

CONTRACT PHARMA

Annual Outsourcing Survey

WELCOME TO OUR 8th Annual **CONTRACT PHARMA** Outsourcing Survey! More than 200 sponsor-side respondents offered up their opinions on outsourcing trends for this year's poll.

On the following pages, we've provided a sample of the findings, focusing mainly on the major outsourcing projections of our respondents, broken out by their business categories. Here's a breakdown of the respondents:

Company Type	Job Function
Top 20 Pharma23.9%	R&D20.6%
Small/Mid-Tier Pharma20.1%	Corporate Mgmt. . . .14.4%
Emerging Biopharma .11.0%	Project Manager . . .10.5%
Virtual Pharma9.6%	Purchasing/Sourcing .10.0%
Generic Pharma7.7%	Business Development7.2%
Top 10 Biopharma . . .6.7%	Prod./Mfg./Pkg.6.7%
Consumer/5.3%	QA/QC/Validation . . .6.2%
OTC Healthcare	Contract Manager . . .5.7%
Specialty Pharma2.9%	Marketing/Sales4.8%
Other12.9%	Clinical Research . . .4.8%
	Supply Chain Manager4.3%
	Regulatory Affairs . . .1.9%
	Other2.9%

Plateau?

Last year, **45%** of respondents believed that they will **spend the same or less on outsourcing spending** in the coming year; this year, that rose to **48%**. Meanwhile, **49%**, told us that they **spent the same or less on outsourcing** in the previous year, down from **51%** in our 2011 survey. One-quarter of respondents said that 2011 saw **no change in outsourcing spending** from 2010.

23% of respondents tell us they had **cancelled outsourcing projects in the previous year** due to the economy; down from **25%** in our 2011 survey. Top 20 Pharma respondents had the highest "cancellation rate" of any company type, at **29%**.

Maybe it's a change in respondents, or maybe it's an industry trend at last, but **55%** of Top 20 Pharma respondents said they use **1-5 preferred vendors**, up from **32%** in last year's survey. Top 20 Pharma is still the second lowest group to focus on that number of preferred providers; Generic Pharma was at **54%**.

Thanks to all of you who took the time to respond to this year's Outsourcing Survey. The winner of our iPad drawing is **Iñigo Pfeiffer, Ph.D.** of Targacept! Congratulations! —GYR

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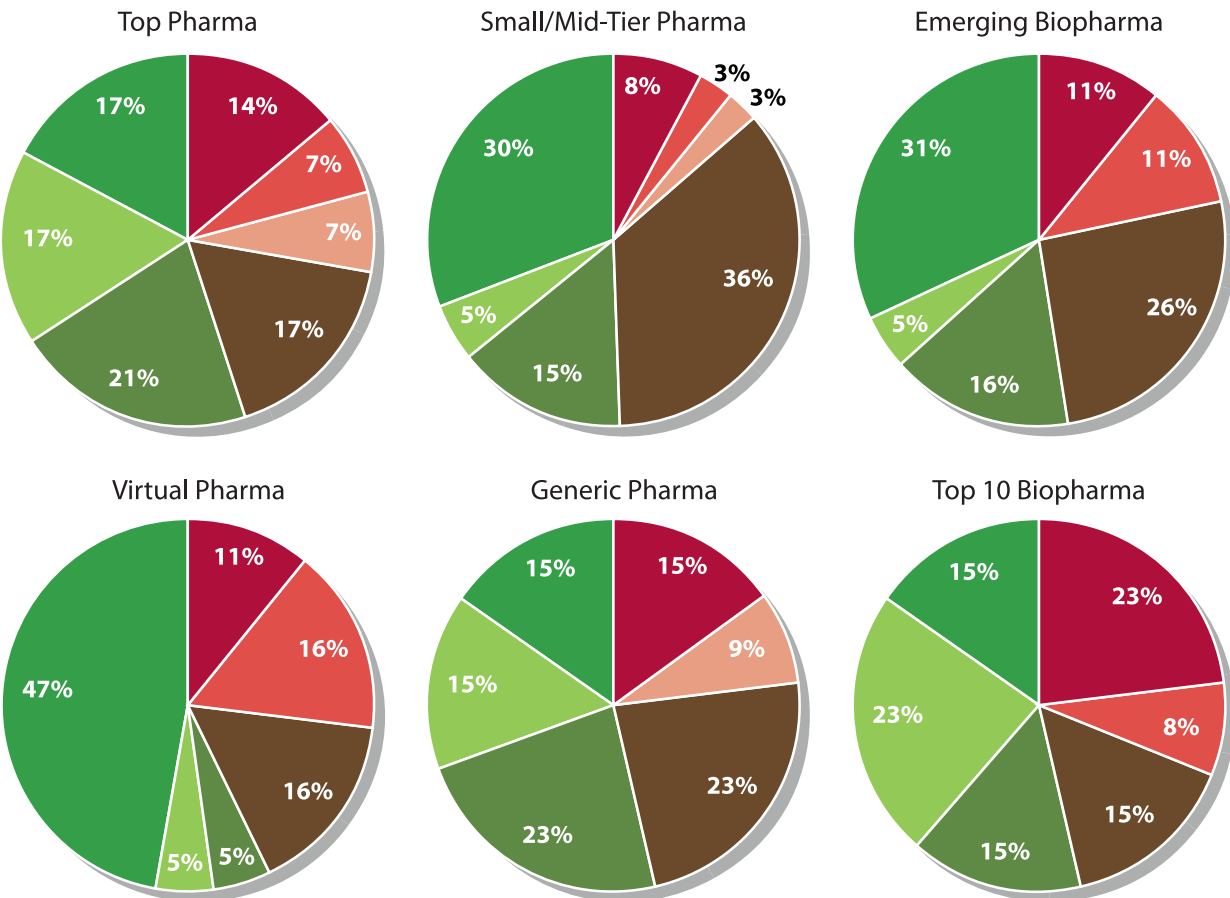
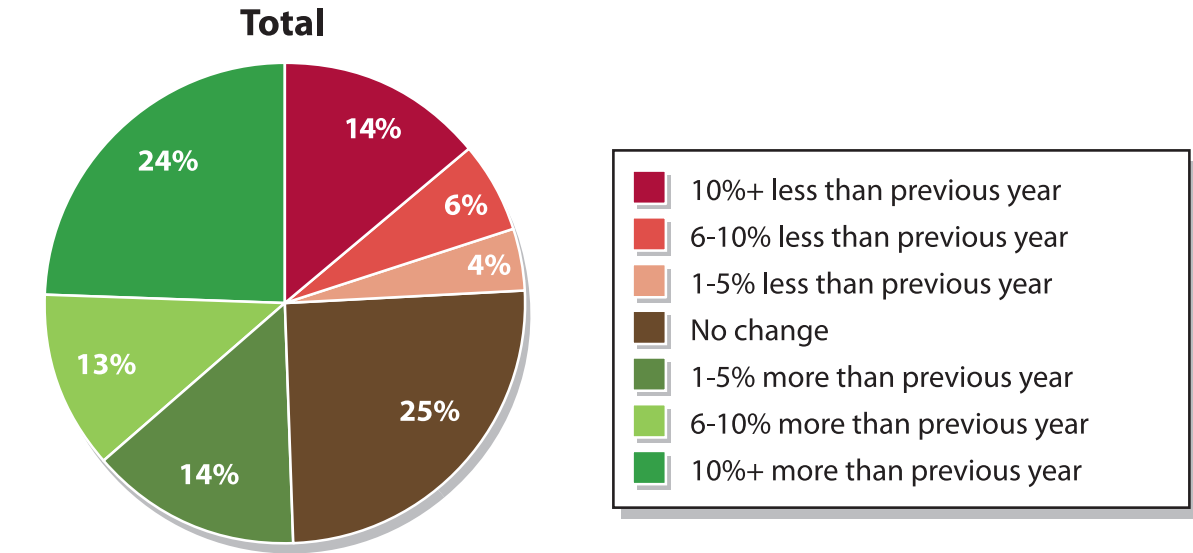
Issue Close Date: December 6th, 2012

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International: Verena Loewenthal (vl@interpress-media.ch)

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How much did your outsourcing spending change in the past year?
(by company type)



Past Imperfect

Respondents who report that their outsourcing spending **GREW** in the previous year: **50%**

WHAT DO THEY DO?

Corporate Management	20.7%
R&D	18.5%
Purchasing/Sourcing	14.1%
Production/Manufacturing/Packaging	9.8%

WHERE DO THEY WORK?

Top 20 Pharma	25.0%
Small/Mid-Tier Pharma	21.7%
Virtual Pharma	12.0%
Emerging Biopharma	10.9%

WHAT TYPES OF OUTSOURCING DO THEY MANAGE?*

Analytical & Testing Services	55.4%
Manufacturing: API	42.4%
Formulation Development	39.1%
Clinical Trials (I-IV)	35.9%
Manufacturing: Solid Dosage	35.9%
CMC	34.8%
R&D Services	33.7%

Respondents who report that their outsourcing spending **SHRANK** in the previous year: **24%**

WHAT DO THEY DO?

R&D	20.5%
Business Development	11.4%
Clinical Research	11.4%
Corporate Management	10.9%

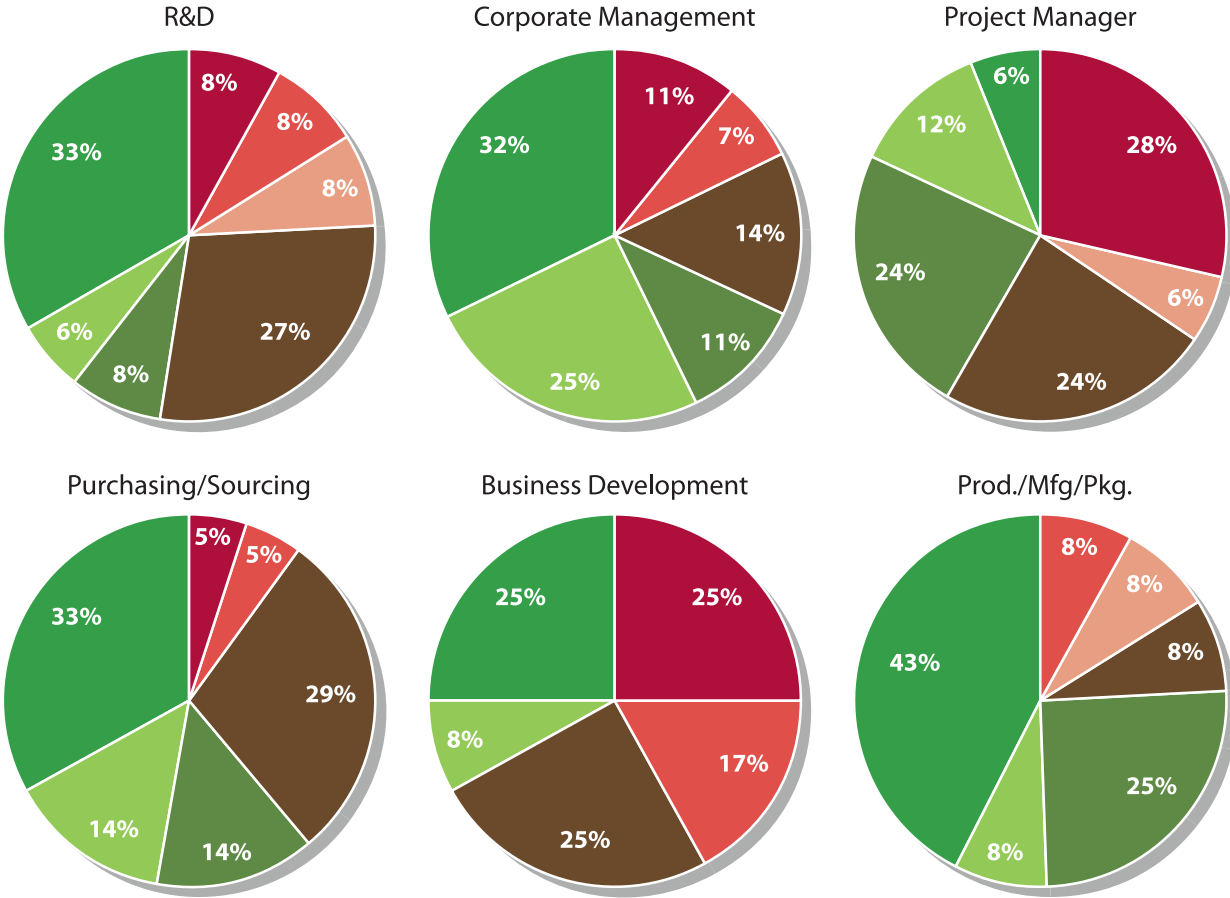
WHERE DO THEY WORK?

Top 20 Pharma	27.3%
Small/Mid-Tier Pharma	11.4%
Virtual Biopharma	11.4%
Other	10.9%

WHAT TYPES OF OUTSOURCING DO THEY MANAGE?*

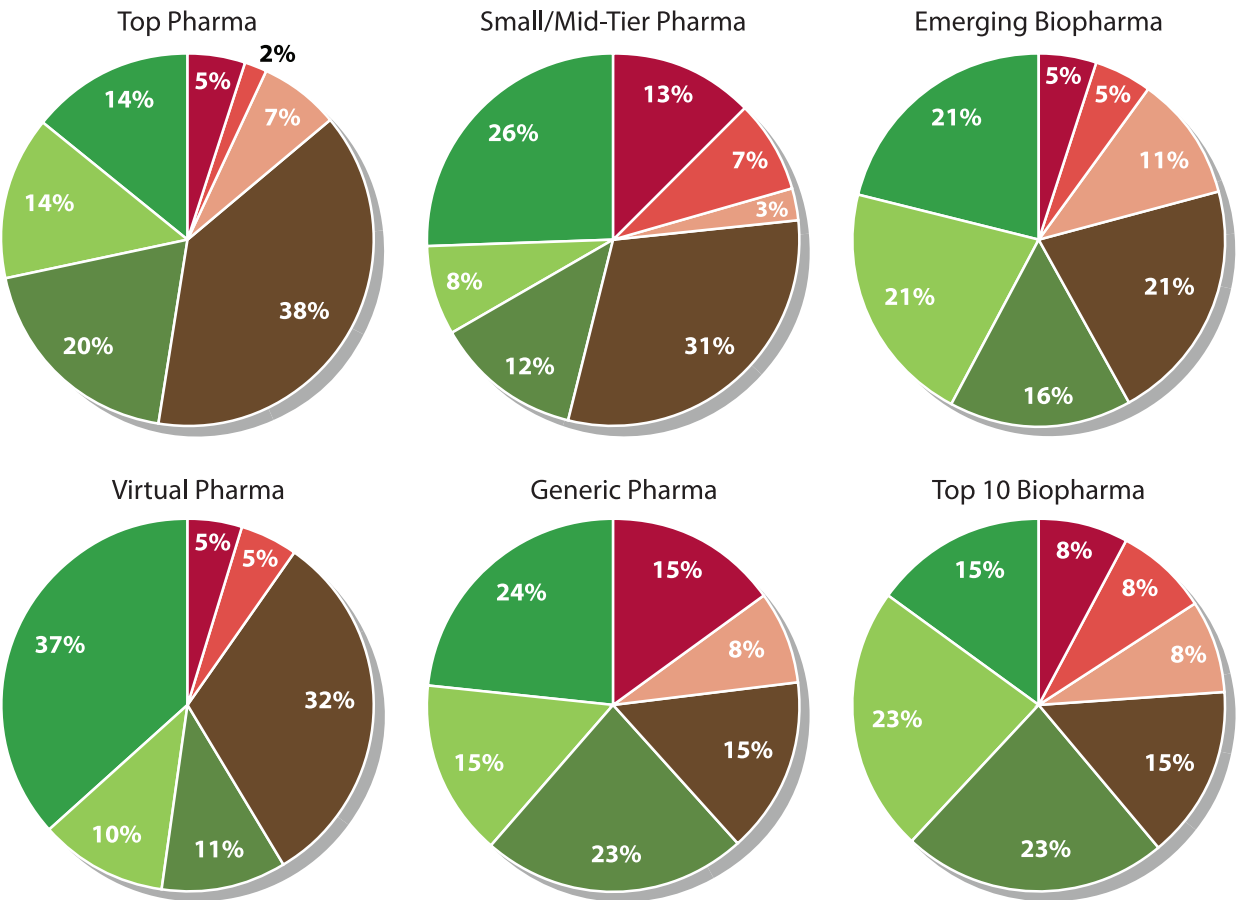
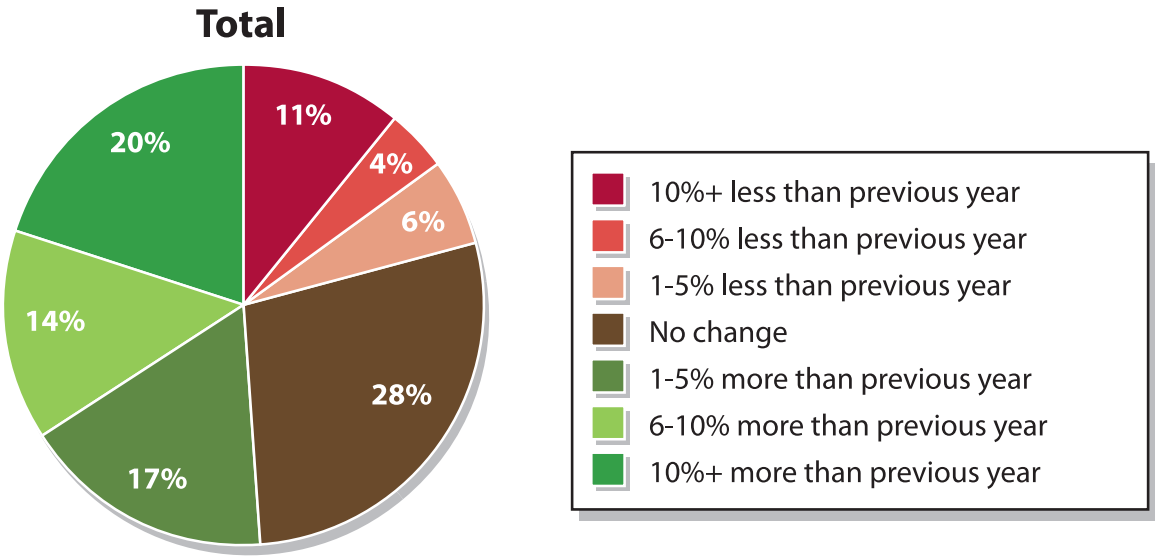
Analytical & Testing Services	40.9%
CMC	31.8%
R&D Services	29.5%
Manufacturing: API	25.0%
Clinical Trials (I-IV)	25.0%
Formulation Development	20.5%
Supply Chain Management	20.5%

* Respondents can select multiple answers for this category)



How much do you expect your outsourcing spending to change in the next year?

