Pharmaceutical Industry Regulatory Readiness & Resources

2024 Survey Report

RAPS REGULATORY AFFAIRS PROFESSIONALS SOCIETY

Executive Summary for 2024 Celegence Sponsored Research in Partnership with the Regulatory Affairs Professionals Society (RAPS)

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Executive Summary – Regulatory Readiness & Resources
Pharmaceuticals

The full RAPS-Celegence sponsored survey report is a compilation of a survey to Regulatory Affairs professionals. A few key findings:

- **Top two challenges** for regulatory affairs show teams are stretched:
  1) Time/bandwidth (45%)
  2) Costs/managing budget (31%)
- 57% indicated they are **under-resourced** to meet all of 2024 priorities
- Positive momentum for **eCTD v4.0**
  - 81% understand the benefits of v4.0
  - 56% see the benefit of increased consistency across submissions
  - 51% see the benefit of reduced time and effort in preparing submissions
- Medical writing remains a critical area for support with **67% using a dossier management system**
- **Artificial Intelligence** shows engagement and increased plans
  - 56% identified a need for AI for data extraction from docs and other sources, 10% using today
  - 53% identified a need for AI for information summarization from different sources, 9% using today
  - 12% are incorporating AI into automated report generation from multiple sources

Thank you to all who took part in the survey and contribute to the industry.

Methodology & Respondent Segments

Methodology

Goal:
Gather data on regulatory readiness and resources in the medical device arena.

Method:
Email survey of regulatory professionals

Timing:
Survey was active for 17 calendar days (12 March 2024 to 1 April 2024) | One invitation and two reminders sent during campaign

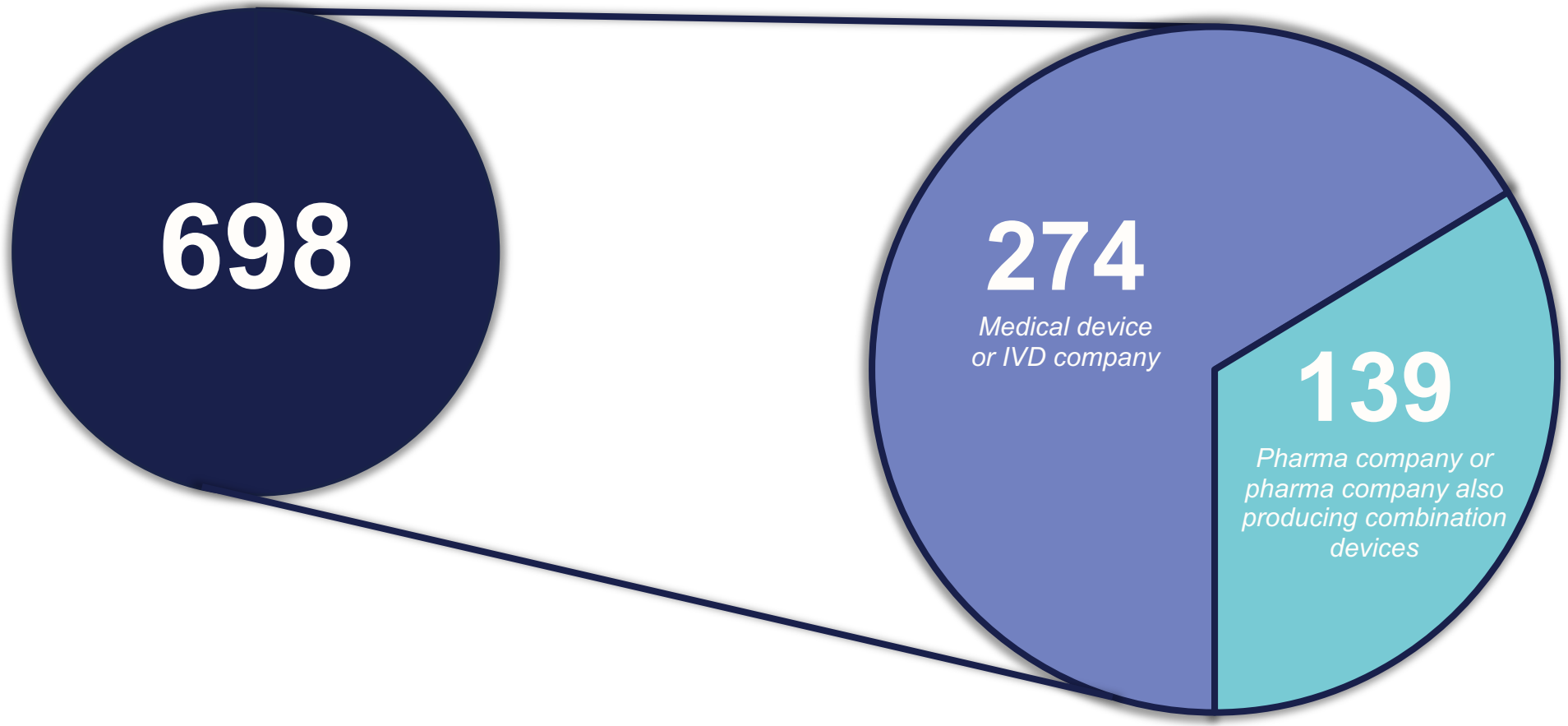
Sample Size:
26,623

Survey Response

There were 698 responses to the Regulatory Readiness and Resources Survey, with 274 respondents reporting they work for a medical devices or IVD company and 139 reporting they work for a pharmaceutical company or a pharmaceutical company that also produces combination devices. All remaining respondents are with CROs, government/non-profit/academic institutions, manufacturers, or other.

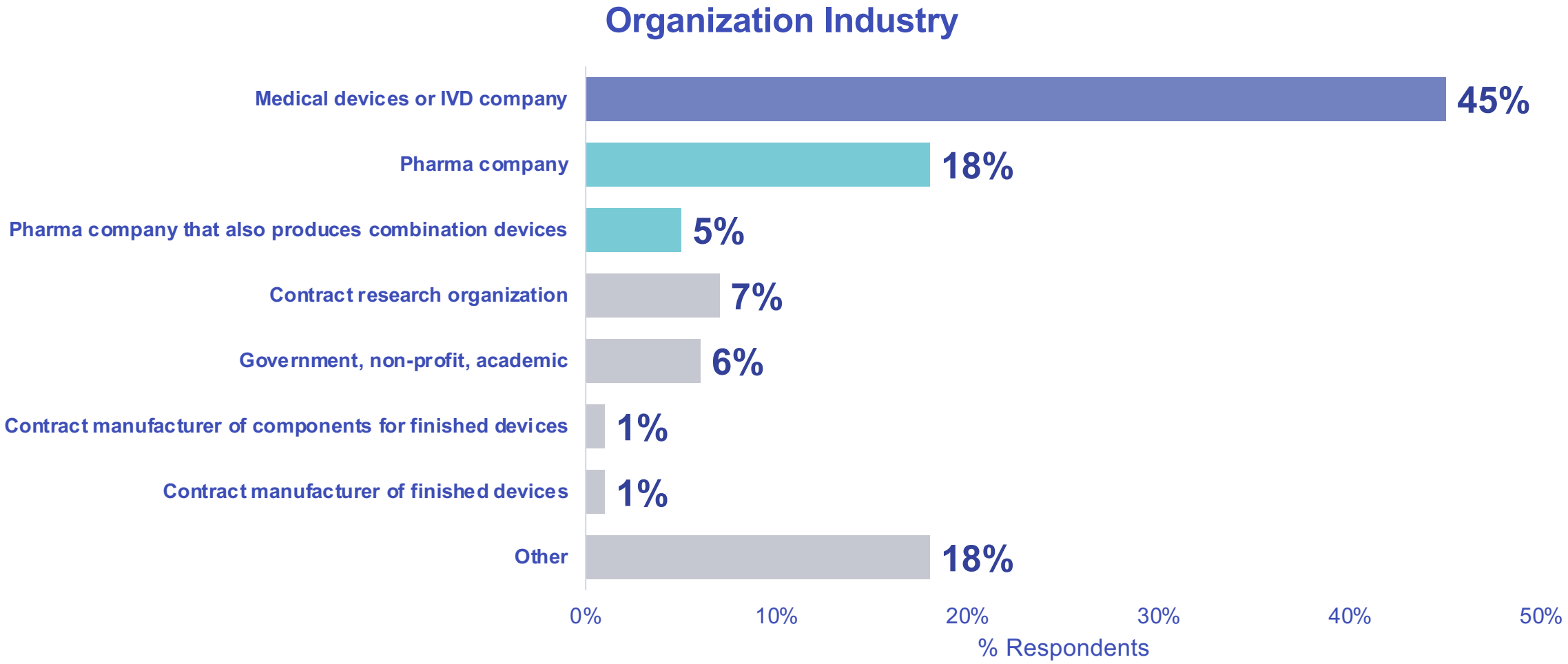
Overall Response

Response by Segment



Organization Industry

Nearly half (45%) of respondents work for a medical devices or IVD company, 18% for a pharmaceutical company, and 5% for a pharmaceuticals company that also produces combination devices.



