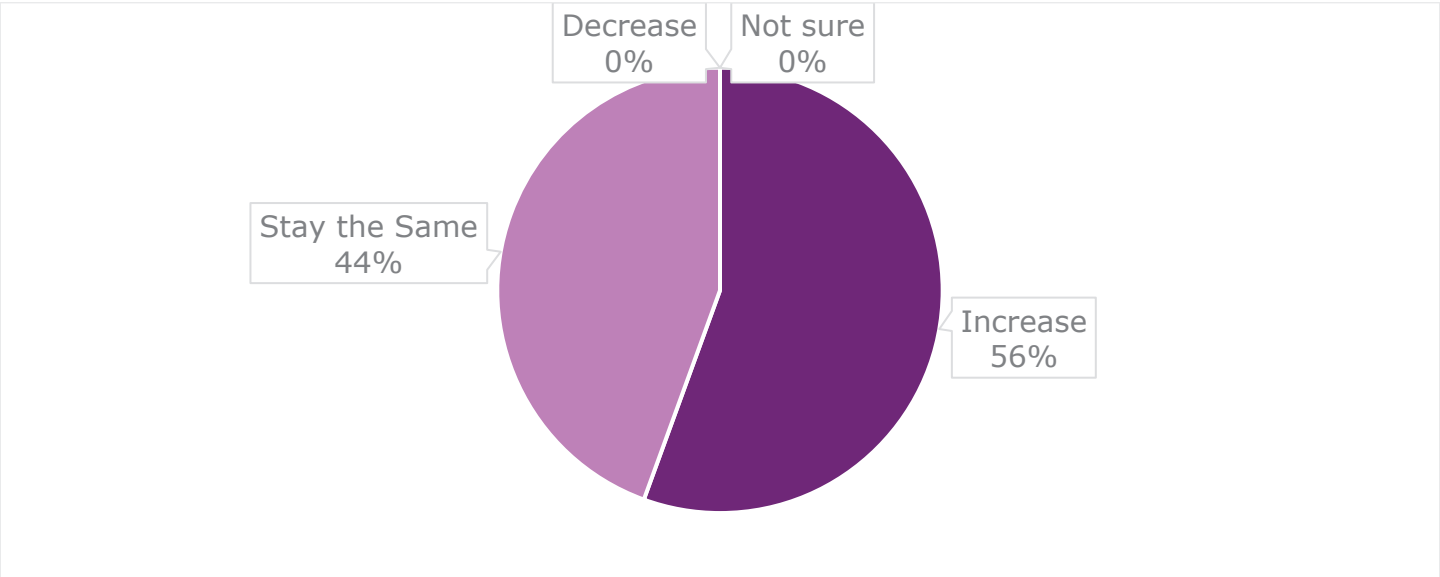
2021 Worldwide Device-related Gross Revenue	Mean	25%	Median	75%
$100M - $500M (2)	$150,000	$50,000	N/A	$250,000
$500M - $1B (2)	$1,250,000	$1,000,000	N/A	$1,500,000
$1B - $5B (3)	$1,833,333	$1,000,000	$1,500,000	$3,000,000
> $5B (5)	$7,950,000	$3,300,000	$6,000,000	$13,575,000

**14 answered "Prefer not to Answer"; 1 answered "Salary not in my budget"*

5. Relative to 2022, I expect my 2023 INTERNAL (employee salary, benefits, etc.) Compliance Spend to:



5. Relative to 2022, I expect my 2023 EXTERNAL (vendors, systems, consultants, outside counsel, etc.) Compliance Spend to:

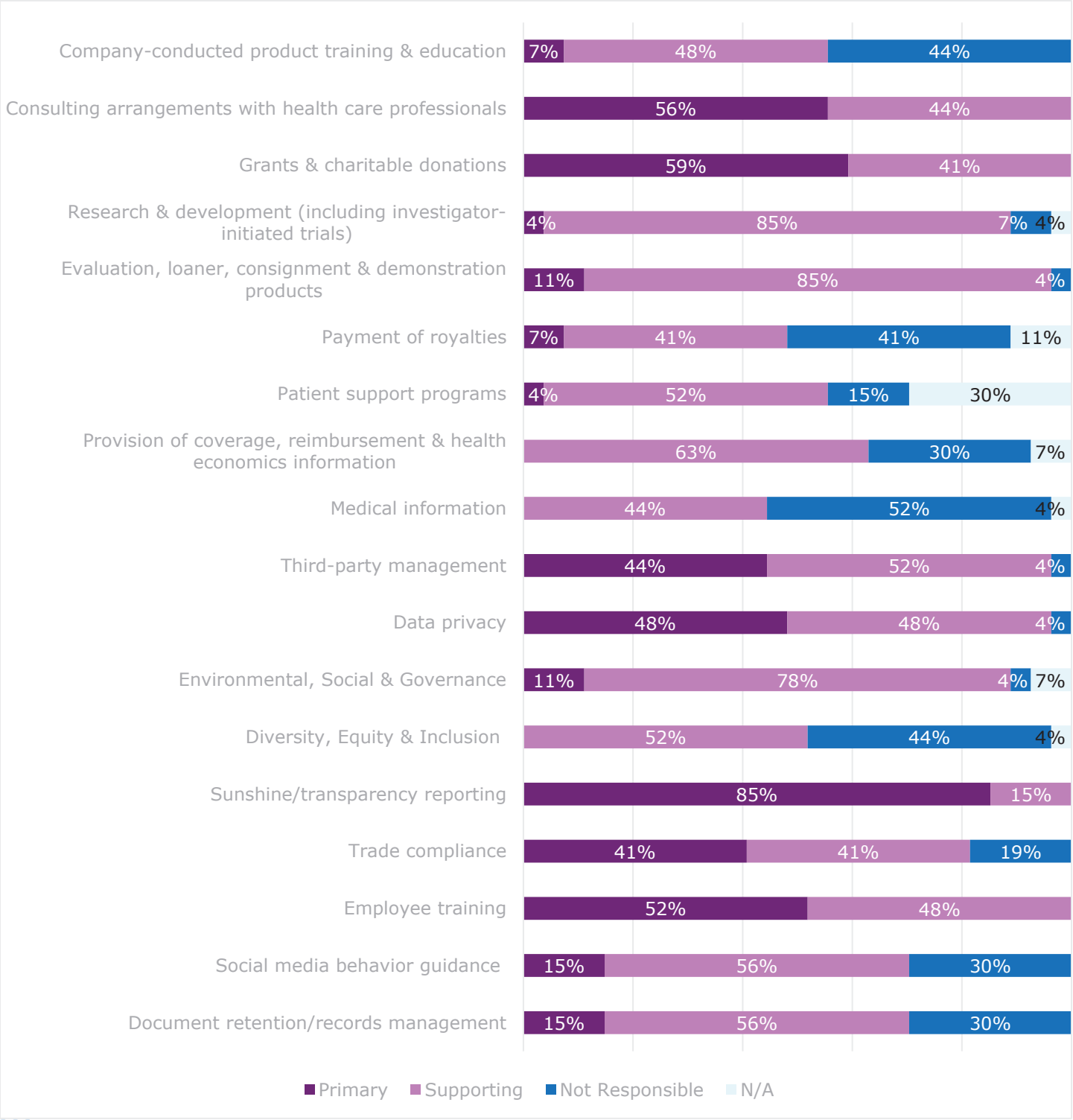


Scope

1. Please indicate which department(s) has responsibility for the below (check all that apply):

	Comp-liance	Legal	Finance	HR	IT	Market-ing	Medical Affairs	Other	N/A
Company-conducted product training & education	30%	15%	0%	15%	0%	70%	48%	41%	0%
Consulting arrangements with health care professionals	85%	67%	15%	0%	0%	41%	41%	22%	0%
Grants & charitable donations	89%	44%	26%	4%	0%	19%	41%	30%	0%
Research & development (including investigator-initiated trials)	56%	48%	11%	0%	0%	19%	44%	67%	0%
Evaluation, loaner, consignment & demonstration products	63%	48%	15%	0%	0%	44%	7%	70%	0%
Payment of royalties	33%	41%	48%	0%	0%	11%	4%	30%	15%
Patient support programs	33%	19%	7%	0%	0%	30%	22%	19%	33%
Provision of coverage, reimbursement & health economics information	30%	26%	4%	0%	0%	15%	33%	70%	11%
Medical information	22%	19%	0%	0%	0%	11%	93%	22%	4%
Third-party management	81%	52%	22%	0%	4%	0%	4%	56%	0%
Data privacy	74%	63%	0%	7%	52%	0%	4%	11%	0%
Environmental, Social & Governance	63%	59%	22%	37%	19%	4%	4%	56%	7%
Diversity, Equity & Inclusion	19%	26%	4%	93%	7%	7%	7%	15%	4%
Sunshine/transparency reporting	93%	11%	41%	0%	4%	0%	4%	11%	0%
Trade compliance	52%	41%	4%	0%	0%	0%	4%	48%	0%
Employee training	81%	26%	19%	89%	30%	33%	26%	48%	0%
Social media behavior guidance	48%	44%	0%	22%	4%	30%	4%	48%	0%
Document retention/records management	41%	74%	15%	19%	37%	4%	0%	37%	0%