(by company type)



Future Shock

Respondents who project that their outsourcing spending will **GROW** in the next year: **51%**

WHAT DO THEY DO?

R&D	18.3%
Purchasing/Sourcing	15.1%
Corporate Management	15.1%
Project Manager	10.8%

WHERE DO THEY WORK?

Top 20 Pharma	21.5%
Small/Mid-Tier Pharma	19.4%
Emerging Biopharma	11.8%
Virtual Pharma	11.8%

WHAT TYPES OF OUTSOURCING DO THEY MANAGE?*

Analytical & Testing Services	57.0%
Manufacturing: API	36.6%
Formulation Development	35.5%
Clinical Trials (I-IV)	34.4%
CMC	34.4%
Manufacturing: Fill/Finish	33.3%
Stability Studies	32.3%

Respondents who project that their outsourcing spending will **SHRINK** in the next year: **21%**

WHAT DO THEY DO?

R&D	21.1%
Corporate Management	18.4%
Business Development	13.2%
Clinical Research	10.5%

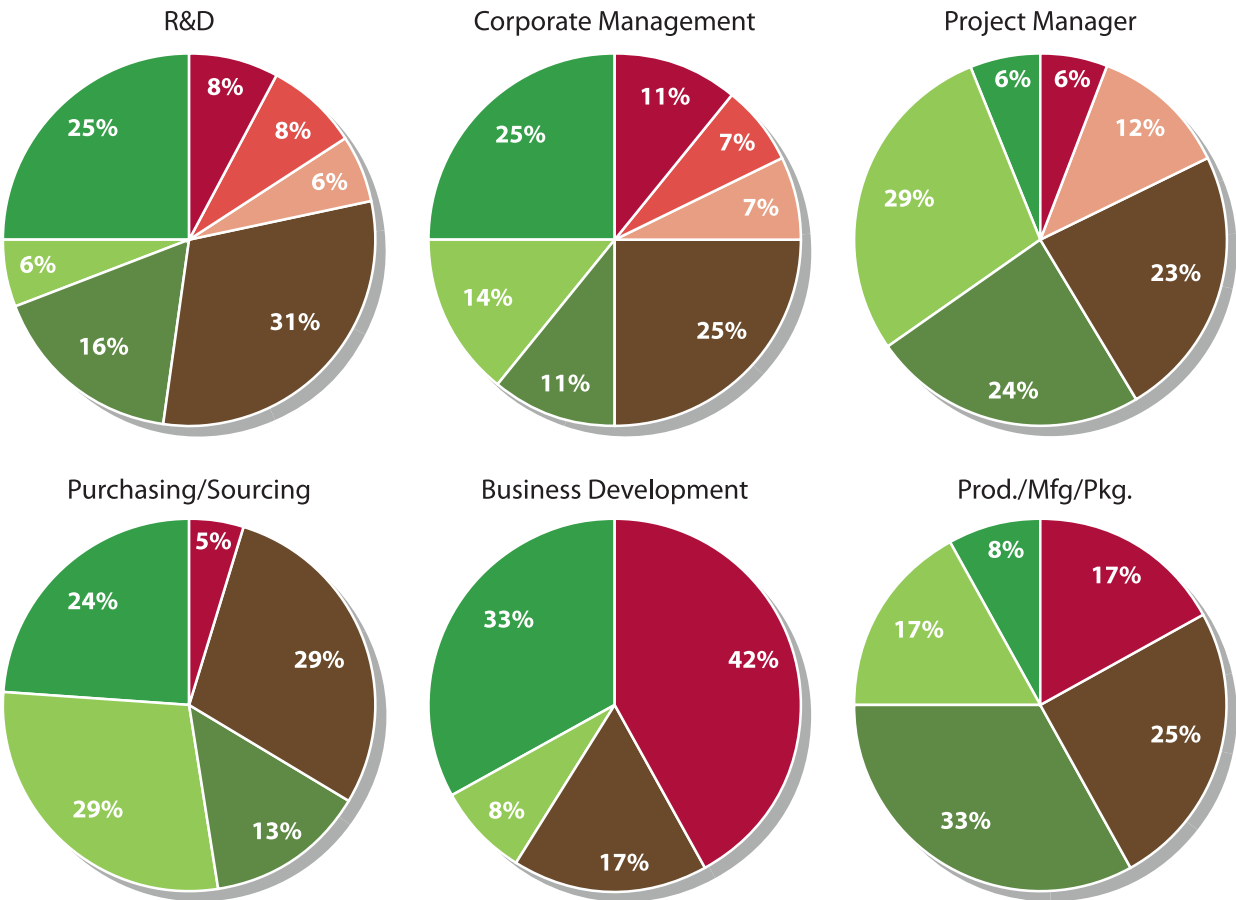
WHERE DO THEY WORK?

Small/Mid-Tier Pharma	23.7%
Top 20 Pharma	15.8%
Emerging Biopharma	10.5%
Specialty Pharma	10.5%

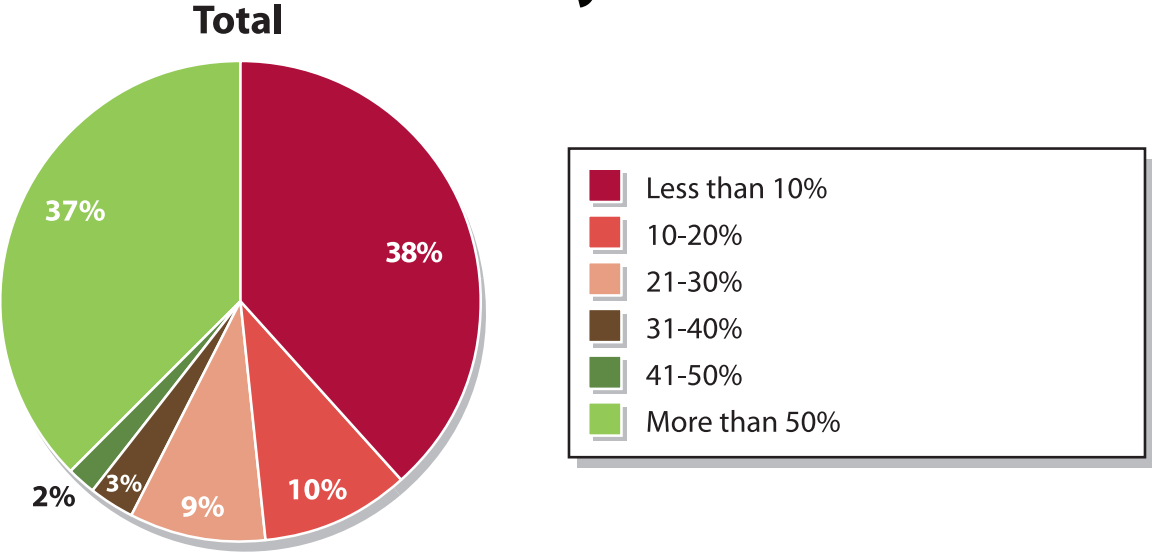
WHAT TYPES OF OUTSOURCING DO THEY MANAGE?*

Analytical & Testing Services	36.8%
Manufacturing: API	36.8%
Formulation Development	34.2%
Manufacturing: Solid Dosage	34.2%
CMC	31.6%
Clinical Trials (I-IV)	28.9%
Process Development/Scale-Up	28.9%

* Respondents can select multiple answers for this category)



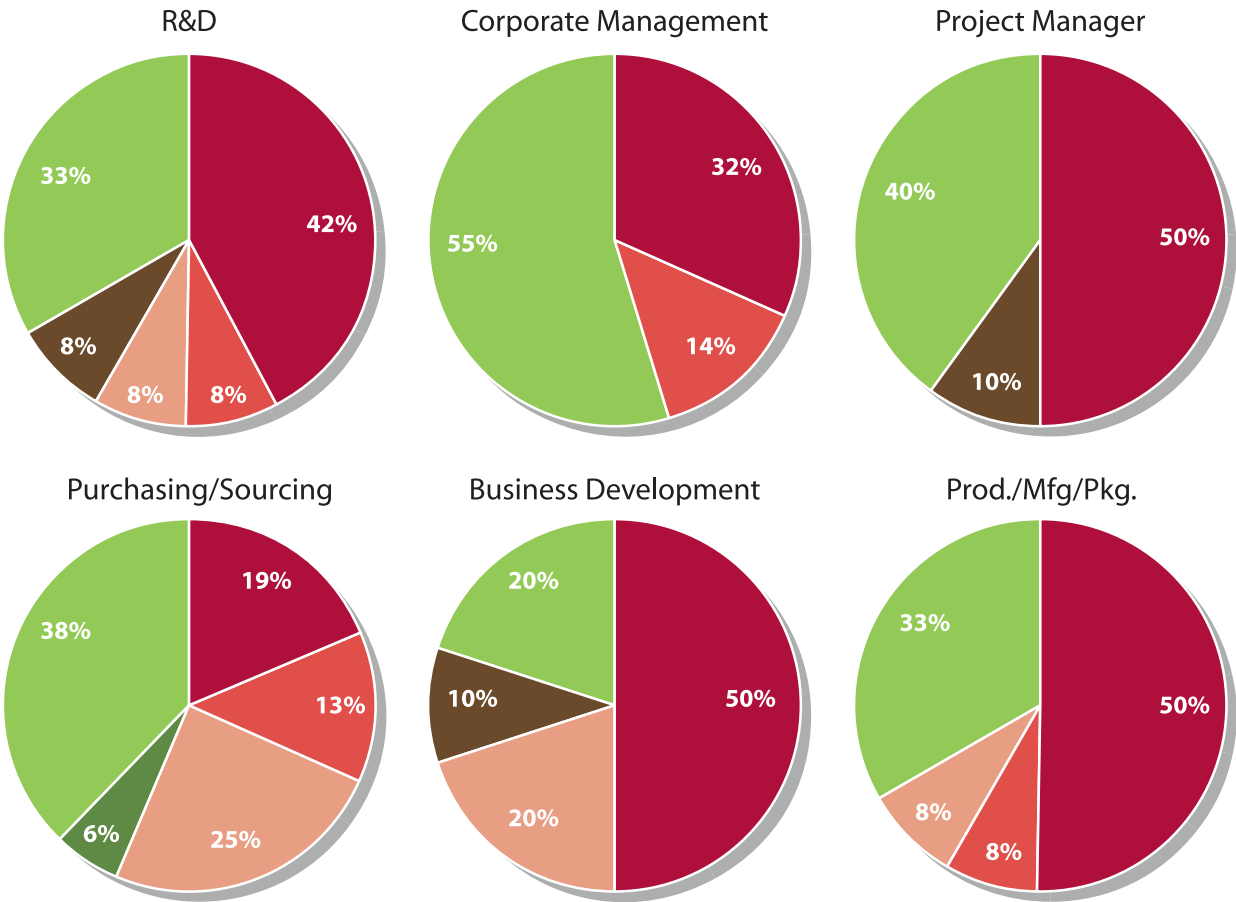
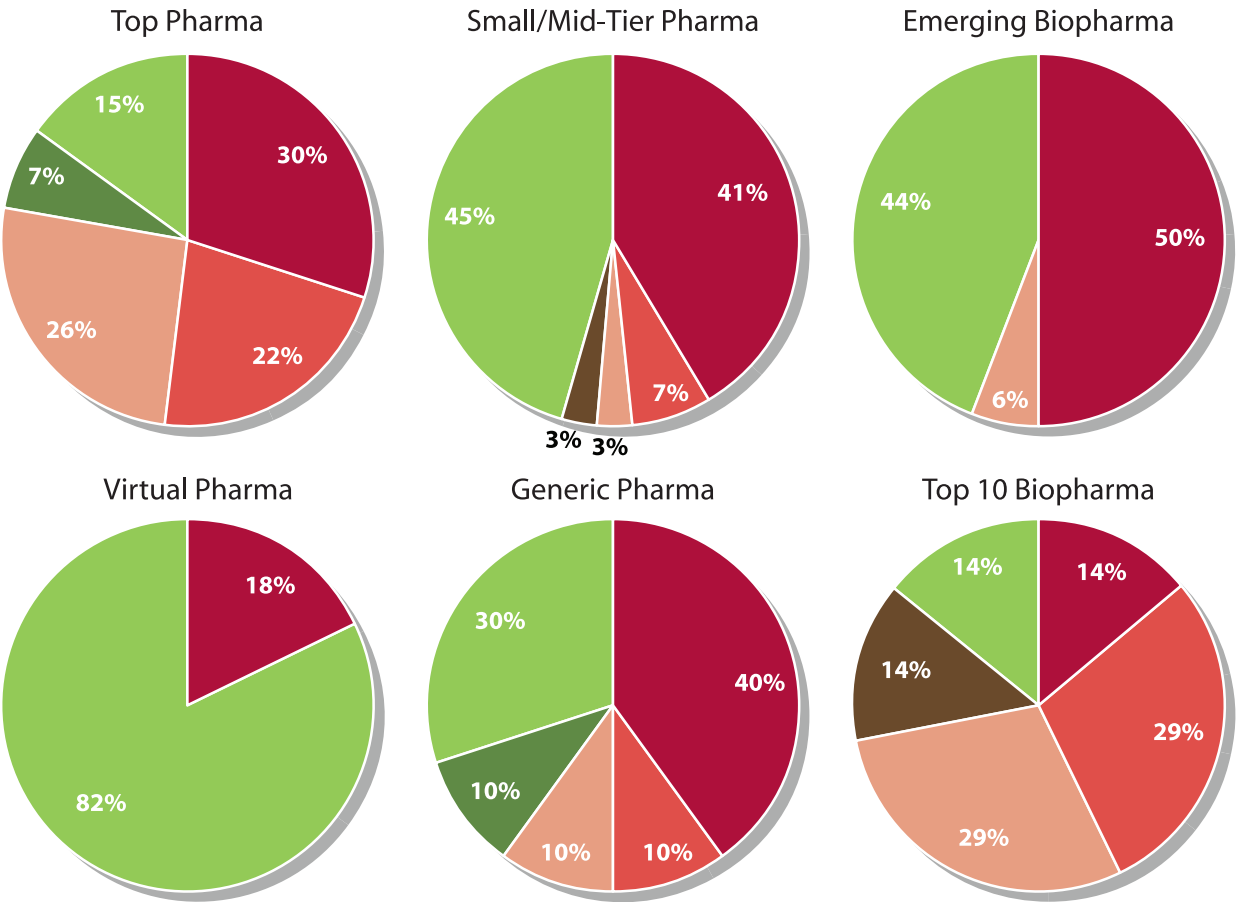
What percentage of your company's commercial (final dosage) manufacturing is done by CMOs?