My organization is best described as:

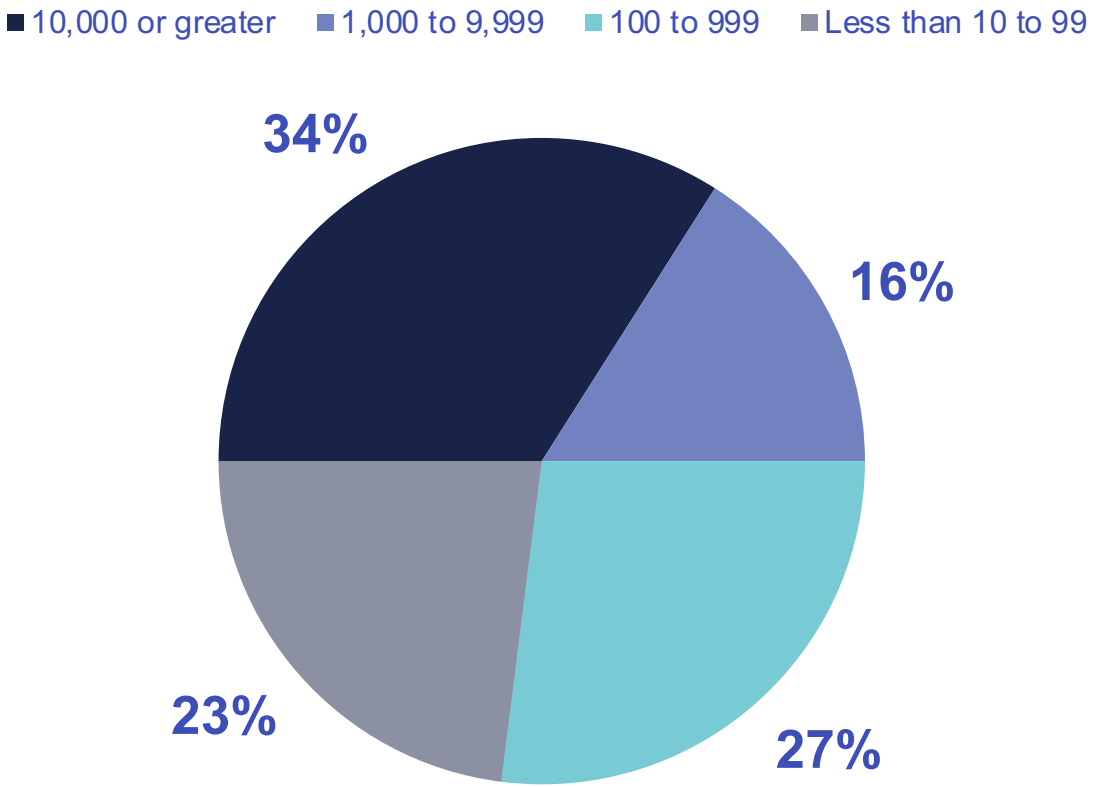
Respondent Organization & Role

Pharmaceuticals

Organization Size & Revenue
Pharmaceuticals

The largest proportion of respondents (34%) work for an organization with 10,000 or greater employees, while 29% report working for a company with revenues between $1 billion and $25 billion.

Organization Size



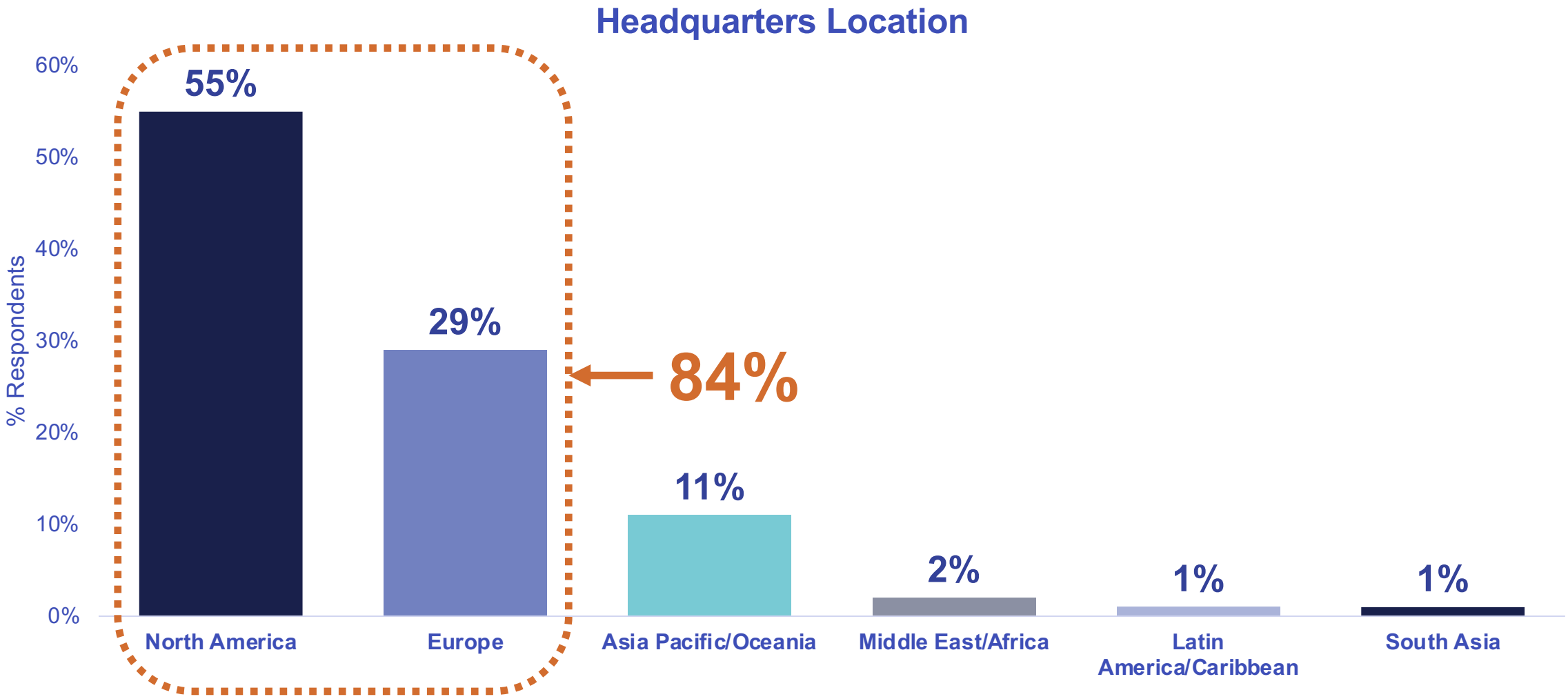
Organization Annual Revenue

Annual Revenue		% Respondents
Less than $10M	$	25%
$10M to $250M	$$	21%
$250M to $1B	$$$	11%
$1B to $25B	$$$$	29%
More than $25B	$$$$$	19%

What is the size of your organization? My company's annual revenue is:

Organization Location
Pharmaceuticals

Among the respondents employed by pharmaceutical companies, 55% indicate that their company's headquarters is in North America, while 29% report their headquarters being in Europe. Another 11% indicate Asia Pacific/Oceania (compared to 5% of respondents employed by medical device companies).