2. Please indicate if your Compliance Department has Primary or Supporting responsibility for each of the below:



Open-Ended

1. Please describe any recent structural challenges your Compliance Department may have faced:

Limited resources
1. As an advisory/support function in a matrixed organization we are constantly adjusting responsibilities around the world to support a business that is restructuring. 2. We have historically had very low turnover rates within the Compliance function over the past 7 years. While by comparison our TO rates remain low, they have increased since COVID began which has made recruitment and on-boarding more difficult.
Added privacy compliance in last few years; still working to integrate with the rest of the compliance department.
Lack of resources for a company our size is the largest challenge we face.
Pace of organizational growth is outpacing our ability to recruit Compliance talent at this time.
We experienced high turnover in 2021 as a result of the Great Resignation and other factors.
No changes; Just 1 person for US & Canada.
New leaders from outside the industry and changes within organization has led to loss of institutional knowledge.
New regulations need to be operationalized outside of E&C and the responsible functions aren't staffed to take on the additional work.
M&A activity.
Functional vs geographic reporting structures.
Issues with Independence and access to the CEO and Board of Directors.
Reduction in headcount resulting in increasing ownership and accountability for certain non-core compliance activities to the business and other functions; risk mitigation by corresponding increased focus on auditing/monitoring of these activities.
I believe our structure is appropriate but we need to build up support staff to support the manager's for the day-to-day activities especially if we want to be more strategic without our program and have solid auditing and monitoring activities. Right now we are lean and we seem to always be fire fighting versus getting ahead of issues and that detracts from our overall build of the compliance program.
Signed a DPA.

2. Please describe any recent structural changes that may have provided significant benefit to your Compliance Department:

Outside general counsel.
Centralizing core compliance processes into a separate global programs department, distinct from investigations and business-focused compliance.
We have hired more attorneys recently and so that is helping to ease the overall workload.
Strong organizational growth and commitment to ethical activity has empowered growth in the Compliance team globally.
Last year, hired first dedicated compliance lawyer. Has allowed for more focus on compliance related issues.
Two years ago, Compliance was removed from the Legal Department and now has a seat on the Executive Team and reports directly to the CEO. This has greatly aided visibility and accountability.
Turnover has allowed us to reassess our staffing needs and structure of risk and compliance and develop new structures to support the business in 2022 and beyond.
Trade Compliance recently moved from Legal to Compliance, leveraging synergies in work done across the teams.
Budget increased from zero dollars to $250,000.
Hiring of Senior Director of Compliance.
M&A activity.
External assessment of the Compliance Program.
We have added a manager whose focus is on data analytics and that manager is building our tools that we can use to flag and investigate non-compliance matters. This covers payments to HCPs, Interactions with HCPs, Grants and Donations, travel and entertainment with HCPs, and third-party due diligence. These analytics will be used to report to senior management as well as to highlight areas of focus to continue to build a sustainable compliance program. The goal is for us to identify the non-compliance matters quickly and retrain or enhance controls to prevent these from occurring in the future.
Bringing ESG and Info Governance to the department.
Our North American sector reorganized to arrange our support to better match the structure of the organizations we support. This change has made us more efficient and effective.
Bringing transparency reporting and HCP consulting arrangements under our department has helped better manage these risks.
Integrated business facing compliance officers into one centralized function, including COEs to support compliance officers.
Signed a DPA.