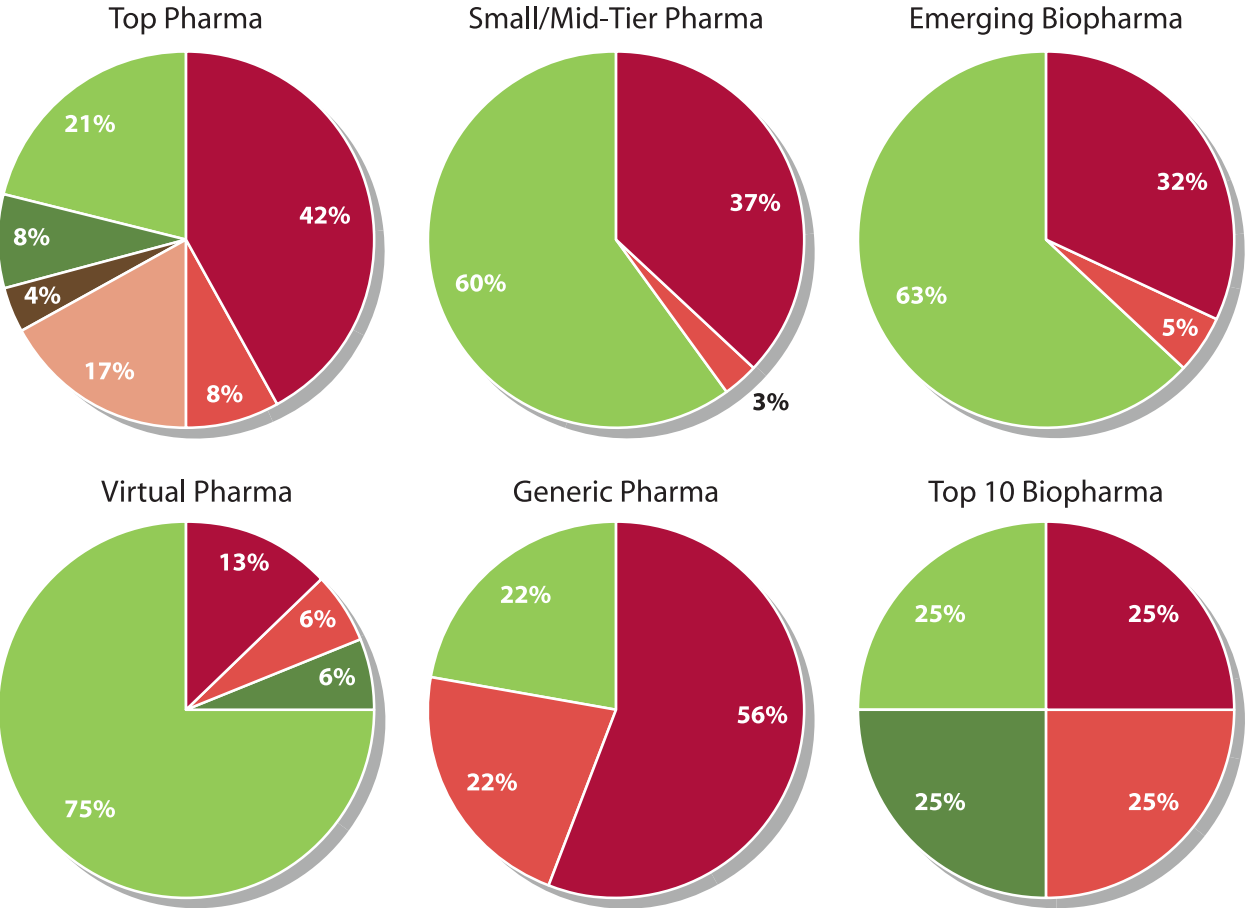
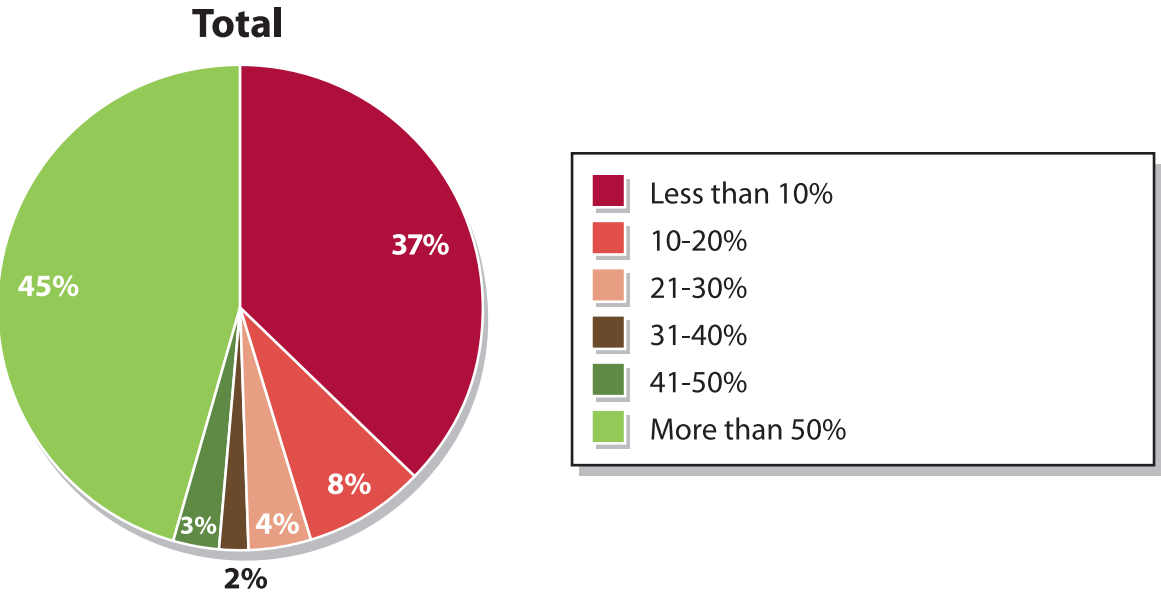
Halfway Home

Of the respondents who say that their companies **outsource at least 50% of their commercial manufacturing** . . .

- 61%** report that they expect to increase their outsourcing spending in the next year
- 59%** work at companies that employ a "preferred provider" model
- 63%** said that more than half of their outsourcing dollars go to preferred providers
- 55%** use CMOs for secondary supply for commercial products
- 40%** report that they will probably or definitely outsource a project to an Asia-based providers in the next year
- 57%** describe their outsourcing as strategic (as opposed to tactical)
- 60%** outsource because their company is virtual, while **25%** do so to focus on core competencies



What percentage of your company's clinical manufacturing is done by CMOs?



Second by Secondary

41% of all respondents said that they use contract service providers as secondary suppliers for commercial supply.

44% said that they use secondary suppliers for clinical materials.

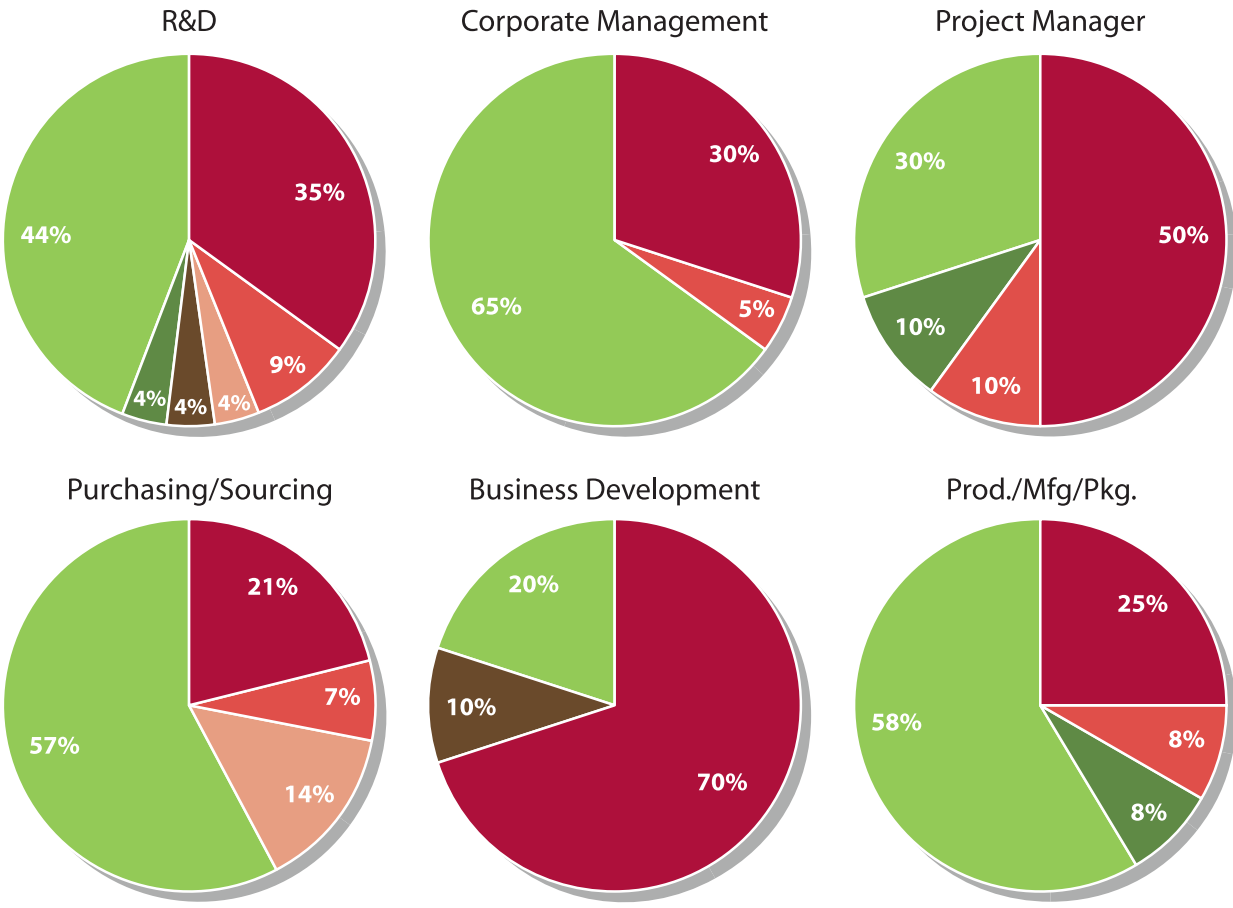
51% said that they use secondary suppliers for APIs.

25% reported that they don't use providers for any of those secondary supplies.

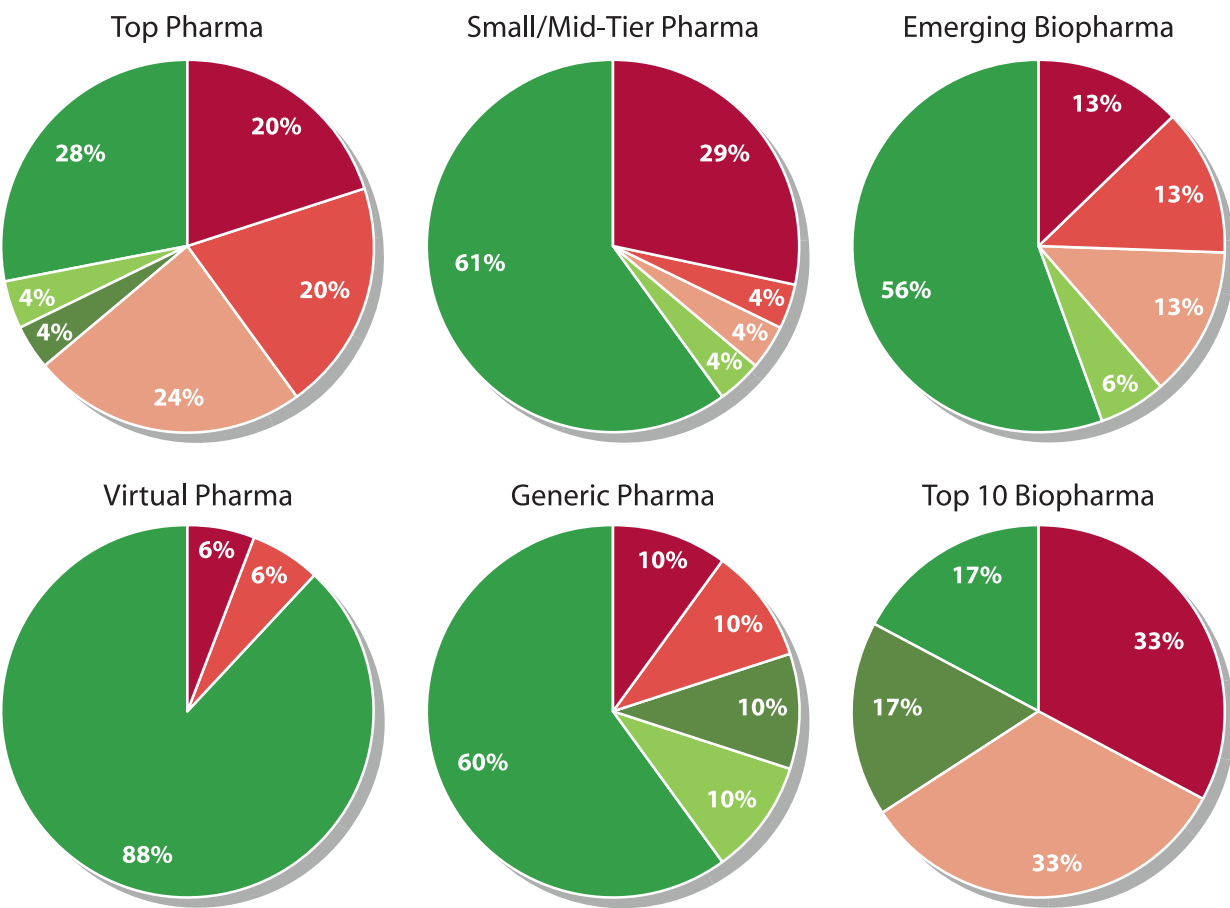
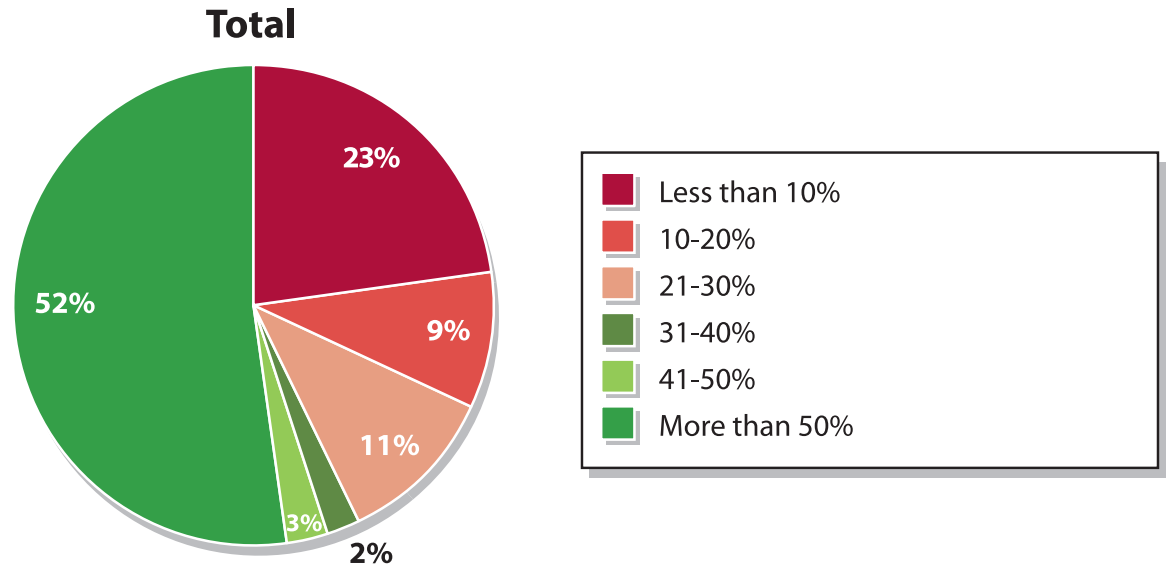
What do we know about the **25%** of respondents who say they use no secondary suppliers?

WHAT DO THEY DO?	WHAT TYPES OF OUTSOURCING DO THEY MANAGE?*
Corporate Management.....23.5%	Analytical & Testing Services.....50.0%
R&D14.7%	R&D Services32.4%
QA/QC/Validation.....8.8%	QA/QC29.4%
Business Development8.8%	Manufacturing: Solid Dosage.....29.4%
	Chemistry.....26.5%
	Clinical Trials (I-IV)26.5%
	Packaging: Commercial26.5%
WHERE DO THEY WORK?	
Other.....23.5%	
Top 20 Pharma17.6%	
Small/Mid-Tier Pharma.....17.6%	
Virtual Pharma.....11.8%	

* Respondents can select multiple answers for this category



What percentage of your company's API manufacturing is outsourced?