Where is your company headquartered?

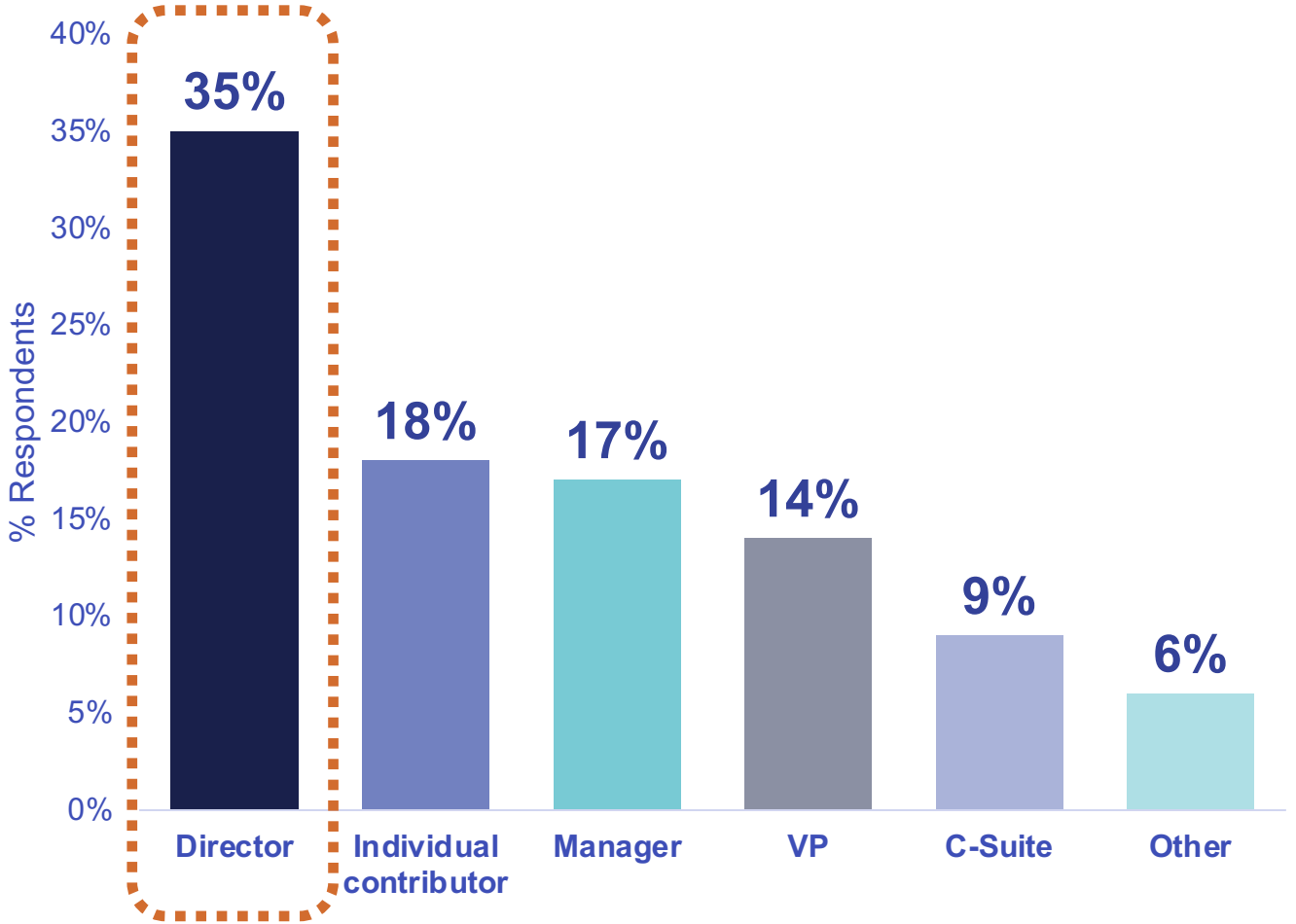
Job Title & Seniority
Pharmaceuticals

Most respondents report holding job titles related to directorship. Similarly, when queried about organizational seniority, the majority identify as directors.

Respondent Job Titles

Job Title	Respondent #
Manager *(mostly RA)*	23
Director / Leader / Head *(mostly RA/some QA)*	62
Specialist / Associate *(mostly RA/some scientists)*	14
Consultant *(unspecified or RA)*	5
Project Manager *(RA & CMC)*	2
President / VP / C-Suite *(Mostly RA/QA & unspecified)*	17
Other	5

Respondent Organizational Seniority



What is your current job title?
My organizational seniority is:

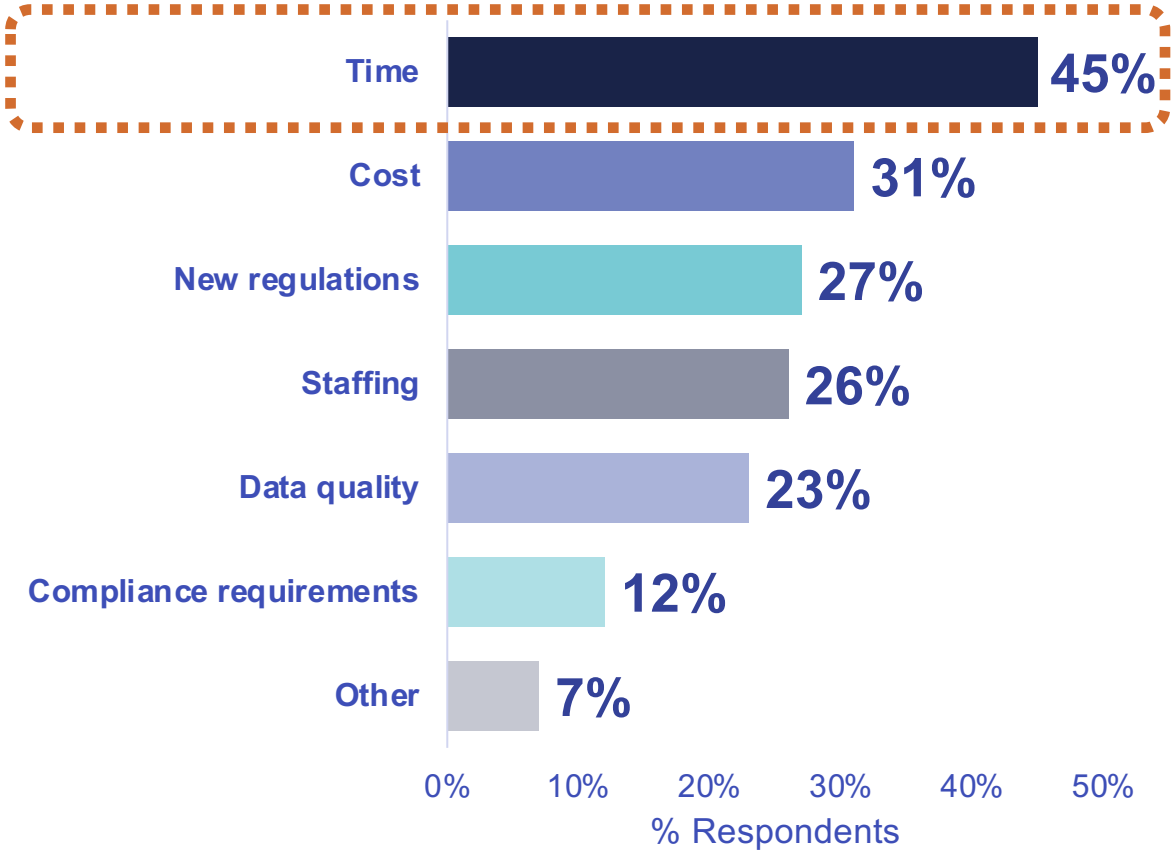
Regulatory Challenges & Readiness

Pharmaceuticals

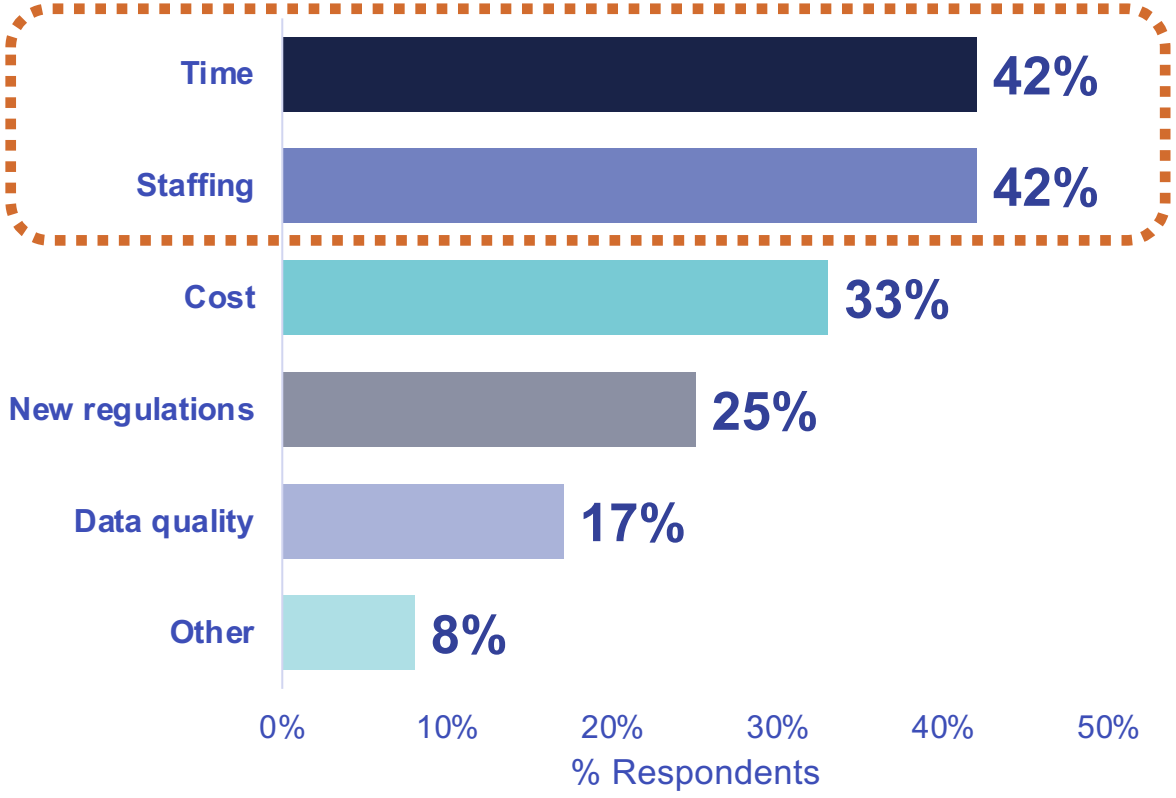
Greatest Regulatory Challenges
Pharmaceuticals

Overall, respondents identify time as their primary challenge this year. C-suite respondents noted time and staffing equally significant challenges.

Greatest Regulatory Challenges



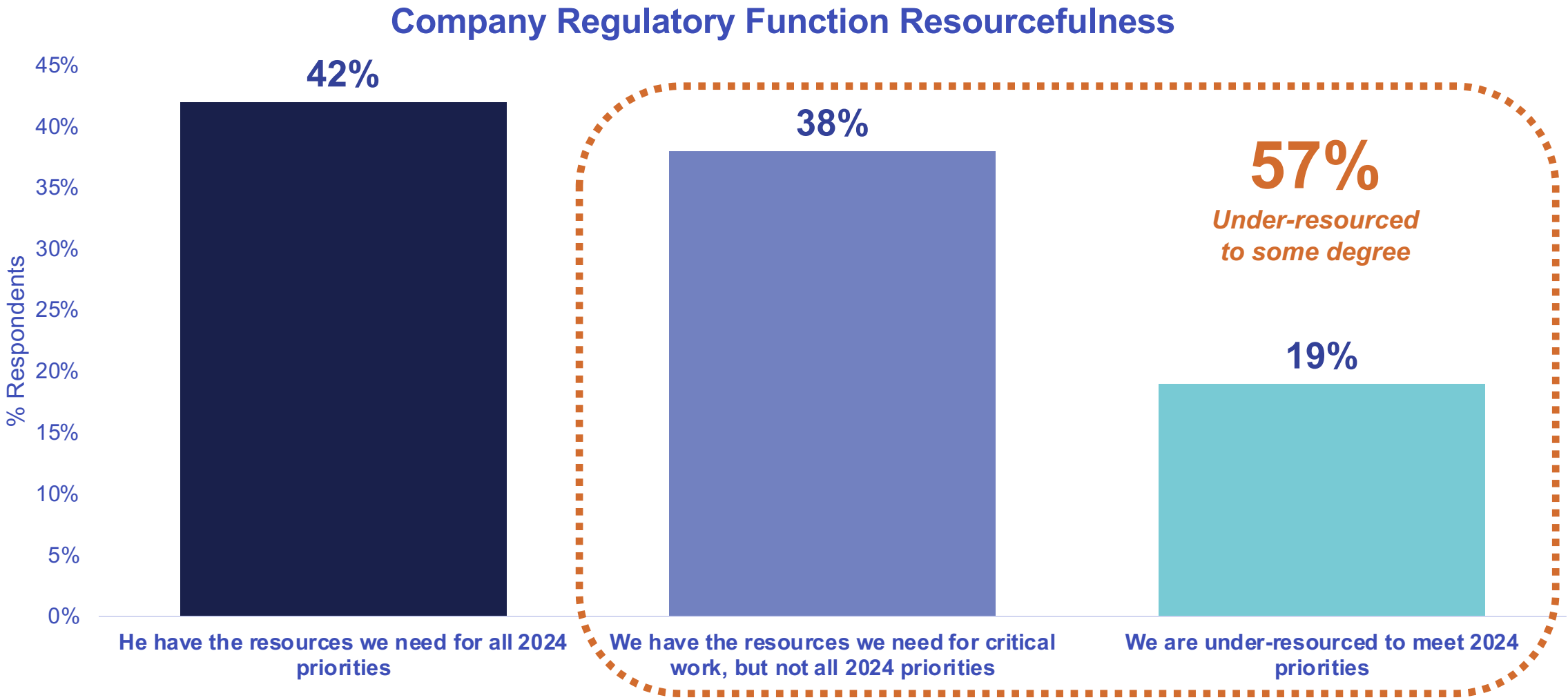
Greatest Regulatory Challenges – C-Suite



What are the greatest regulatory challenges your organization is facing this year? (Select two options.)

Resource Readiness vs. 2024 Priorities
Pharmaceuticals

57% of respondents acknowledge resource constraints within their companies when it comes to fulfilling their 2024 priorities. Specifically, 38% report having sufficient resources for critical tasks, but not for all the priorities set for this year.



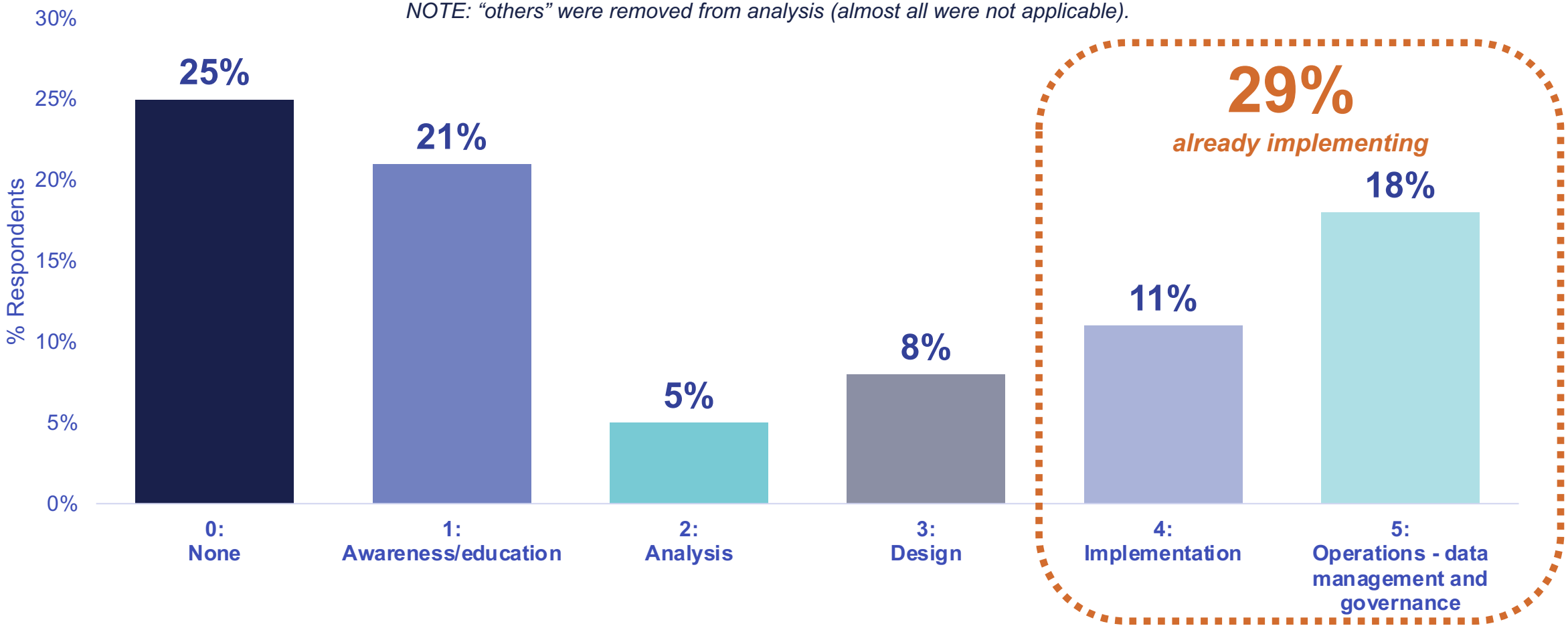
How well-resourced is your company's regulatory function to meet your 2024 priorities?

Stages of IDMP Readiness
Pharmaceuticals

25% of respondents have not yet started or completed any phases related to IDMP readiness. Meanwhile, 21% are currently in the awareness, analysis, or design stages (stages 1-3). 11% have initiated or completed the implementation stage, and 18% have reached the operations stage.

Initiated/Complete Stages of IDMP Readiness

NOTE: "others" were removed from analysis (almost all were not applicable).



My organization has initiated/completed the following stages of IDMP readiness:

eCTD v4.0

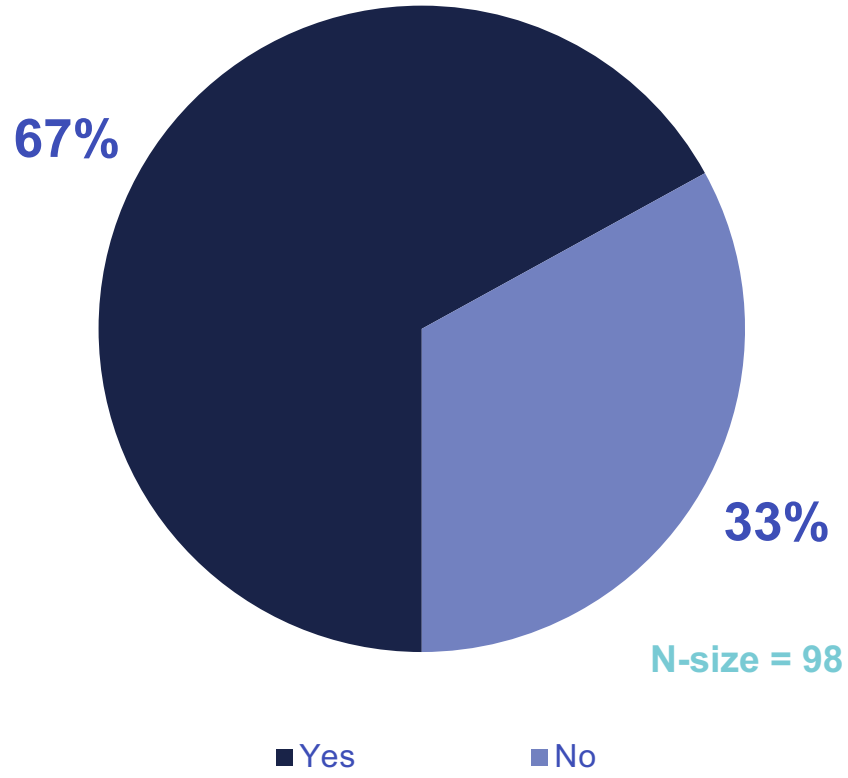
Pharmaceuticals

eCTD v4.0 Submissions Planning
Pharmaceuticals

67% of respondents say they are planning to prepare submissions in eCTD v4.0 format. Comments around this include some saying it is not in their position scope, they are unsure, or it is not currently required for them.

Planning Submissions in eCTD v4.0

Do you plan to prepare submissions in eCTD v4.0 format?



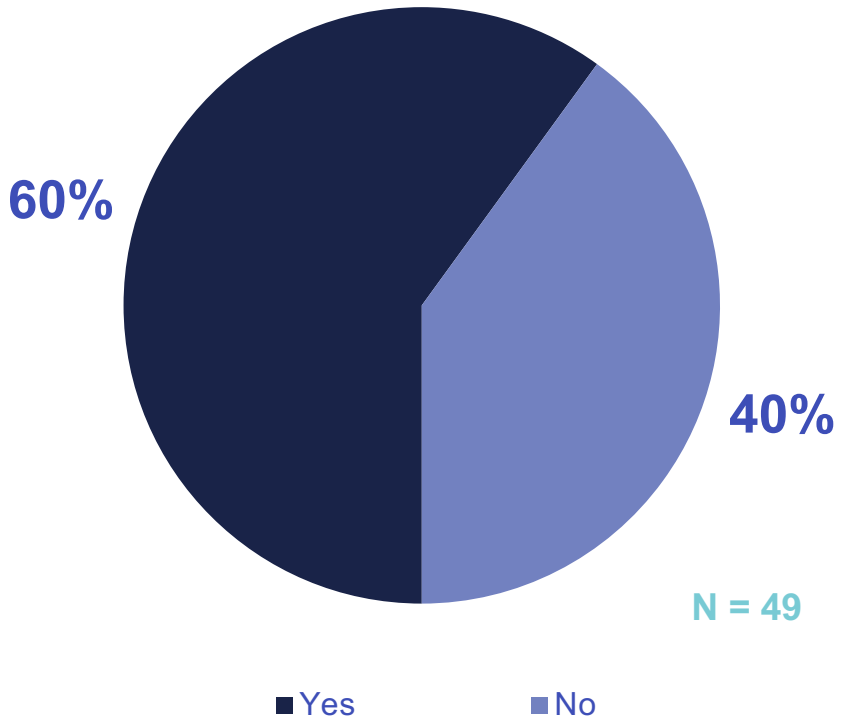
Comments:

We will use whatever format our Publisher uses.
We currently submit to CVM at FDA and Australia/NZ, therefore no eCTD format.
I will need to look this up. My company is a small, early phase biotech that is not up to date on many aspects of regulatory compliance.
But not for another couple of years.
Personally not involved. RA does BLA
Not sure
Unsure at this time. Monitoring.
Vendor performs this task.
Not in scope of my position
Not yet, also we work with a third party publisher.
Not required in Pakistan where I am based
I don't know

eCTD v4.0 Impact Readiness Assessment Planning
Pharmaceuticals

60% of respondents indicate they have done or plan to do an eCTD v4.0 readiness impact assessment.