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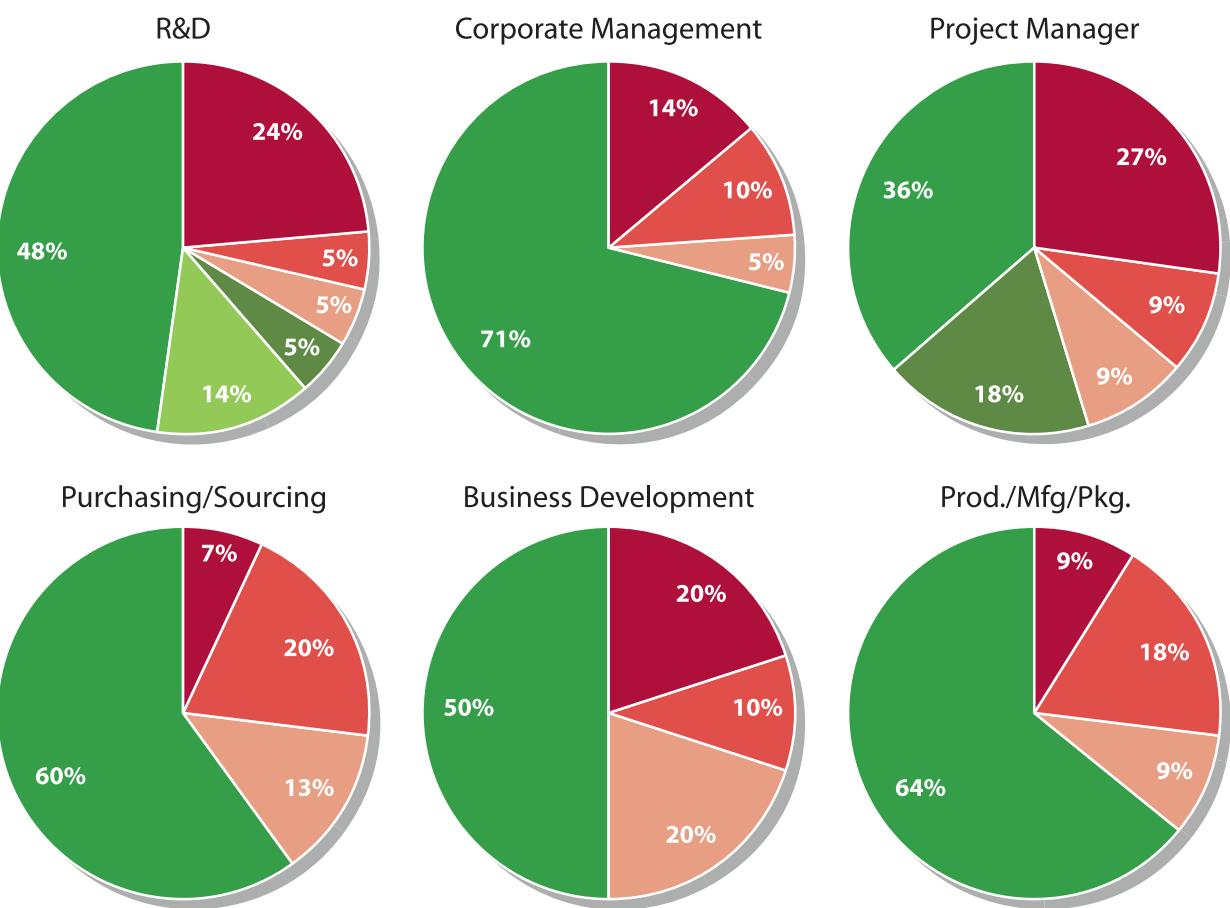
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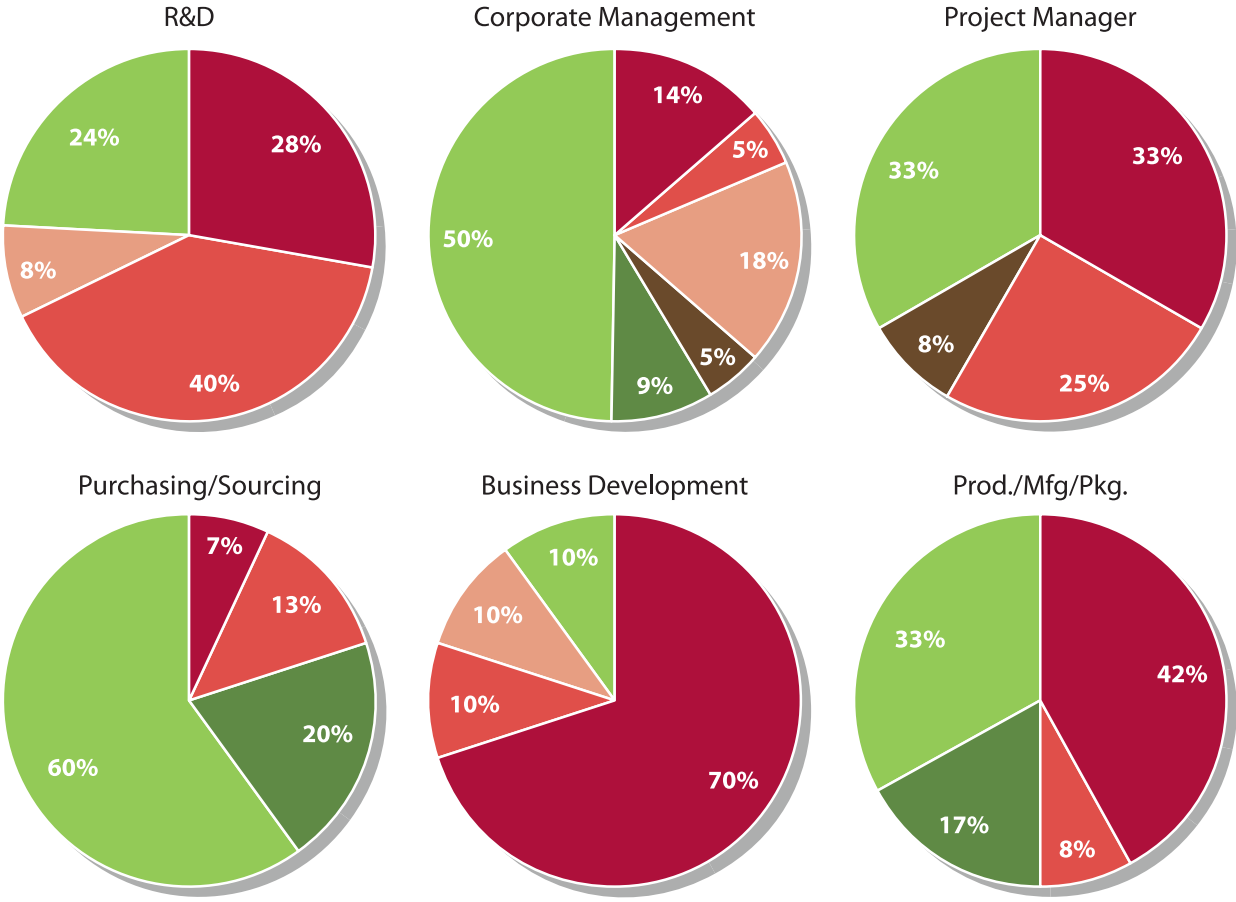
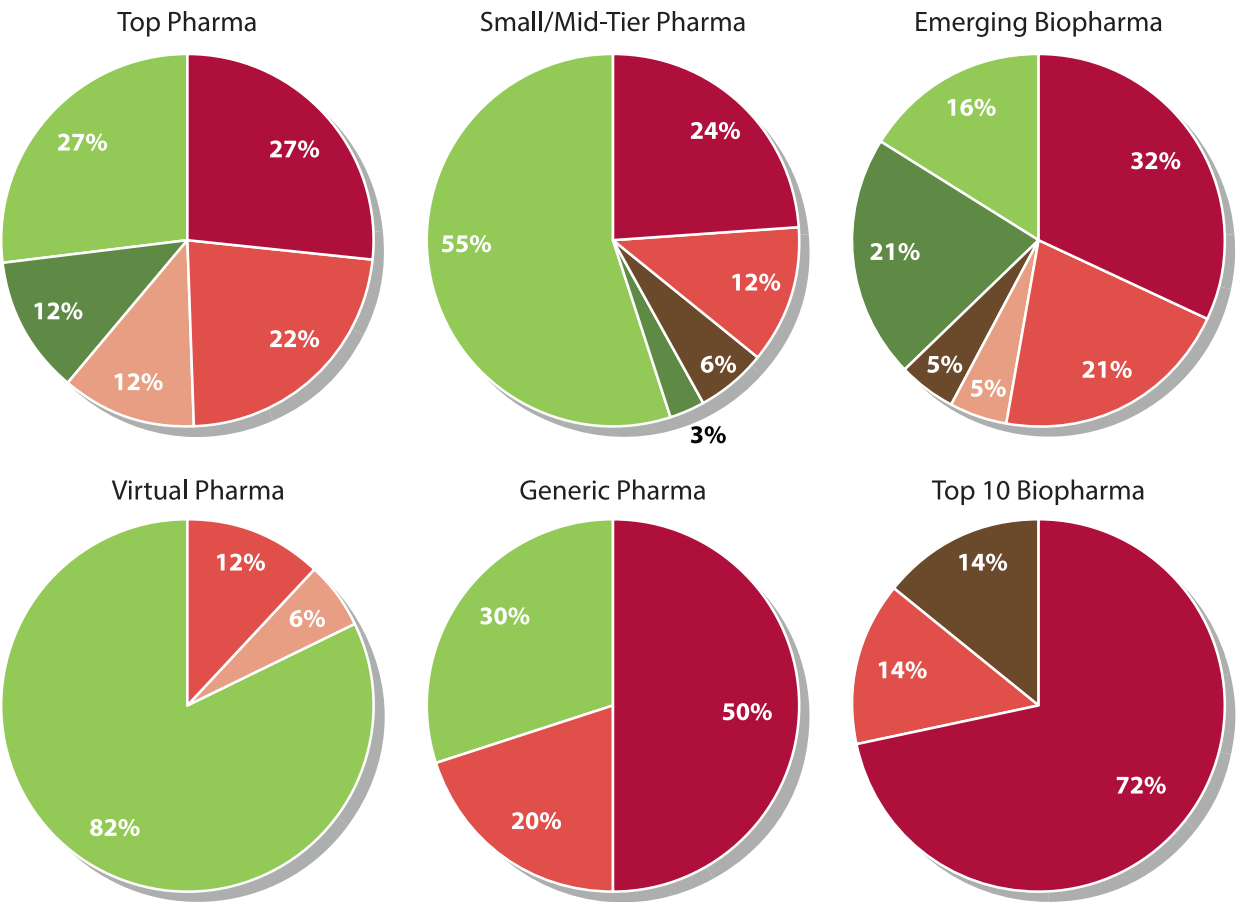
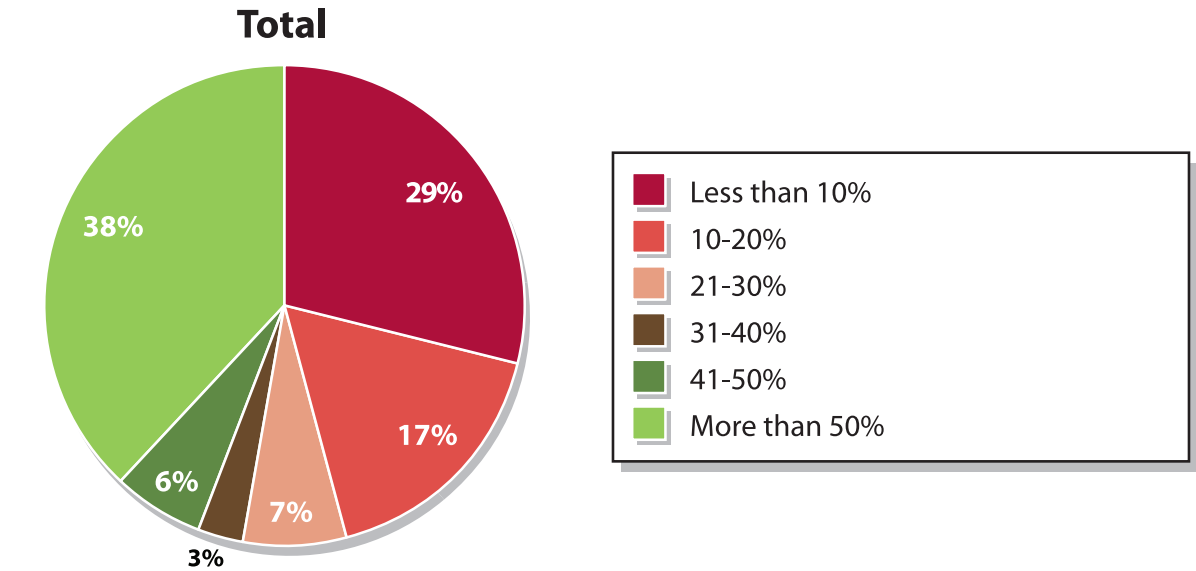


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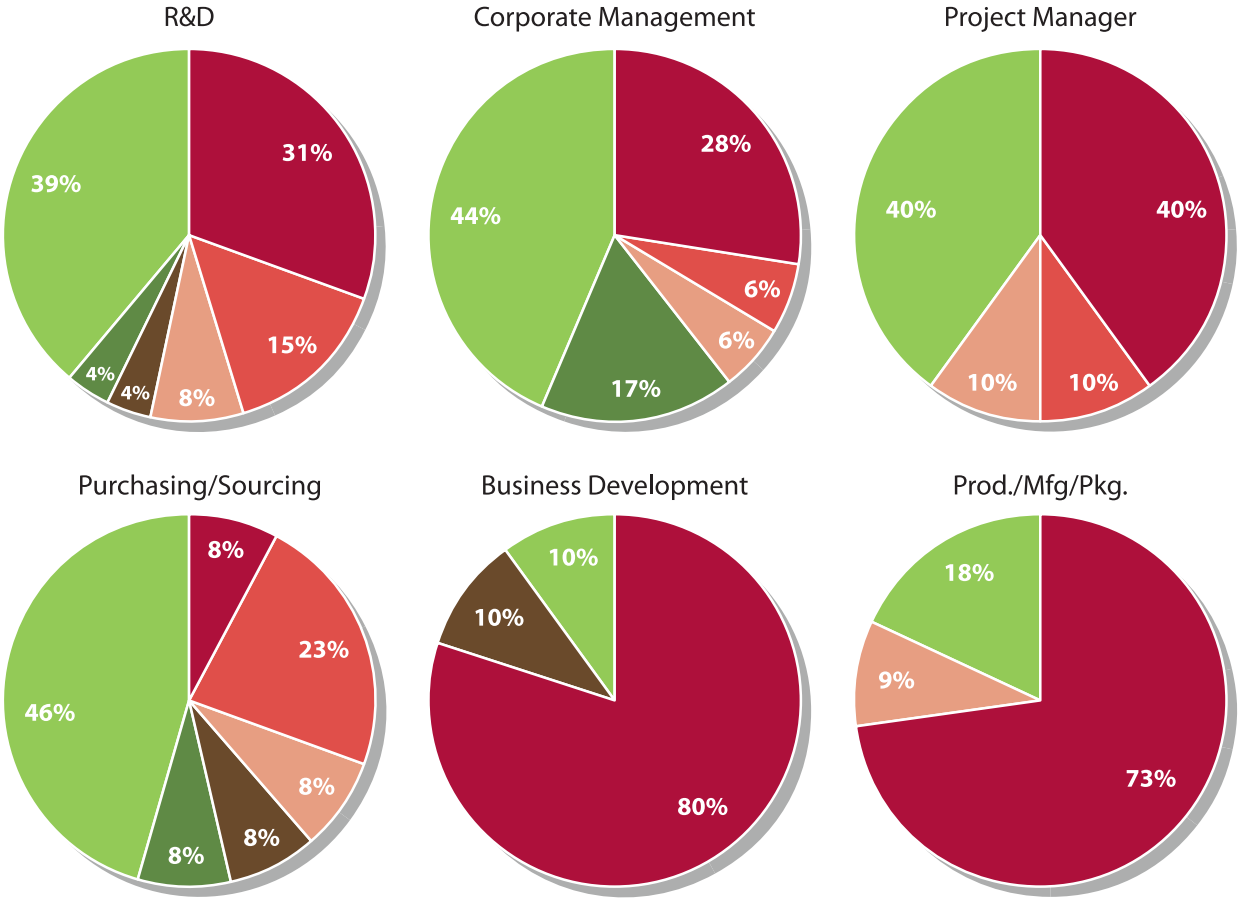
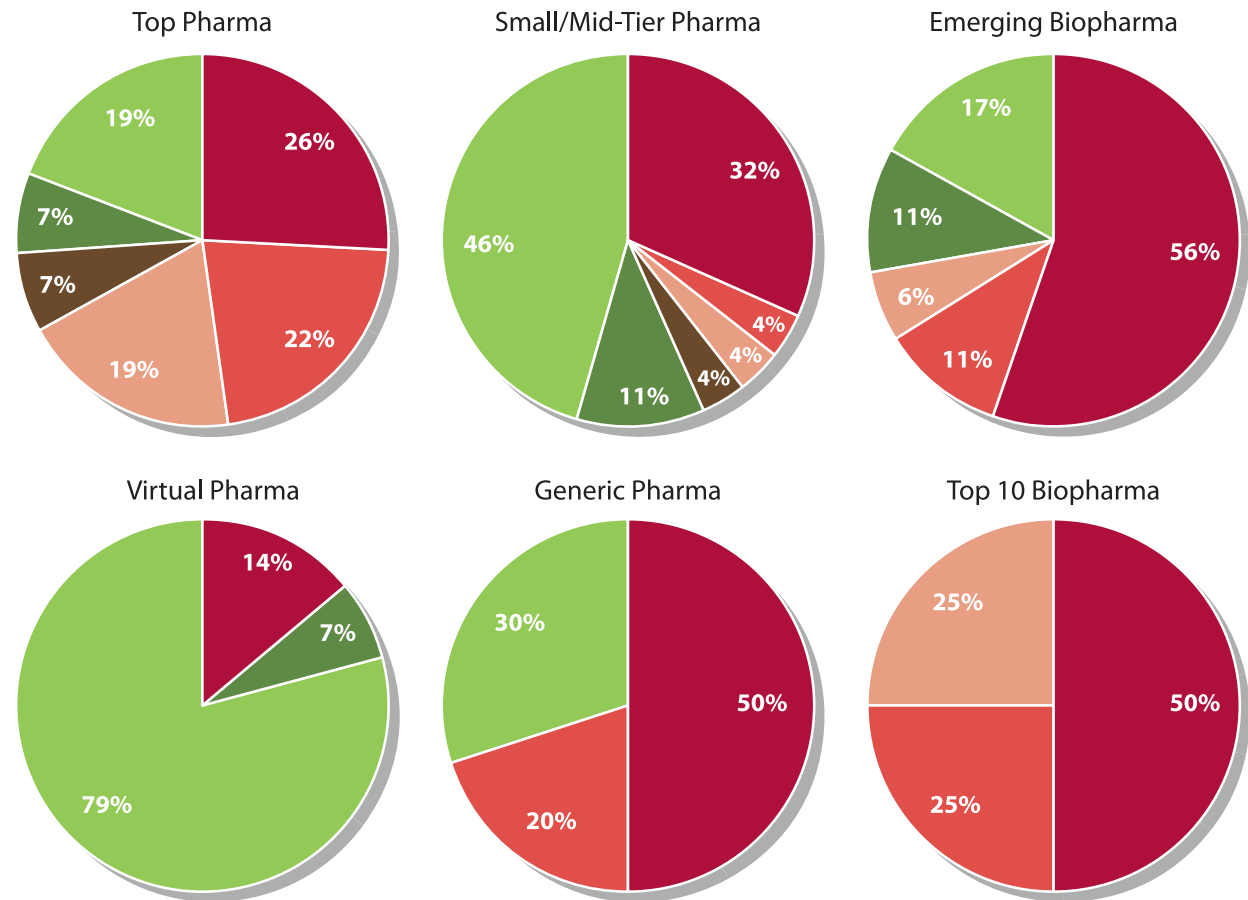
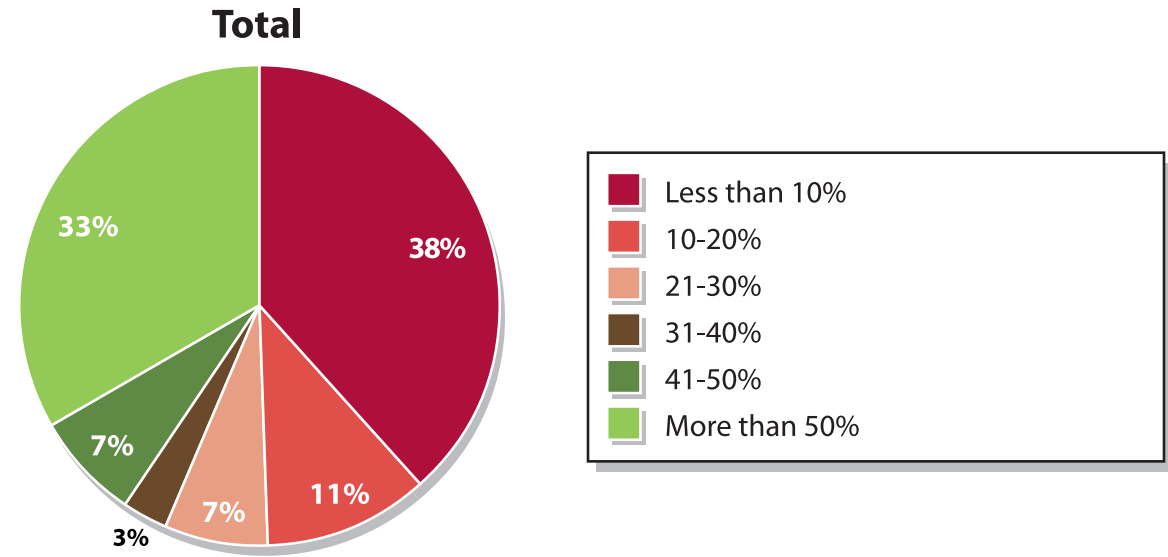


What percentage of your company's analytical testing is outsourced?