Planning eCTD v4.0 Impact Readiness Assessment



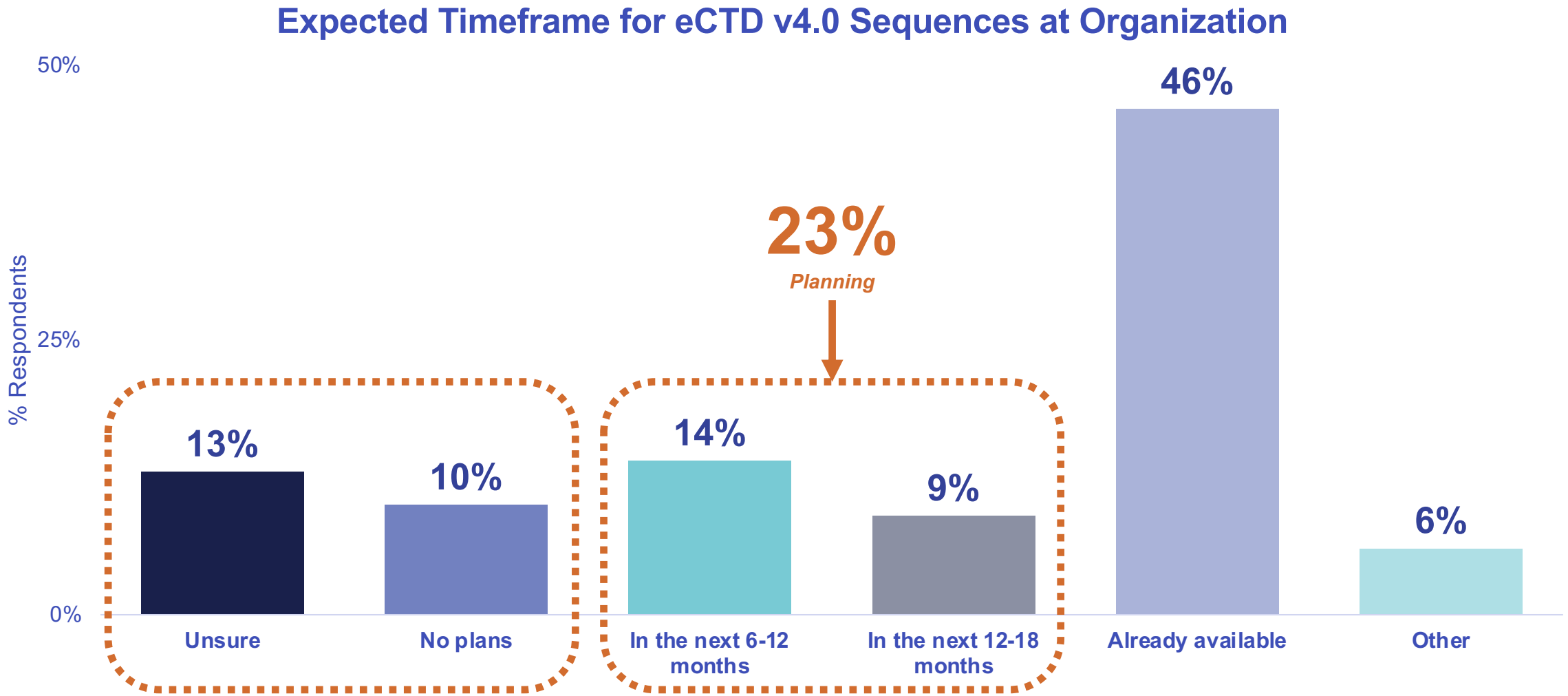
Comments:

Do not know
Working with our vendor on that issue.
Using CRO for publishing
Done at the HQ but not at the affiliate level

Have you or do you plan to do an eCTD 4.0 impact readiness assessment?

eCTD v4.0 Expected Timeframe
Pharmaceuticals

Nearly half of respondents (46%) say their organization already has sequences in eCTD v4.0 available. Another 23% plan to have sequences available in the next six to 18 months. Nearly a quarter are either unsure or have no plans.



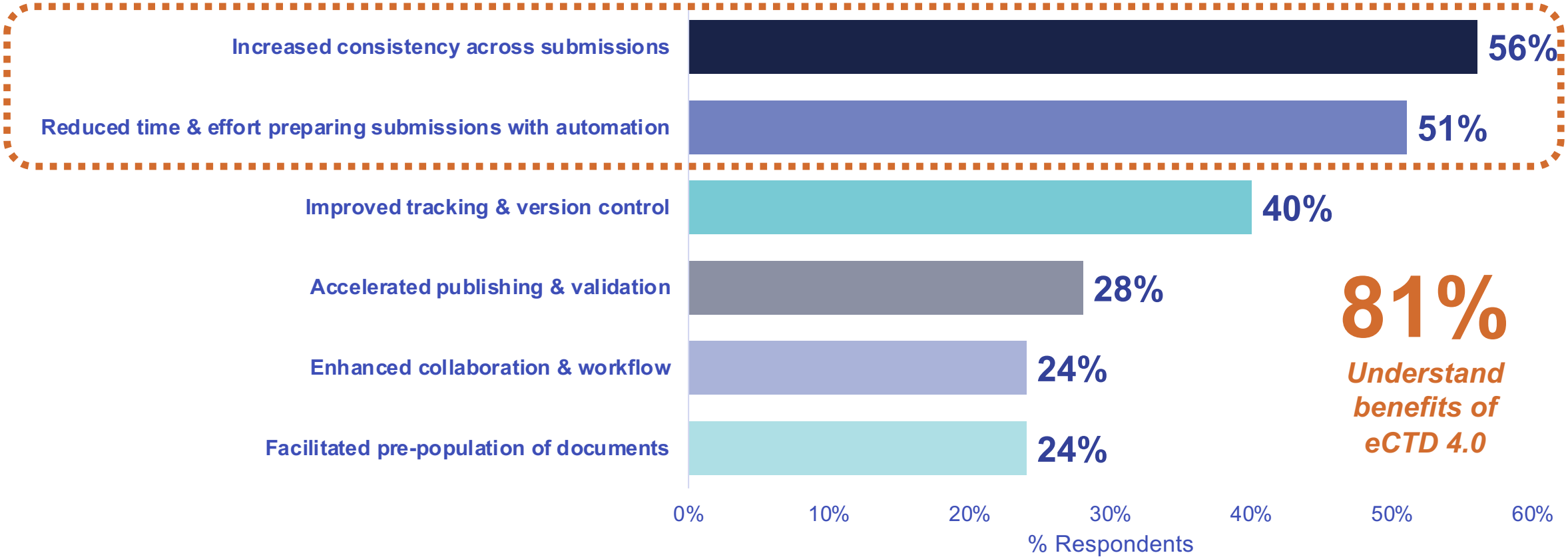
When do you expect to have sequences in eCTD v4.0 available in your organization?

eCTD v4.0 Benefits
Pharmaceuticals

Respondents cite increased consistency across submissions and reduced time and effort preparing submissions with automation as the top benefits from reuse of documentation with eCTD v4.0. 19% say they are not able to realize a benefit.

Benefits from Reuse of Documentation with eCTD v4.0

NOTE: "Others" were % and mostly not applicable responses



81%

Understand benefits of eCTD 4.0

How can your organization benefit from the reuse of documentation enabled by the transition to eCTD v4.0 from eCTD v3.2? (Select all that apply.)

Future Investments

Pharmaceuticals

Future Resource Investments
Pharmaceuticals

Respondents indicated that they might invest in change management systems, improving regulatory intelligence and post-market surveillance in the next 12 months.