(by company type)

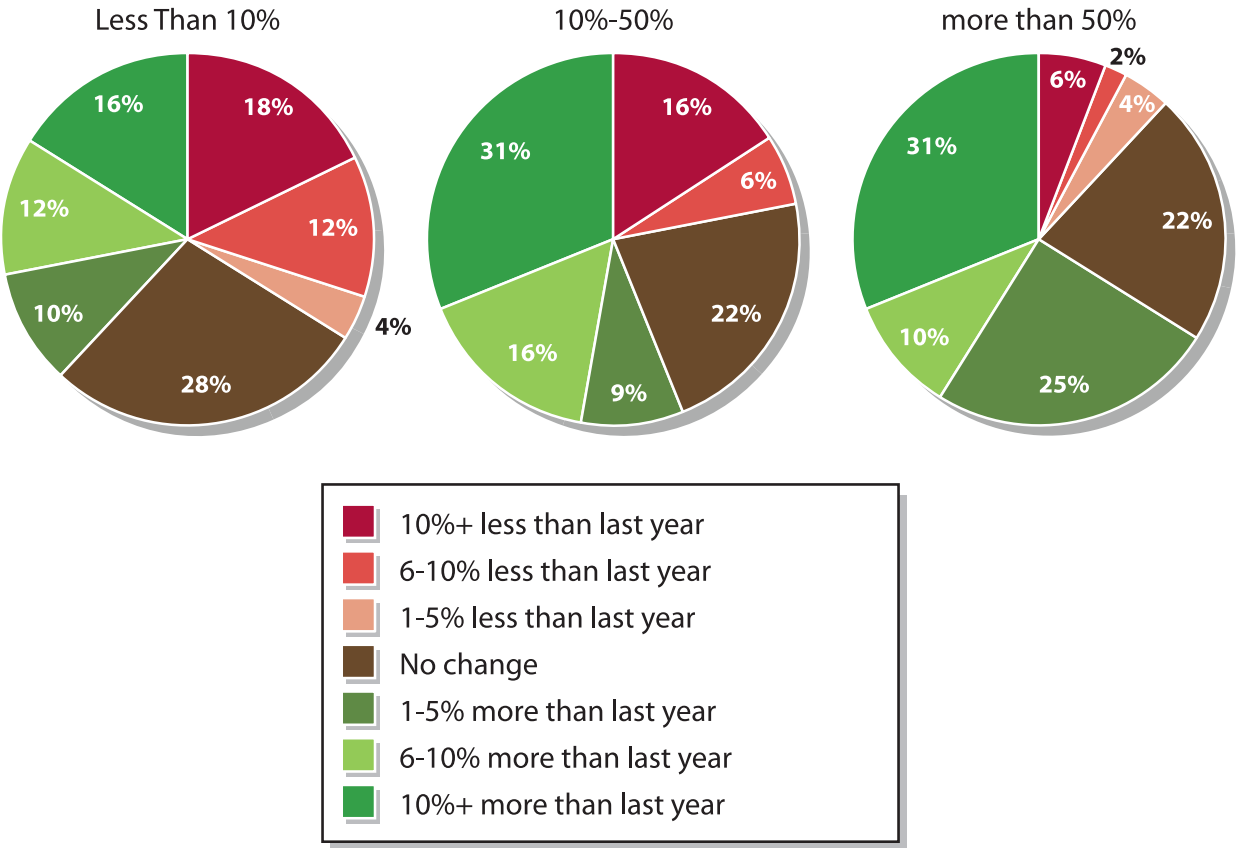


What percentage of your company's
Nonclinical Work is outsourced?



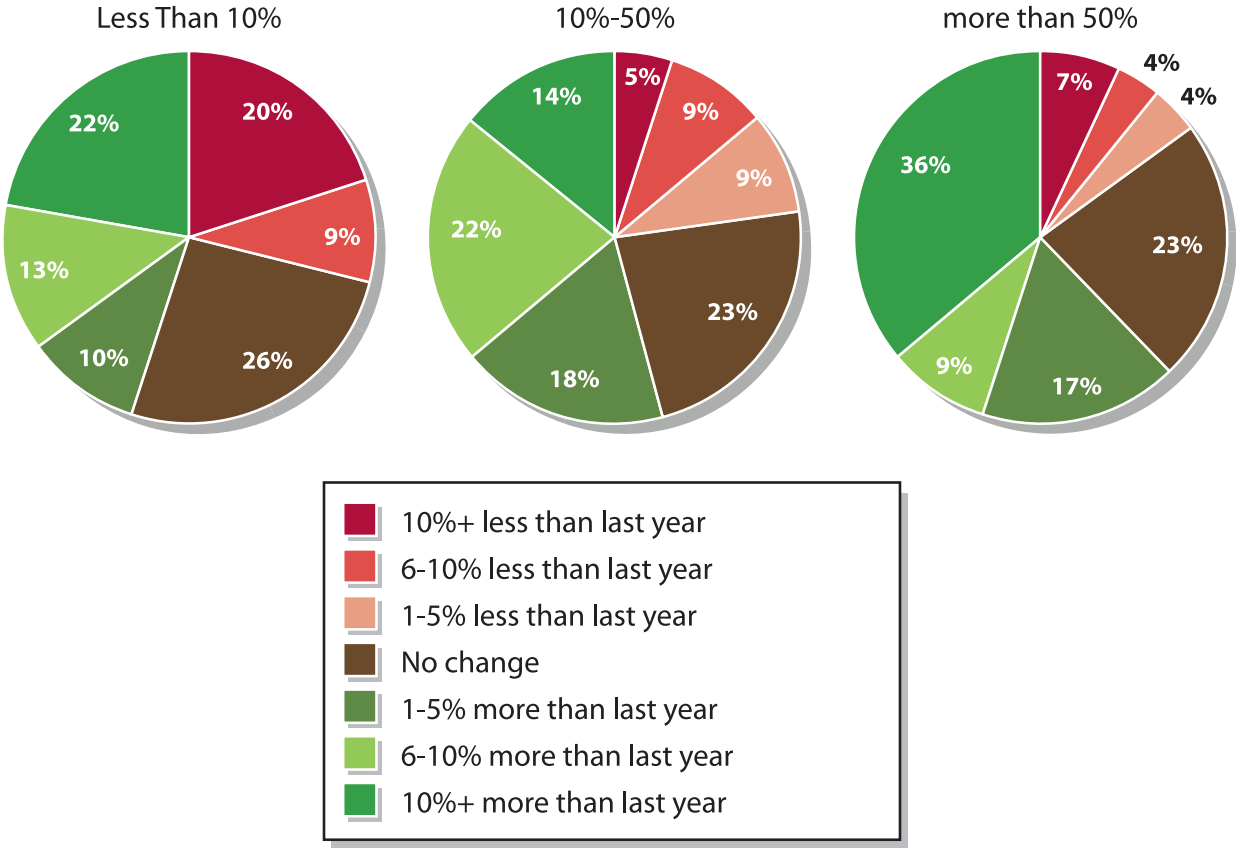
How much did your outsourcing
spending change in the past year?

(by how much COMMERCIAL manufacturing is outsourced)



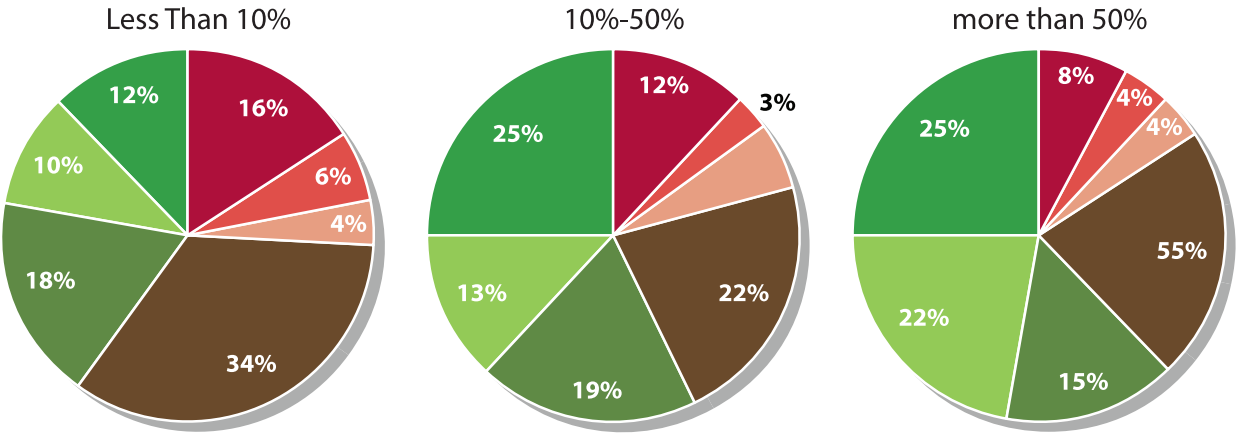
How much did your outsourcing
spending change in the past year?

(by how much CLINICAL manufacturing is outsourced)



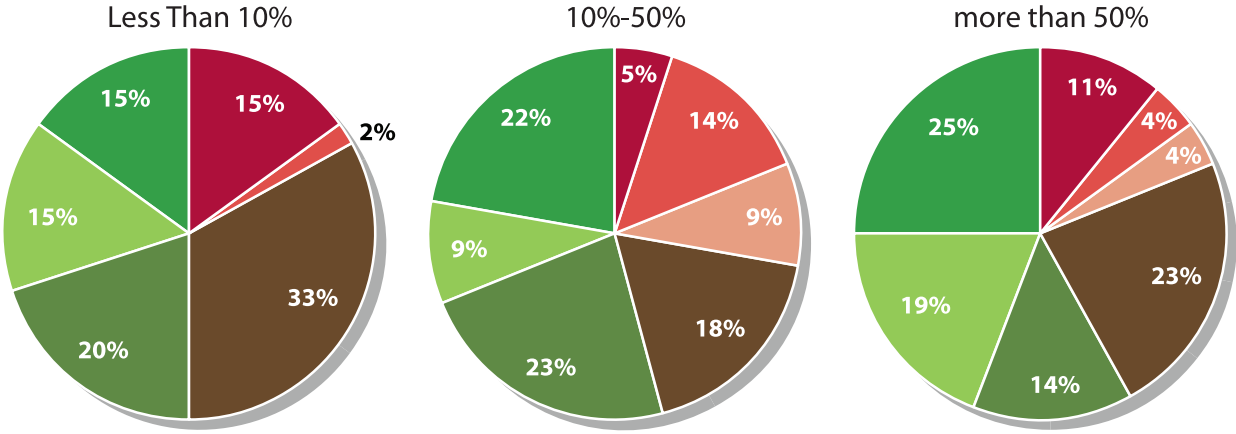
How much do you expect your outsourcing
spending to change in the next year?

(by how much COMMERCIAL manufacturing is outsourced)

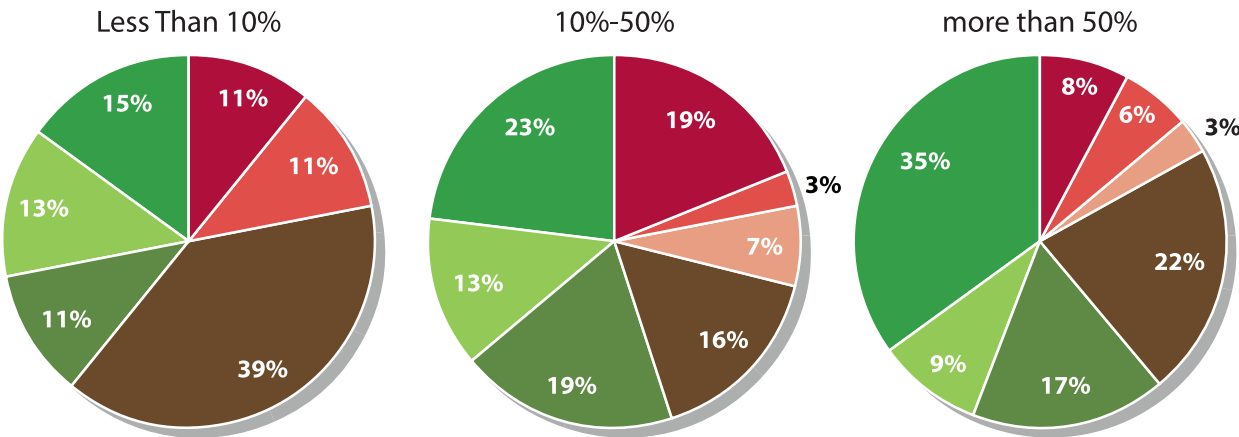


How much do you expect your outsourcing
spending to change in the next year?

(by how much CLINICAL manufacturing is outsourced)

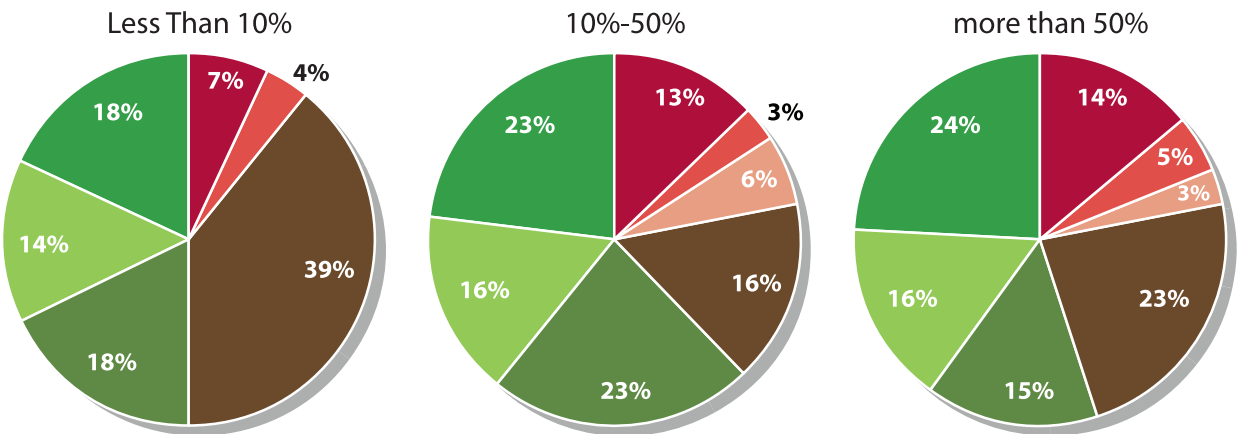


How much did your outsourcing spending change in the past year?
(by how much API is outsourced)

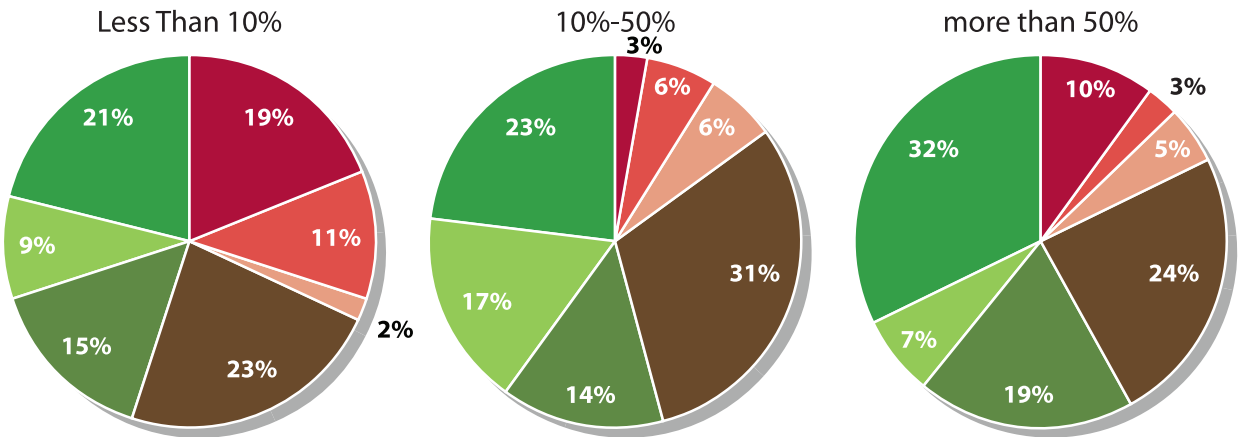


10%+ less than last year
6-10% less than last year
1-5% less than last year
No change
1-5% more than last year
6-10% more than last year
10%+ more than last year

How much do you expect your outsourcing spending to change in the next year?
(by how much API is outsourced)