Company Resource Investments – Next 12 Months

Future Investments	No investment 1	2	3	4	High investment 5	N-size
Improving regulatory intelligence	21%	20%	26%	24%	9%	66
Change management including risk management documentation	16%	15%	40%	21%	8%	62
Post-market surveillance	26%	16%	39%	13%	6%	62
Complaints management – post-market / pre-market	23%	23%	26%	23%	5%	61
QMS – documentation and setup (MDSAP, ISO, QSR)	23%	13%	39%	23%	3%	62
MDR/IVDR maintenance	52%	17%	22%	8%	2%	60
MDR/IVDR conversion	51%	12%	25%	10%	1%	68

NOTE: data were sorted from highest % 5, then 4, 3, 2, and lowest % 1.

On a scale from 1 to 5 with 1 being no investment and 5 being high investment, how will your company invest in resources during the next 12 months?

Artificial Intelligence (AI) Use

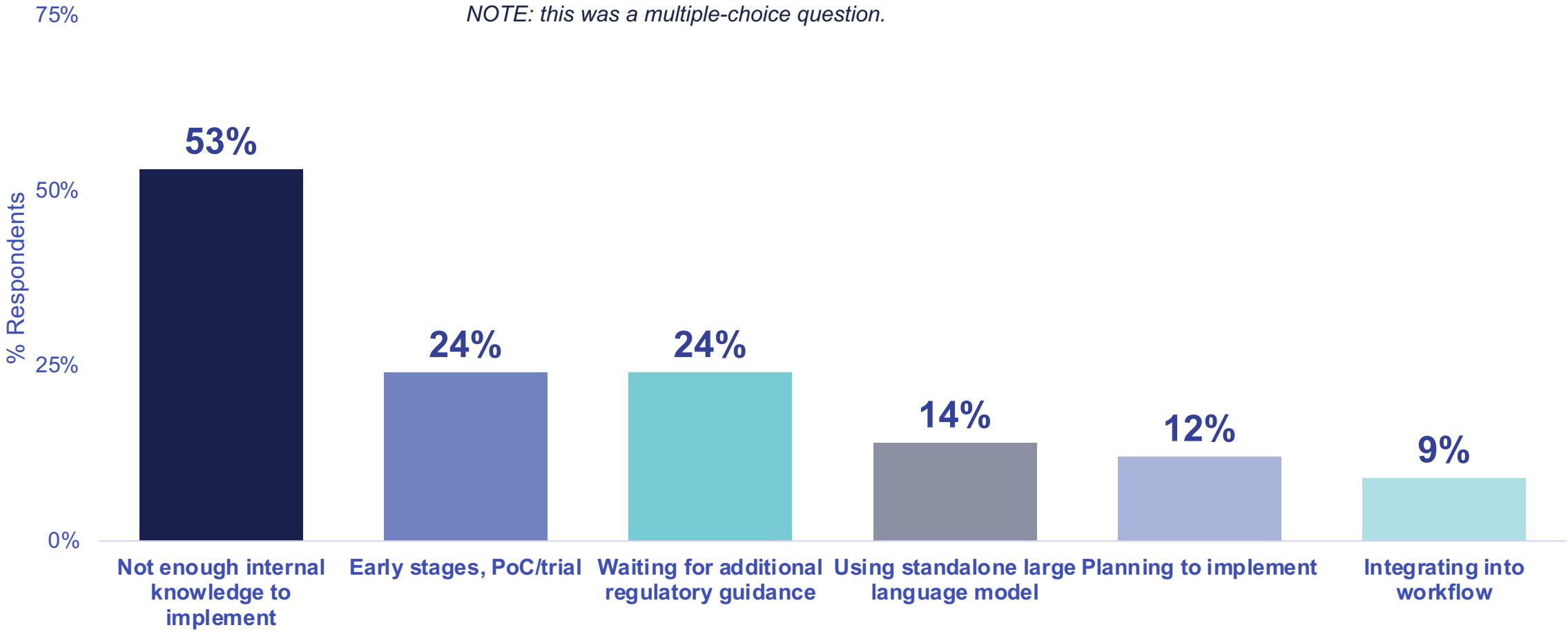
Pharmaceuticals

Artificial Intelligence Use
Pharmaceuticals

Several respondents indicated there is not enough internal knowledge to implement AI at their company. However, many said they are in the early stages and/or are waiting for additional regulatory guidance. A few are already using a standalone LLM, planning to implement AI, and/or were already integrating AI into workflow.

Company Artificial Intelligence (AI) Use

NOTE: this was a multiple-choice question.



How is your company currently using/integrating Artificial Intelligence? (Select all that apply.)

Artificial Intelligence Use & Needs

Pharmaceuticals

Most respondents note that they have either identified needs or expressed no need for AI in various areas, while many fewer are using AI. The highest use of AI is around automated report generation from multiple sources. The top AI uses and needs identified were data extraction from documents and other types of sources and information summarization from different sources.

Artificial Intelligence (AI) Use & Needs

Using	
Automated report generation from multiple sources	12%
Data extraction from documents and other types of sources	10%
Document management (classify, organize, discover, redact)	9%
Compliance gap analysis	9%
Risk mitigation	9%
Medical writing – content generation	9%
Information summarization from different sources	9%
Incorporated into company's medical device product(s)	5%
Submission planning and tracking	4%
Post-market surveillance analytics	4%

Identified Need	
Data extraction from documents and other types of sources	56%
Information summarization from different sources	53%
Medical writing – content generation	50%
Submission planning and tracking	48%
Risk mitigation	48%
Document management (classify, organize, discover, redact)	47%
Post-market surveillance analytics	41%
Compliance gap analysis	41%
Automated report generation from multiple sources	35%
Incorporated into company's medical device product(s)	20%

No Need	
Incorporated into company's medical device product(s)	75%
Post-market surveillance analytics	54%
Automated report generation from multiple sources	53%
Compliance gap analysis	50%
Submission planning and tracking	48%
Document management (classify, organize, discover, redact)	44%
Risk mitigation	43%
Medical writing – content generation	41%
Information summarization from different sources	38%
Data extraction from documents and other types of sources	33%

What are your primary use cases for Artificial Intelligence (AI)?