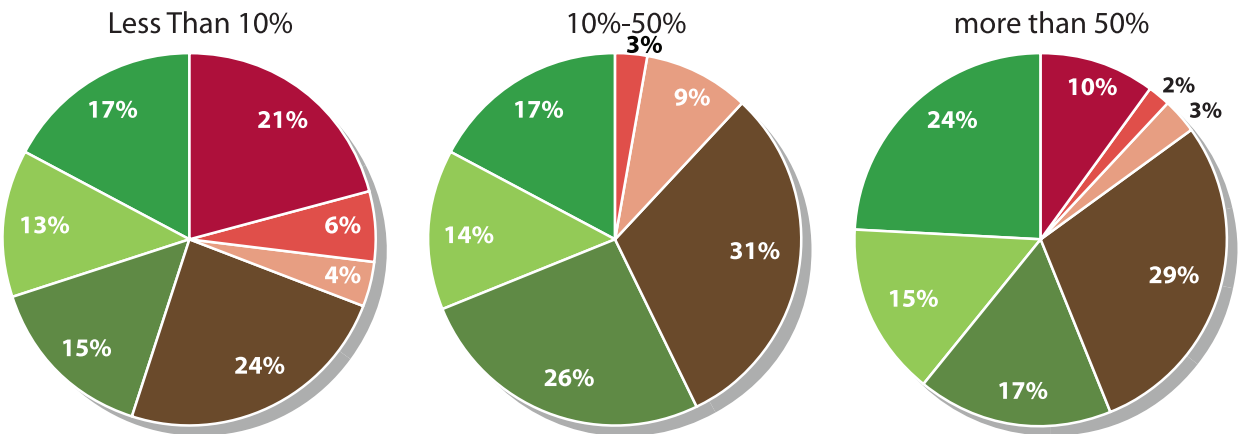


How much did your outsourcing spending change in the past year?
(by how much Nonclinical Work is outsourced)



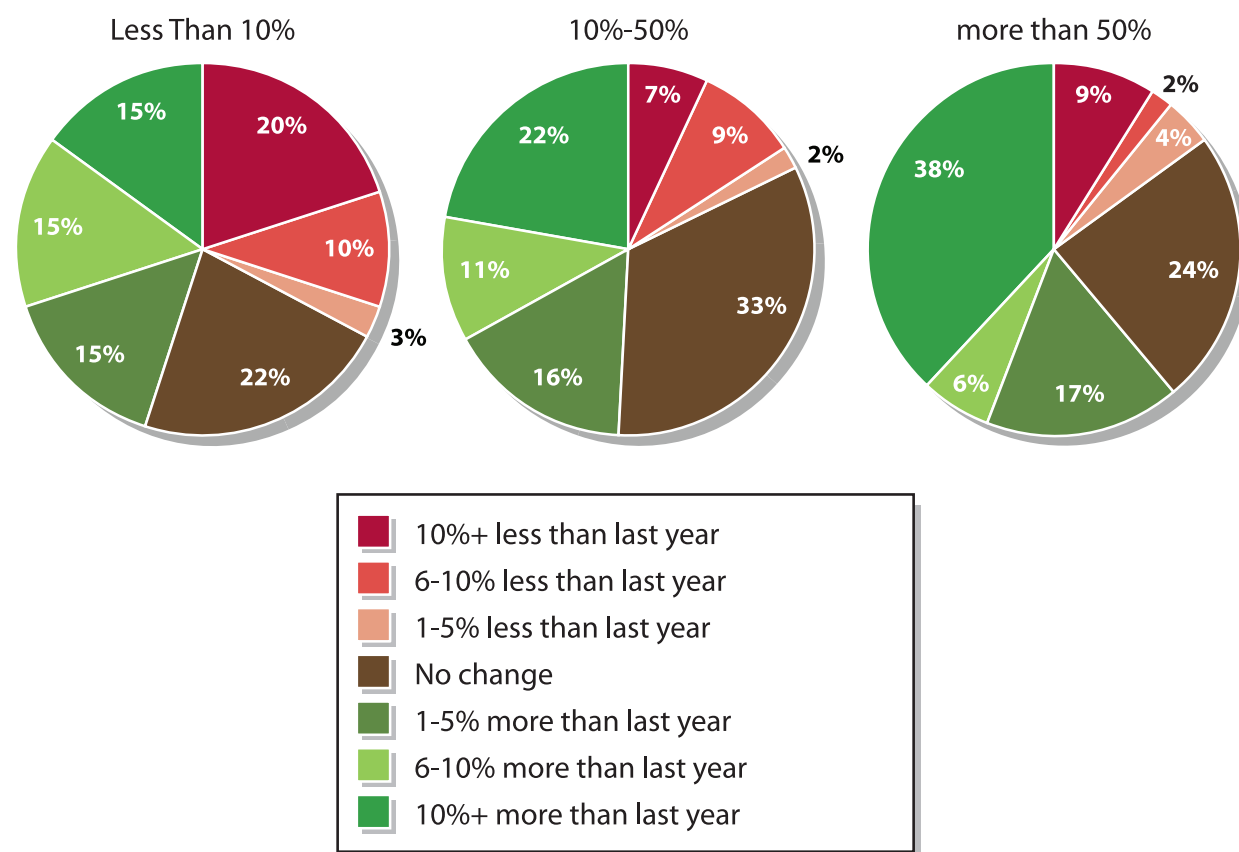
10%+ less than last year
6-10% less than last year
1-5% less than last year
No change
1-5% more than last year
6-10% more than last year
10%+ more than last year

How much do you expect your outsourcing spending to change in the next year?
(by how much Nonclinical Work is outsourced)



How much did your outsourcing spending change in the past year?

(by how much Analytical Testing is outsourced)



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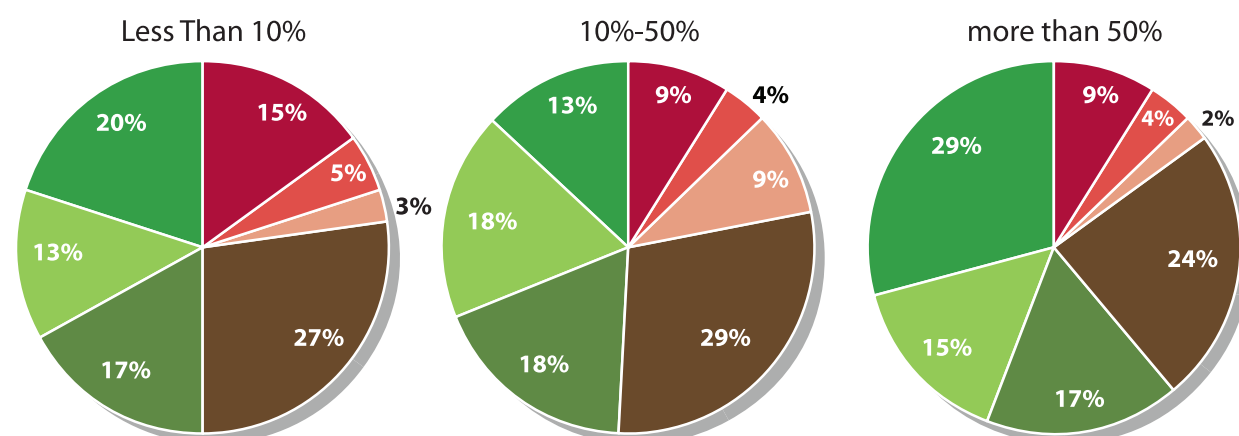


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How much do you expect your outsourcing spending to change in the next year?

(by how much Analytical Testing is outsourced)



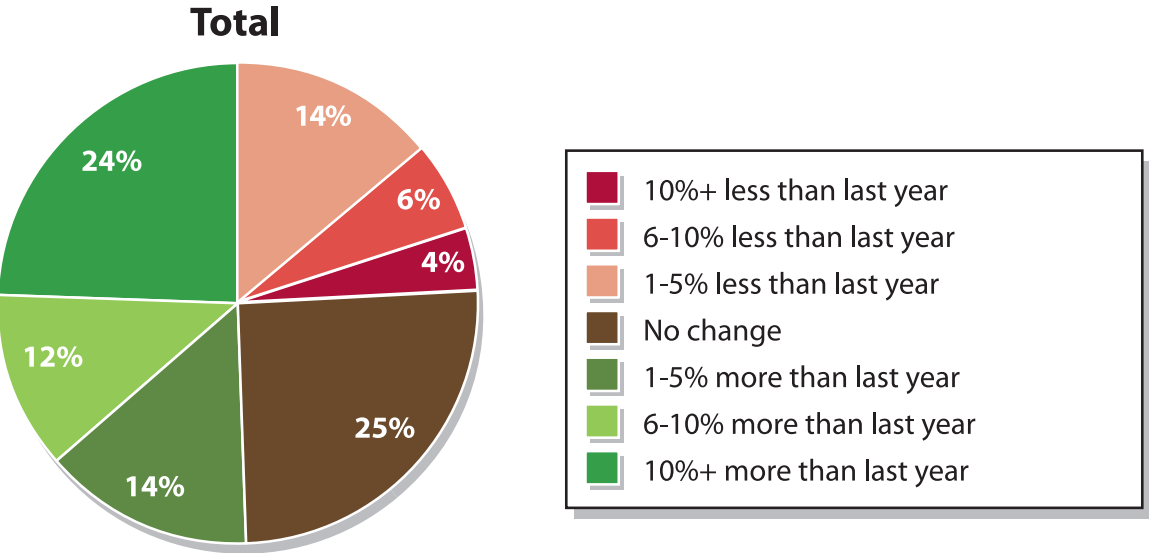
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How much did your outsourcing spending change in the past year?

(by outsourcing decision)



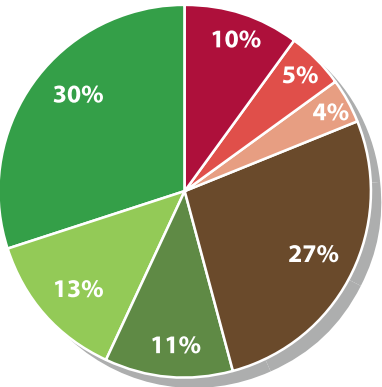
Outsourcing Decisions

WHAT TYPES OF OUTSOURCING DECISIONS ARE YOU INVOLVED IN?*

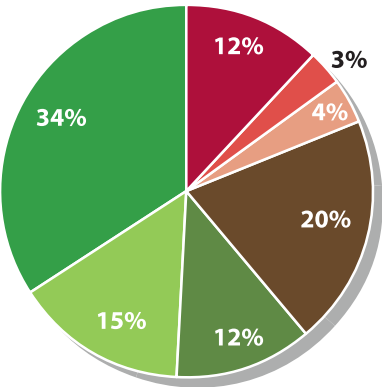
Analytical & Testing Services.....	50.2%	Validation Services	19.1%
Formulation Development	31.6%	Manufacturing: Injectable Dosage.....	18.7%
Manufacturing: API	31.1%	Labeling	18.2%
R&D Services.....	31.1%	Manufacturing: Parenterals	17.7%
Clinical Trials (Phase I-IV).....	29.2%	Drug Delivery Systems	17.2%
CMC.....	28.7%	Manufacturing: High Potency	16.7%
Manufacturing: Solid Dosage.....	28.2%	Manufacturing: Oral Liquid Dosage	16.7%
Chemistry.....	26.8%	Regulatory Filing	16.3%
Process Development / Scale-Up	26.3%	Logistics	15.3%
Stability Studies	26.3%	Preclinical / Toxicology	15.3%
Manufacturing: Fill/Finish	25.4%	Manufacturing: Biologics, Finished Dosage	13.9%
QA/QC	23.0%	Manufacturing: Biologics, Bulk	13.4%
Supply Chain Management	23.0%	Sterility Testing	12.9%
Methods Development / Validation	22.5%	Microbiology	12.0%
Packaging: Commercial.....	21.5%	Sales	12.0%
Manufacturing: Clinical Trials Materials.....	20.1%	Clinical Logistics	11.5%
Packaging: Clinical.....	20.1%	IT	8.1%

* Respondents can select multiple answers for this category

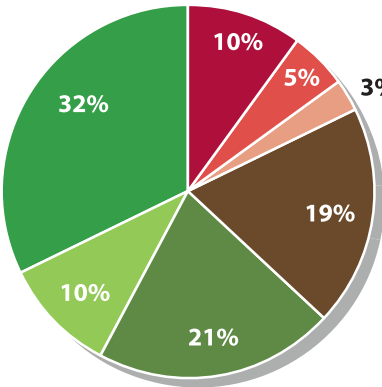
Analytical & Testing Services



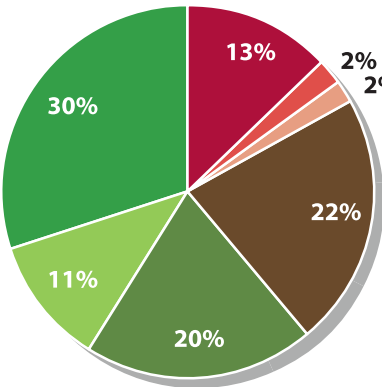
Formulation Development



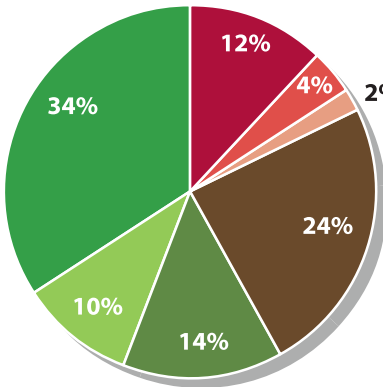
Manufacturing: API



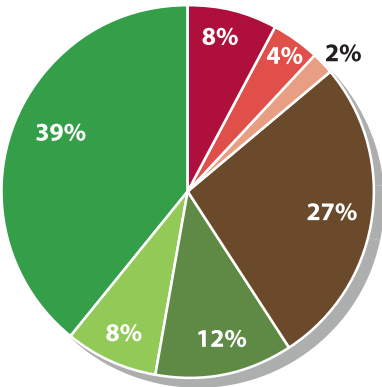
Manufacturing: Solid Dosage



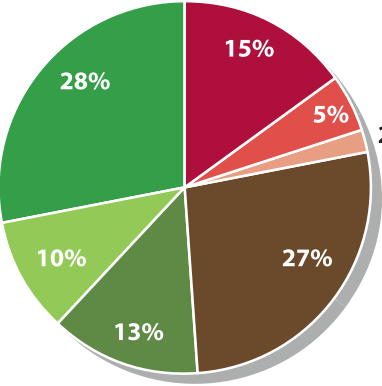
Chemistry



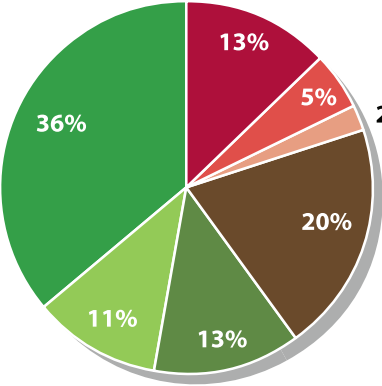
Process Development / Scale-Up



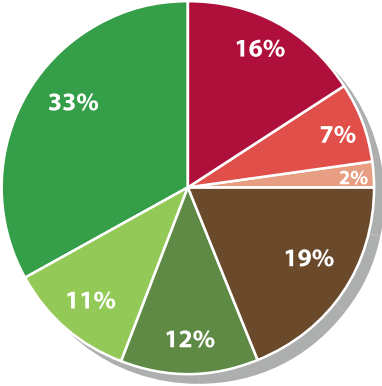
R&D Services



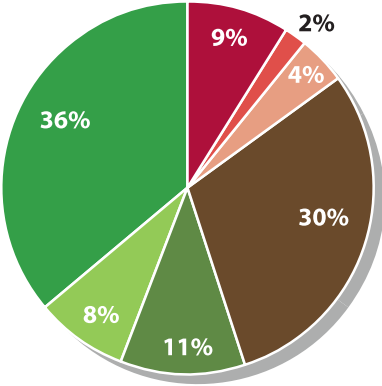
Clinical Trials (Phase I-IV)



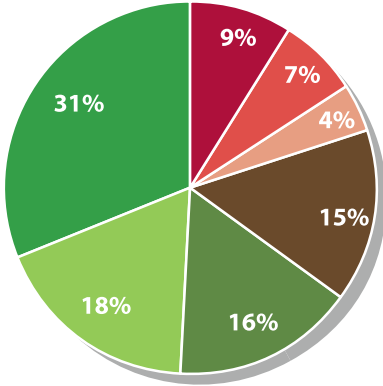
CMC



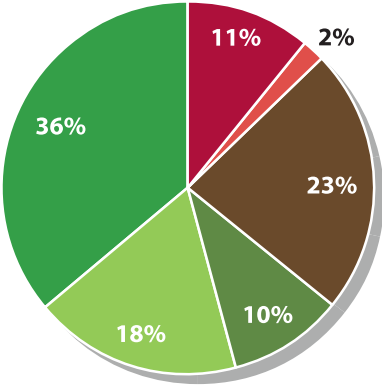
Stability Studies



Manufacturing: Fill/Finish

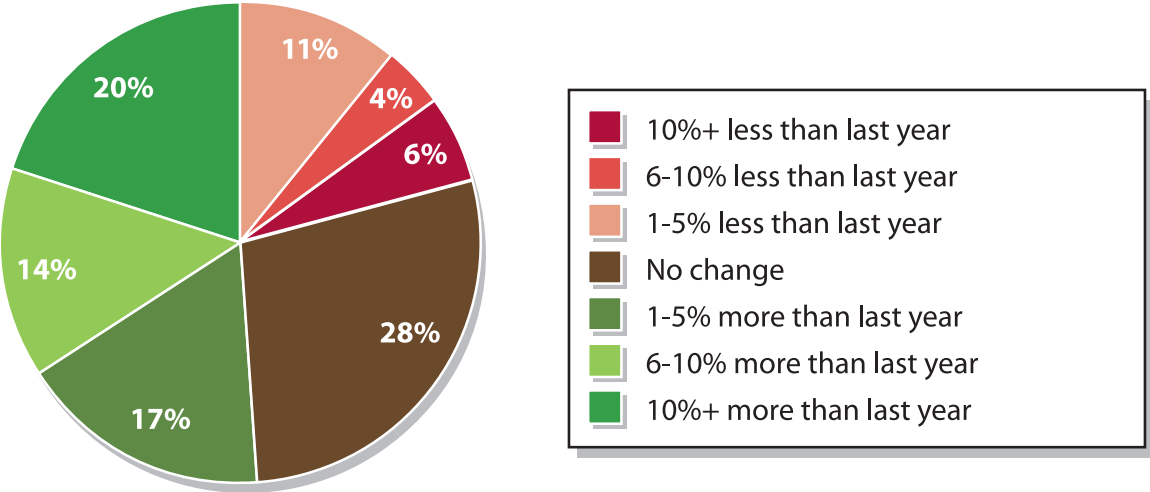


QA/QC

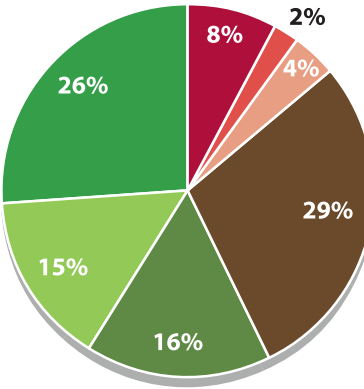


How much do you expect your outsourcing spending to change in the next year?
(by outsourcing decision)

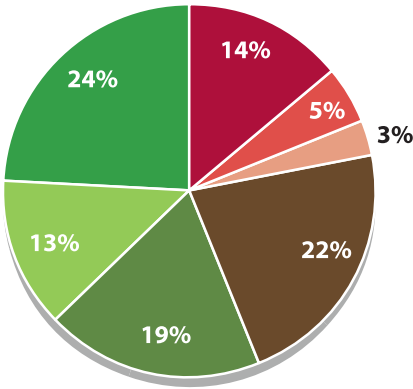
Total



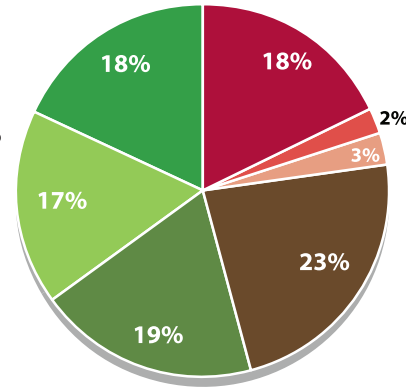
Analytical & Testing Services



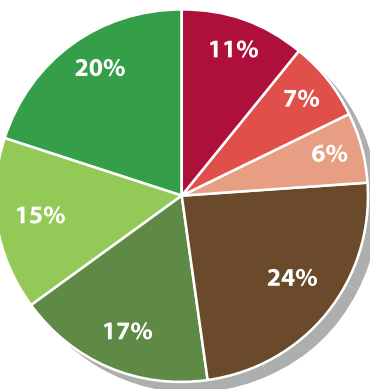
Formulation Development



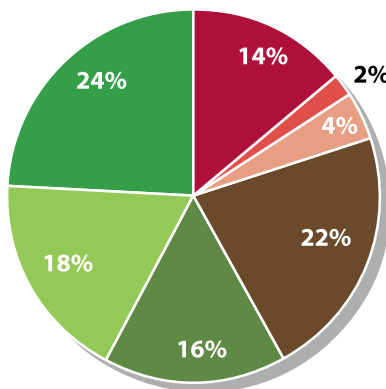
Manufacturing: API



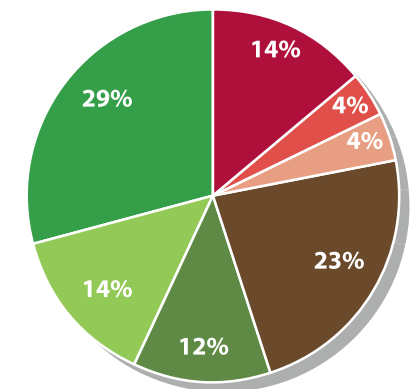
Manufacturing: Solid Dosage



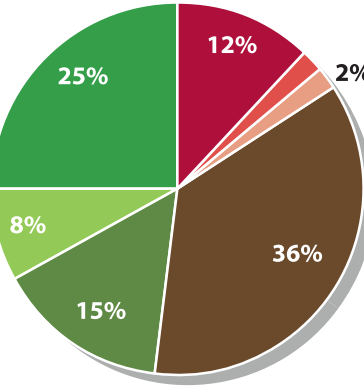
Chemistry



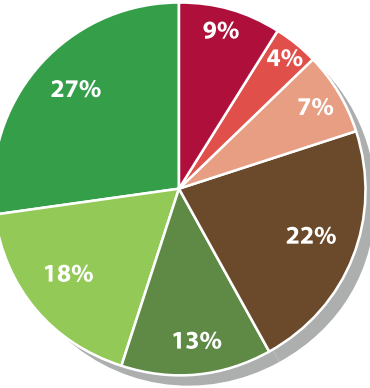
Process Development / Scale-Up



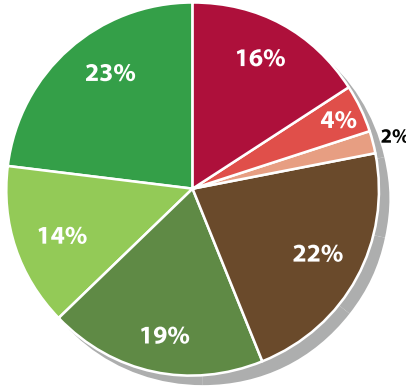
R&D Services



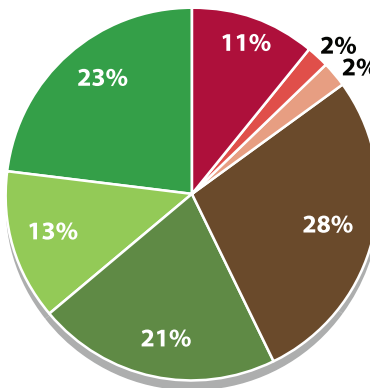
Clinical Trials (Phase I-IV)



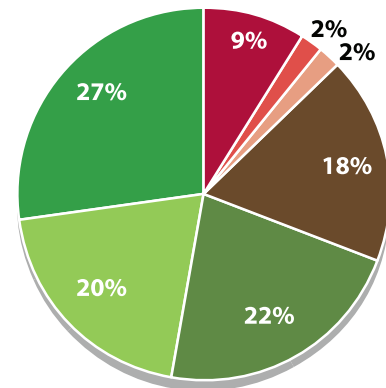
CMC



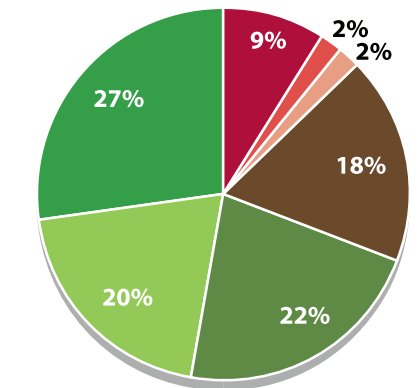
Stability Studies



Manufacturing: Fill/Finish

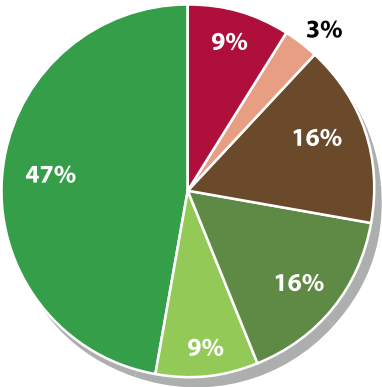


QA/QC

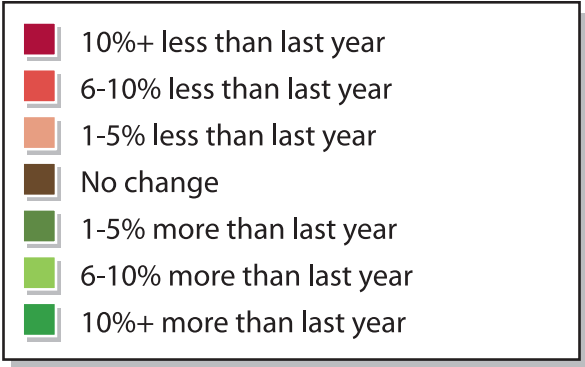
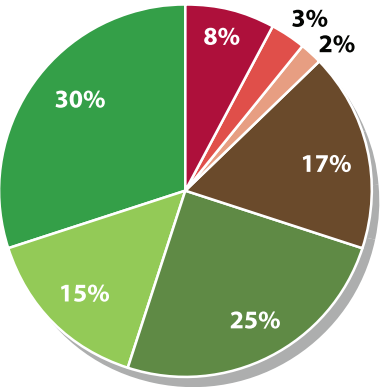


How much did your outsourcing spending change in the past year?

More than \$1 million in annual Bulk Manufacturing spend

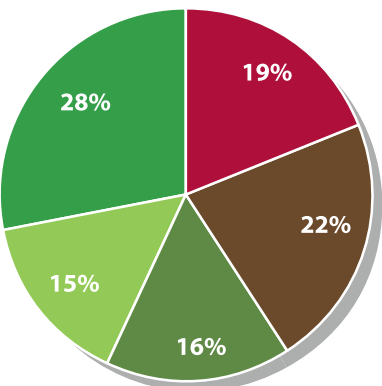


More than \$1 million in annual Commercial Manufacturing spend

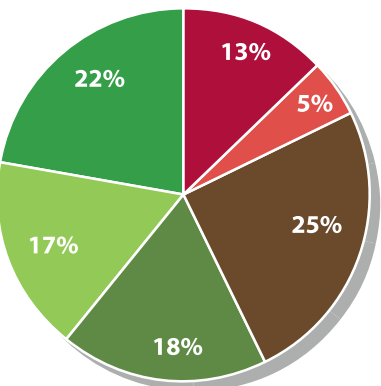


How much do you expect your outsourcing spending to change in the next year?

More than \$1 million in annual Bulk Manufacturing spend

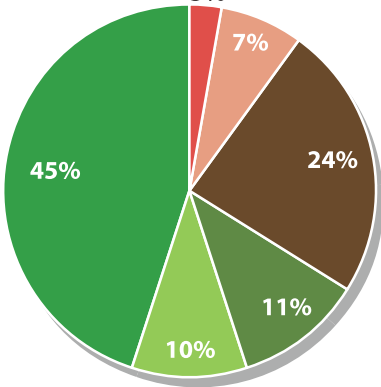


More than \$1 million in annual Commercial Manufacturing spend

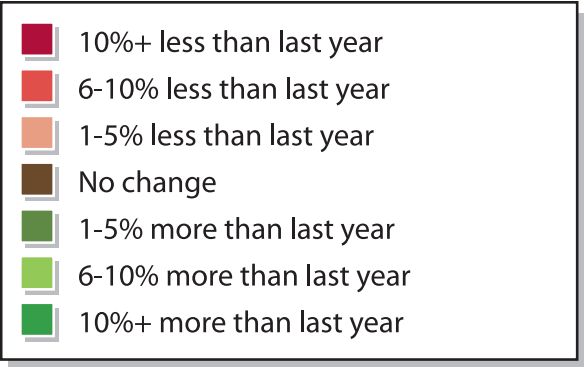
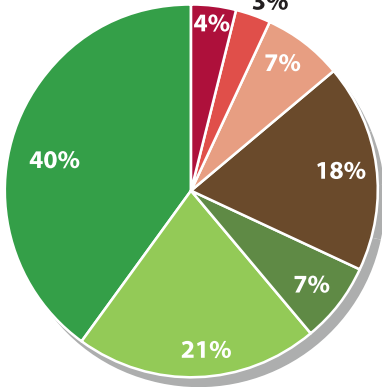


How much did your outsourcing spending change in the past year?

More than \$1 million in annual R&D spend

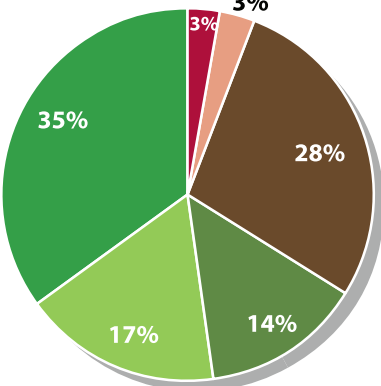


More than \$1 million in annual Clinical Trial Materials Manufacturing spend

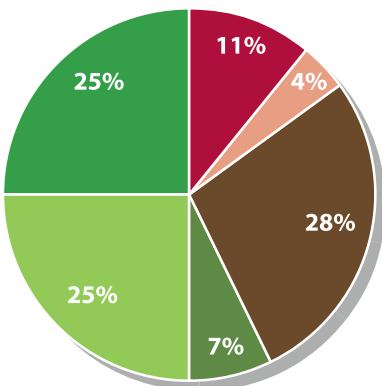


How much do you expect your outsourcing spending to change in the next year?

More than \$1 million in annual R&D spend

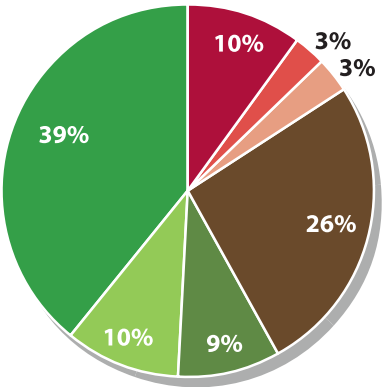


More than \$1 million in annual Clinical Trial Materials Manufacturing spend

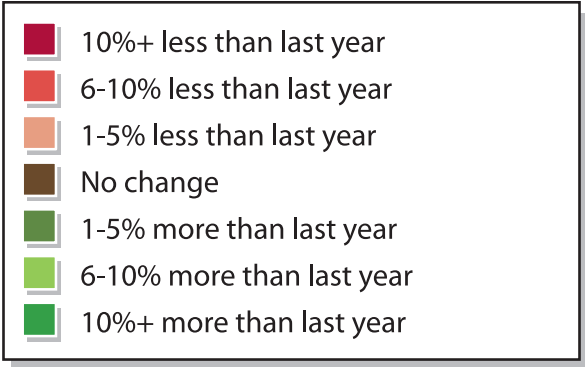
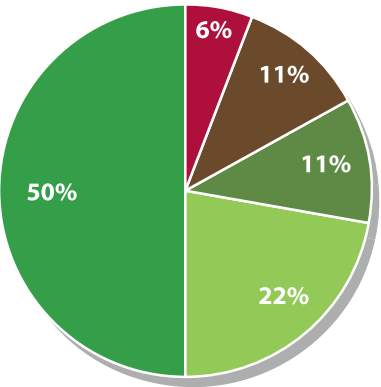


How much did your outsourcing spending change in the past year?

More than \$1 million in annual Clinical Trials (not mfg.) spend

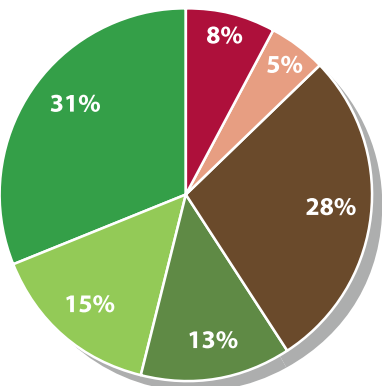


More than \$1 million in annual Commercial Packaging spend

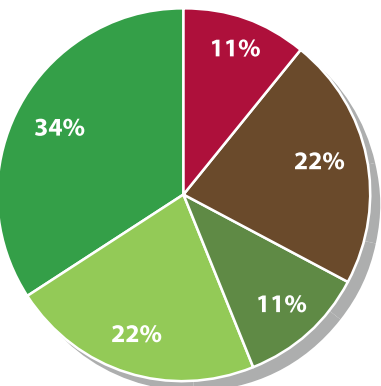


How much do you expect your outsourcing spending to change in the next year?

More than \$1 million in annual Clinical Trials (not mfg.) spend

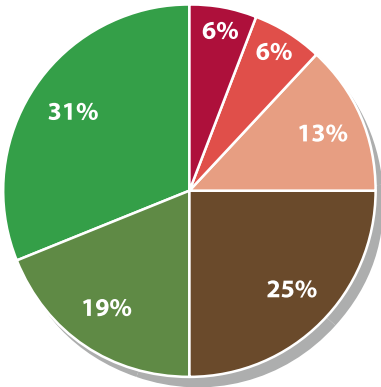


More than \$1 million in annual Commercial Packaging spend

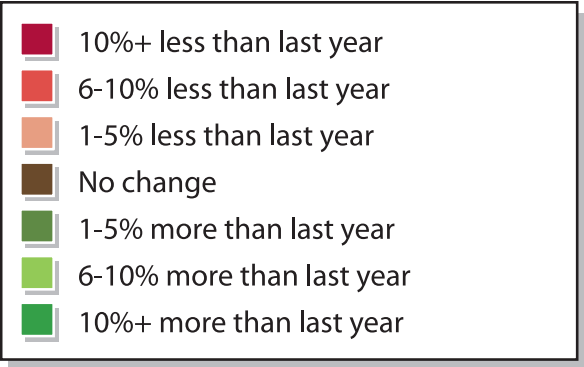
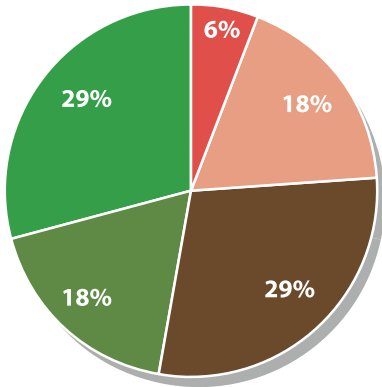


How much did your outsourcing spending change in the past year?

More than \$1 million in annual Analytical & Testing spend

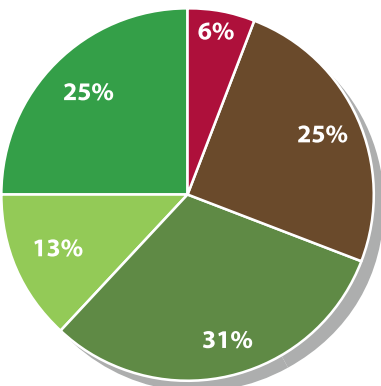


More than \$1 million in annual Preclinical Services spend

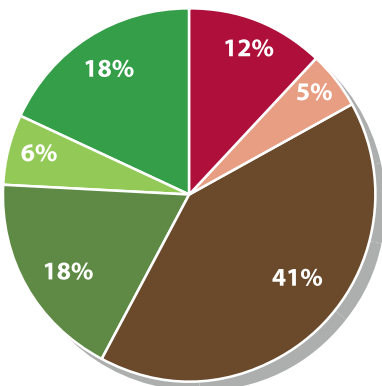


How much do you expect your outsourcing spending to change in the next year?