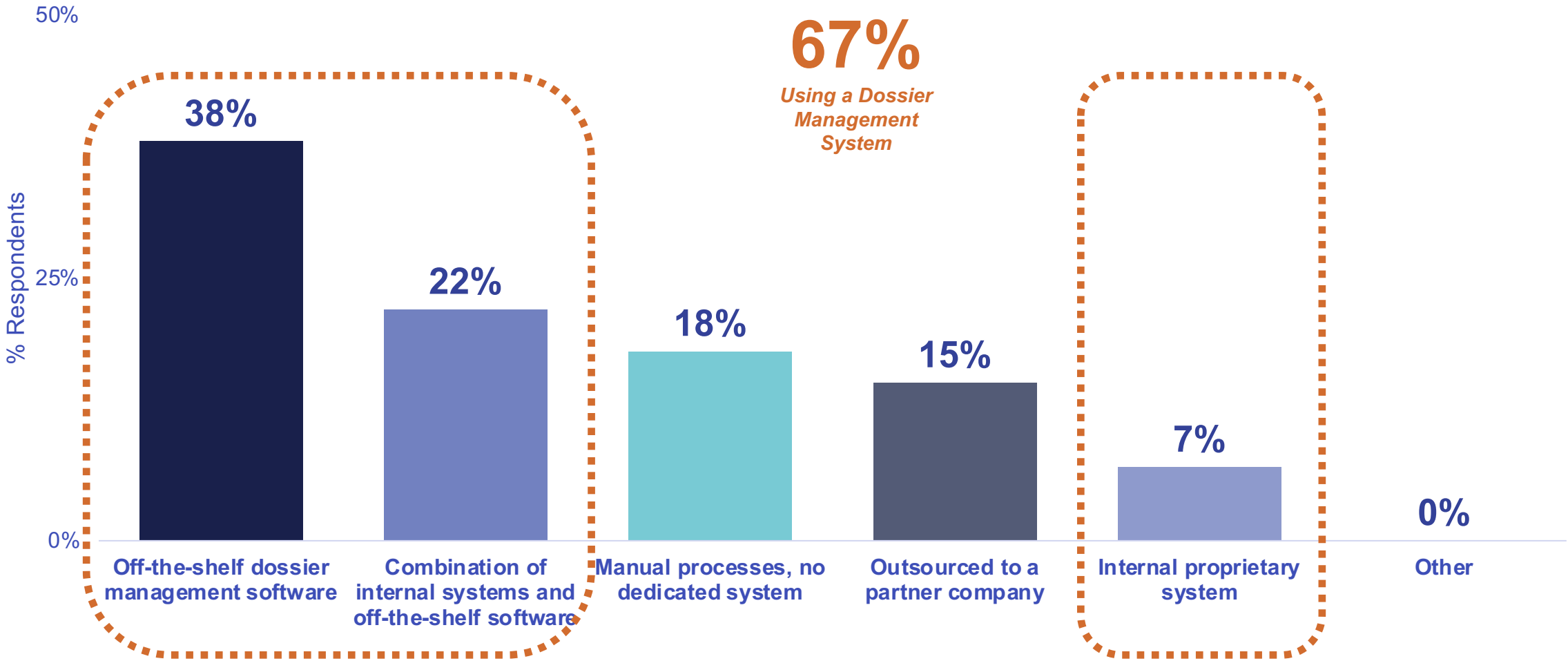
Medical Writing Environment

Pharmaceuticals

Regulatory Dossier Management
Pharmaceuticals

Of the 67% of respondents who are using a regulatory dossier management system, 7% are using an internal proprietary system, 38% are using off-the-shelf dossier management software, and 22% are using a combination of the two. It's worth noting that unlike medical devices respondents, only 18% have no dedicated system (compared to 45%) and 15% outsource this function (compared to 2%).

System Used for Managing Regulatory Dossiers



Which system is your company primarily using for managing regulatory dossiers?

Regulatory Intelligence & Compliance

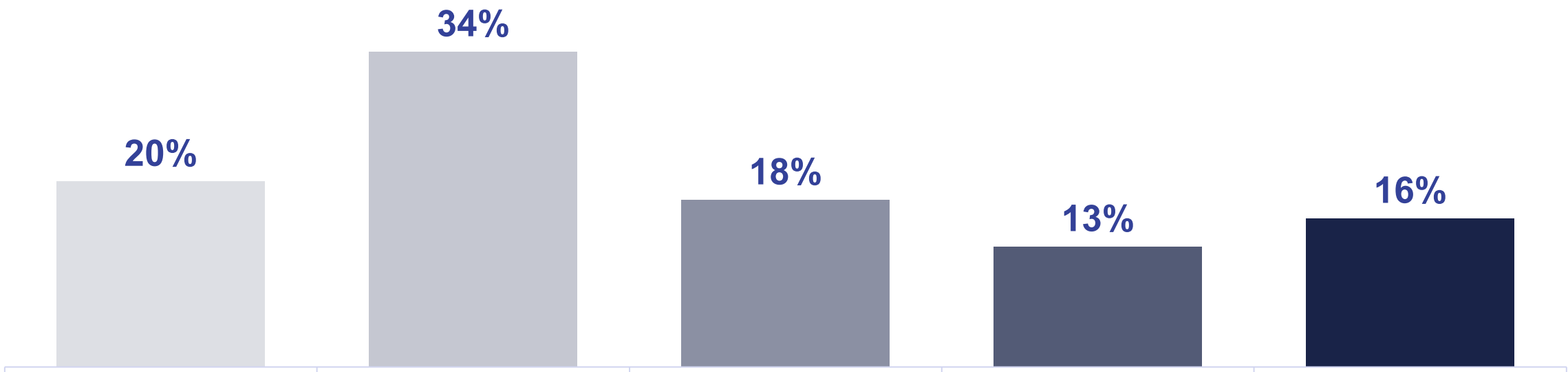
Pharmaceuticals

Regulatory Intelligence & Monitoring Capabilities
Pharmaceuticals

Just over a third (34%) of respondents characterize their regulatory intelligence and monitoring capabilities as reactive, while 20% call them minimal.

Company's Current Regulatory Intelligence & Monitoring Capabilities Rating

Minimal	Reactive	Emerging	Strategic	Comprehensive
Lacking systematic processes & rely on manual research to stay informed	*Monitoring regulations but often reactive to changes, rather than proactive*	*Having adequate processes but needing help analyzing the implications of changes.*	*Researching is a strategic function, but lacking automation.*	*Having robust processes, dedicated staff & automation to identify upcoming changes.*



How would you rate your company's current regulatory intelligence and monitoring capabilities?

Pre- & Post-Market Regulatory Compliance

Pharmaceuticals

Most respondents say their company has dedicated regulatory affairs teams for pre- and post-market compliance. A notable percentage of respondents say pre-market compliance is shared among different departments. 17% selected “other” for post-market compliance, all citing that it is not applicable to them.

	Primarily responsible for pre-market compliance
Dedicated regulatory affairs team	39%
Collaboratively managed by Quality assurance	23%
Regulatory responsibilities shared among different departments	32%
Outsourced to a third-party	2%
Other	4%

	Primarily responsible for post-market compliance
Dedicated regulatory affairs team	31%
Collaboratively managed by Quality assurance	24%
Regulatory responsibilities shared among different departments	24%
Outsourced to a third-party	4%
Other	17% *(all n/a)*

Who is primarily responsible for post-market regulatory compliance in your organization?

QMS Challenges

Pharmaceuticals

Quality Management System (QMS) Challenges
Pharmaceuticals

The cost of maintaining compliance was cited as a modest challenge for respondents, as was difficulty keeping documents updated with changes and having unorganized documents slowing down audits. Version control of documents globally was not a challenge for almost half (47%) of respondents.

Company's Challenges Relative to QMS Documentation & Compliance

QMS Challenges	Not a challenge 1	2	3	4	Top challenge 5	N-size
Cost of maintaining compliance	26%	16%	26%	18%	**14%**	50
Difficulty keeping documents updated with changes.	22%	22%	25%	20%	**12%**	51
Unorganized documents slowing down audits.	25%	33%	18%	14%	**10%**	51
Lack of resources to maintain documentation.	23%	17%	34%	19%	**8%**	53
Manual documentation processes leading to errors.	29%	16%	20%	29%	**6%**	49
Specific compliance across regulations like ISO 13485, 21 CFR 820, etc.	31%	23%	29%	10%	**6%**	48
Version control of documents across global sites.	47%	12%	20%	18%	**2%**	49

NOTE: data were sorted from highest % 5, then 4, 3, 2, and lowest % 1.

On a scale from 1 to 5, with 1 being not a challenge and 5 being a top challenge, please rate each possible challenge below relative to your company's quality management system (QMS) documentation and compliance:

Compliance Skillsets

Pharmaceuticals

Compliance Skillset Capabilities
Pharmaceuticals

Though respondents infrequently report high skill levels for most compliance skillsets, knowledge of changing global regulatory landscapes and clinical evaluation and literature review process capabilities have the highest response for high skill level. Cybersecurity and software compliance guidance and requirements is the most limited skill level.

Company's Current Capabilities Relative to Compliance Skillsets

Compliance Skillsets	Limited Skill 1	2	3	4	Highly Skilled 5	N-size
Knowledge of changing global regulatory landscapes	7%	9%	43%	24%	17%	46
Clinical evaluation and literature review process capabilities	15%	7%	35%	30%	13%	46
Data science and analytics for post-market surveillance	18%	18%	40%	18%	7%	45
MDR/IVDR maintenance requirements	36%	16%	30%	14%	5%	44
Expertise in specific regulatory requirements – MDR/IVDR	37%	13%	28%	17%	4%	46
Cybersecurity and software compliance guidance & requirements	16%	16%	34%	32%	2%	44

NOTE: data were sorted from highest % 5, then 4, 3, 2, and lowest % 1.

On a scale from 1 to 5, with 1 being limited skill and 5 being highly skilled, please rate your company's current capabilities relative to the compliance skill sets below:

For more information, contact:

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