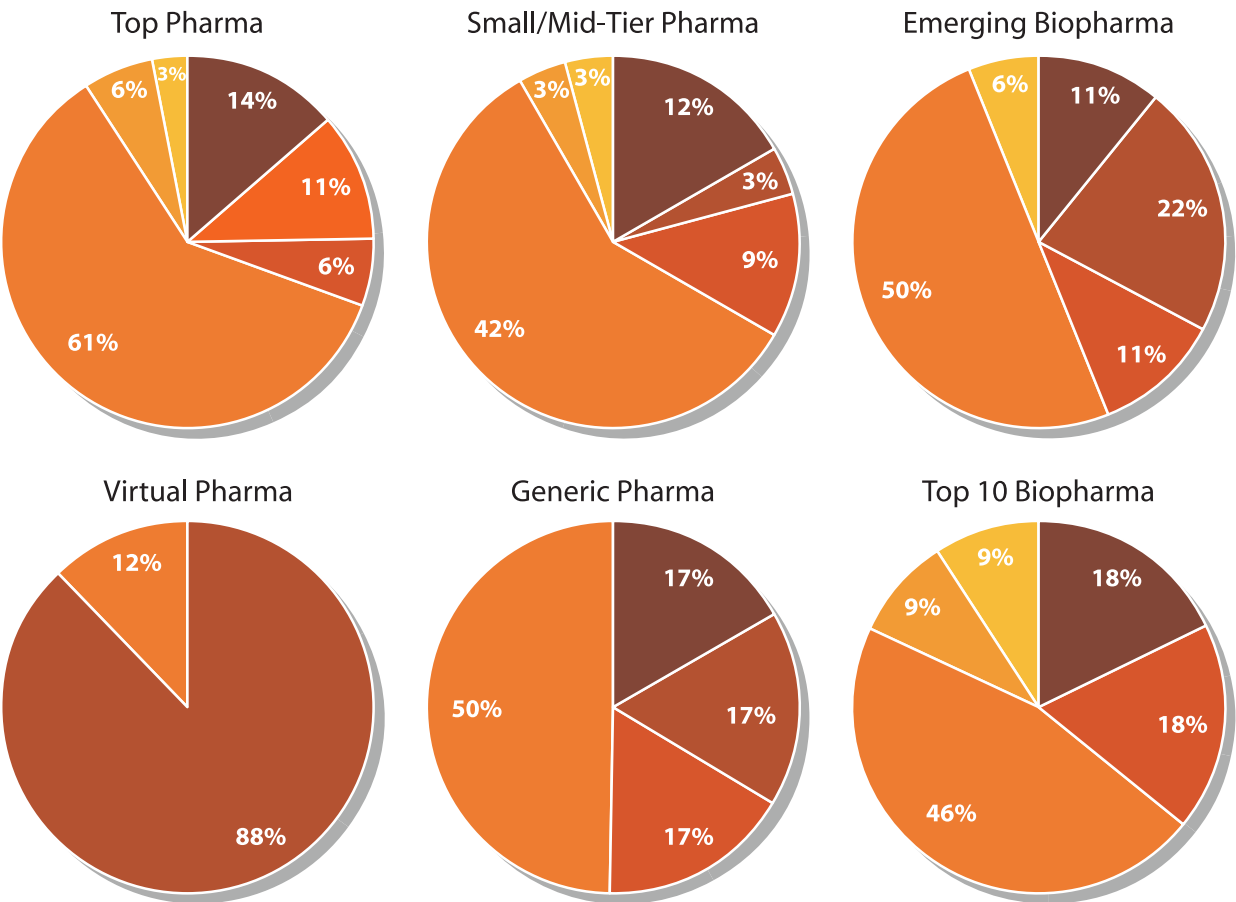
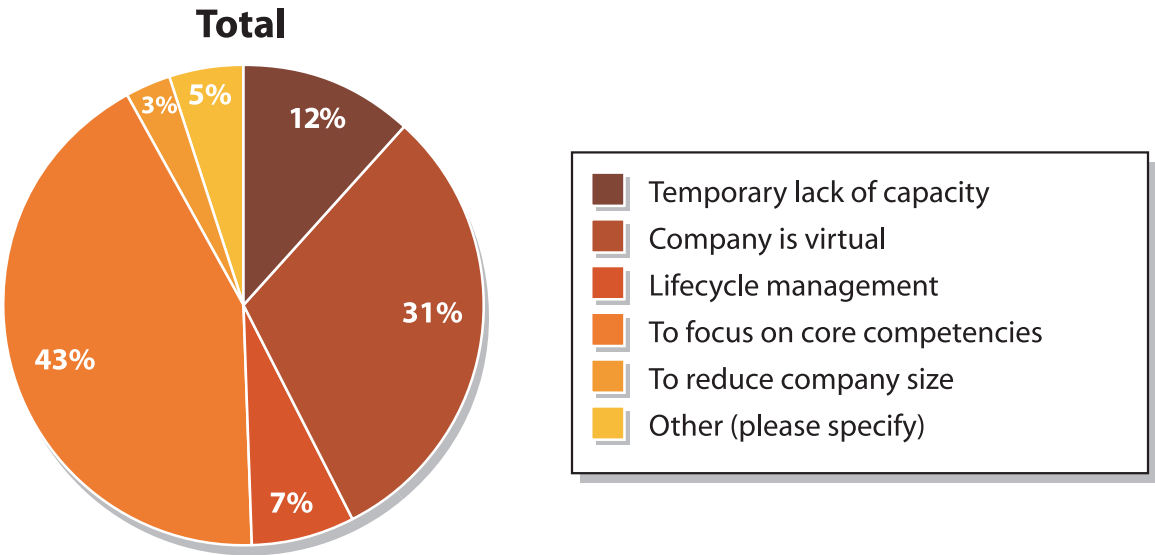
More than \$1 million in annual Analytical & Testing spend



More than \$1 million in annual Preclinical Services spend



Why does your company outsource?



Peace Core

43% of those who responded to the question, “Why do you outsource?” told us it’s to “focus on core competencies”

WHAT DO THEY DO?

Purchasing/Sourcing	19.7%
R&D	16.7%
Project Manager	16.7%
Corporate Management	10.6%

WHERE DO THEY WORK?

Top 20 Pharma	33.3%
Small/Mid-Tier Pharma	21.2%
Emerging Biopharma	13.6%
Generic Pharma	9.1%

WHAT TYPES OF OUTSOURCING DO THEY MANAGE?*

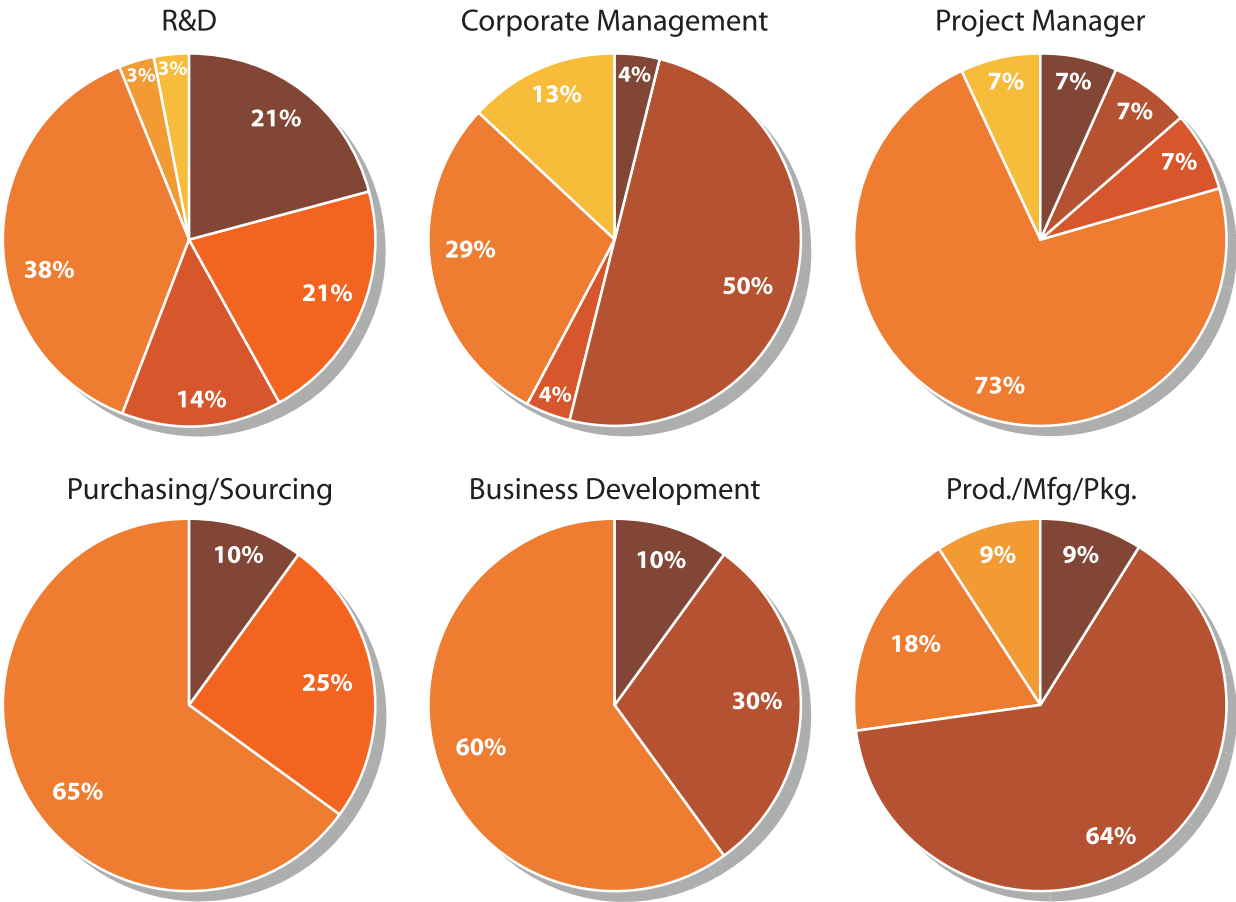
Analytical & Testing Services	56.1%
R&D Services	33.3%
Clinical Trials (I-IV)	31.8%
Formulation Development	31.8%
Manufacturing: Solid Dosage	30.3%
CMC	28.8%
Stability Studies	28.8%

HOW MUCH DID THEIR OUTSOURCING SPENDING CHANGE FROM THE PREVIOUS YEAR?

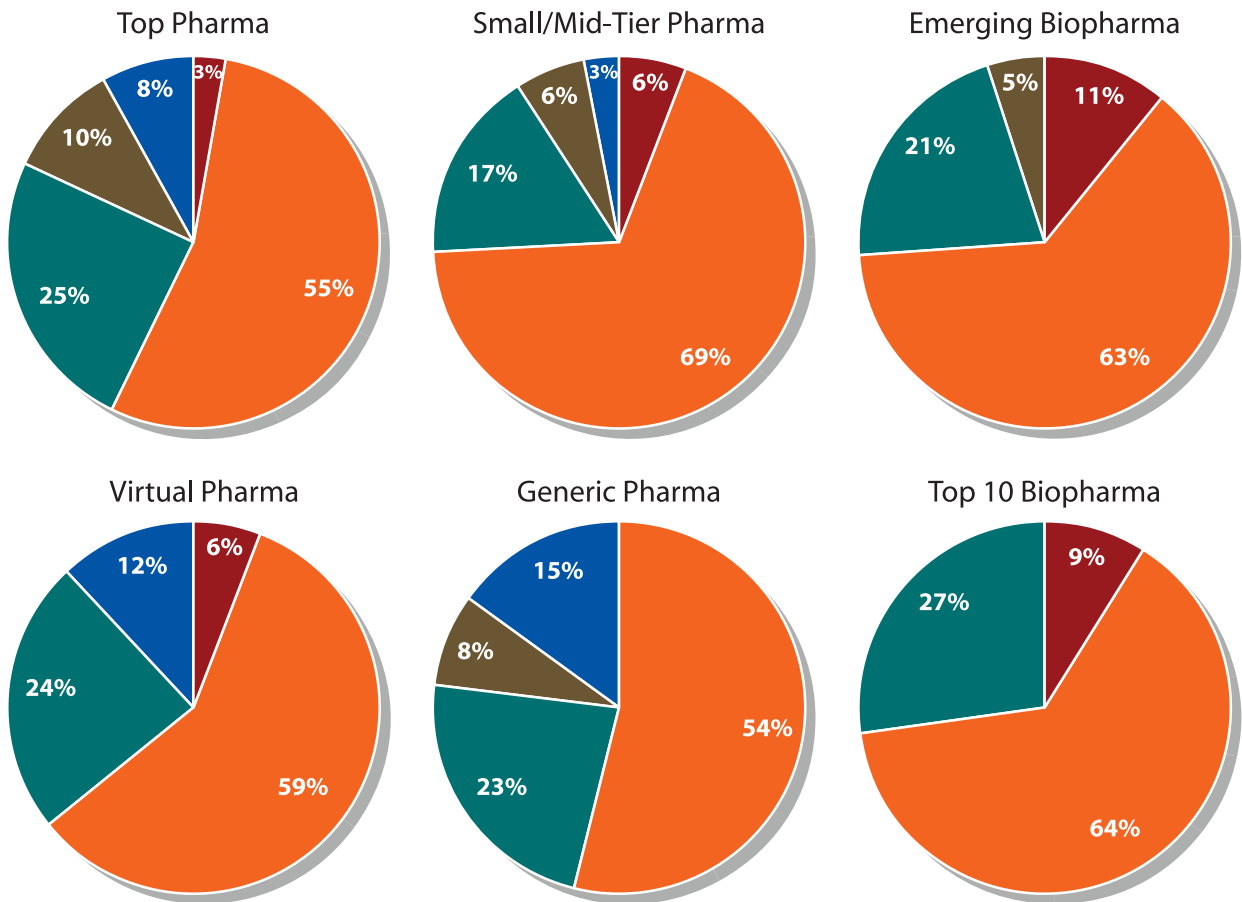
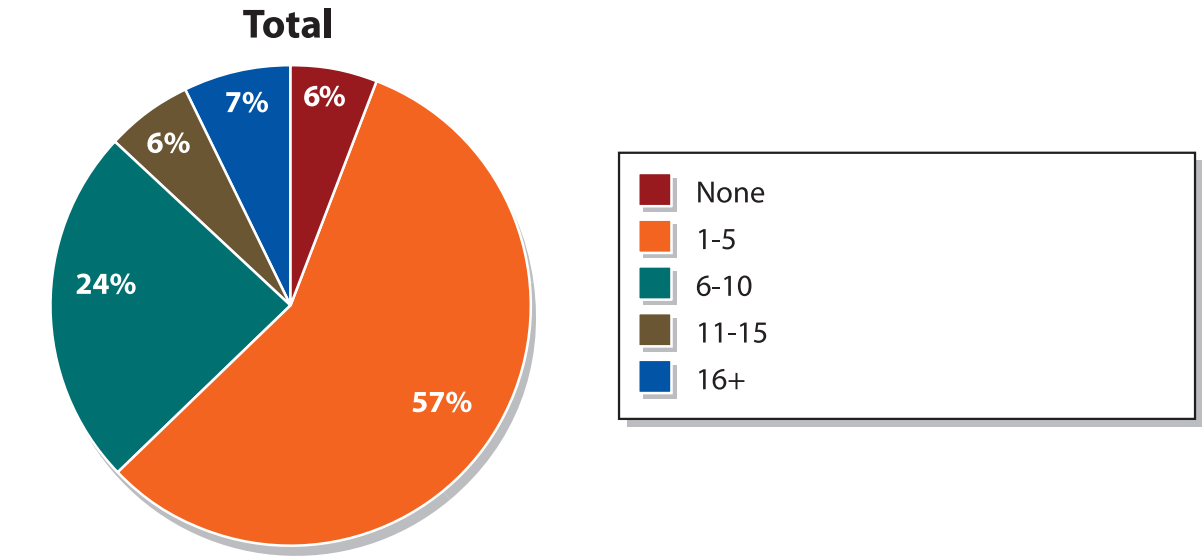
10%+ less than previous year	13.6%
6-10% less than previous year	3.0%
1-5% less than previous year	3.0%
Did not change	28.8%
1-5% more than previous year	13.6%
6-10% more than previous year	16.7%
10%+ more than previous year	21.2%

HOW MUCH DO THEY EXPECT THEIR OUTSOURCING SPENDING TO CHANGE IN THE NEXT YEAR?

10%+ less than last year	6.1%
6-10% less than last year	4.5%
1-5% less than last year	6.1%
Will not change	28.8%
1-5% more than last year	15.2%
6-10% more than last year	18.2%
10%+ more than last year	21.2%



How many preferred vendors do you use?



Preferences Panel

55% of respondents said that more than half of their outsourcing dollars go to preferred providers.

WHAT DO THEY DO?

R&D	24.4%
Purchasing/Sourcing	16.7%
Corporate Management	15.6%
QA/QC/Validation	10.0%

WHERE DO THEY WORK?

Top 20 Pharma	30.0%
Small/Mid-Tier Pharma	26.7%
Emerging Biopharma	11.1%
Virtual Pharma	8.9%

WHAT TYPES OF OUTSOURCING DO THEY MANAGE?*

Analytical & Testing Services	60.0%
R&D Services	42.2%
Stability Studies	33.3%
Formulation Development	32.2%
Chemistry	31.1%
CMC	31.1%
Manufacturing: API	31.1%

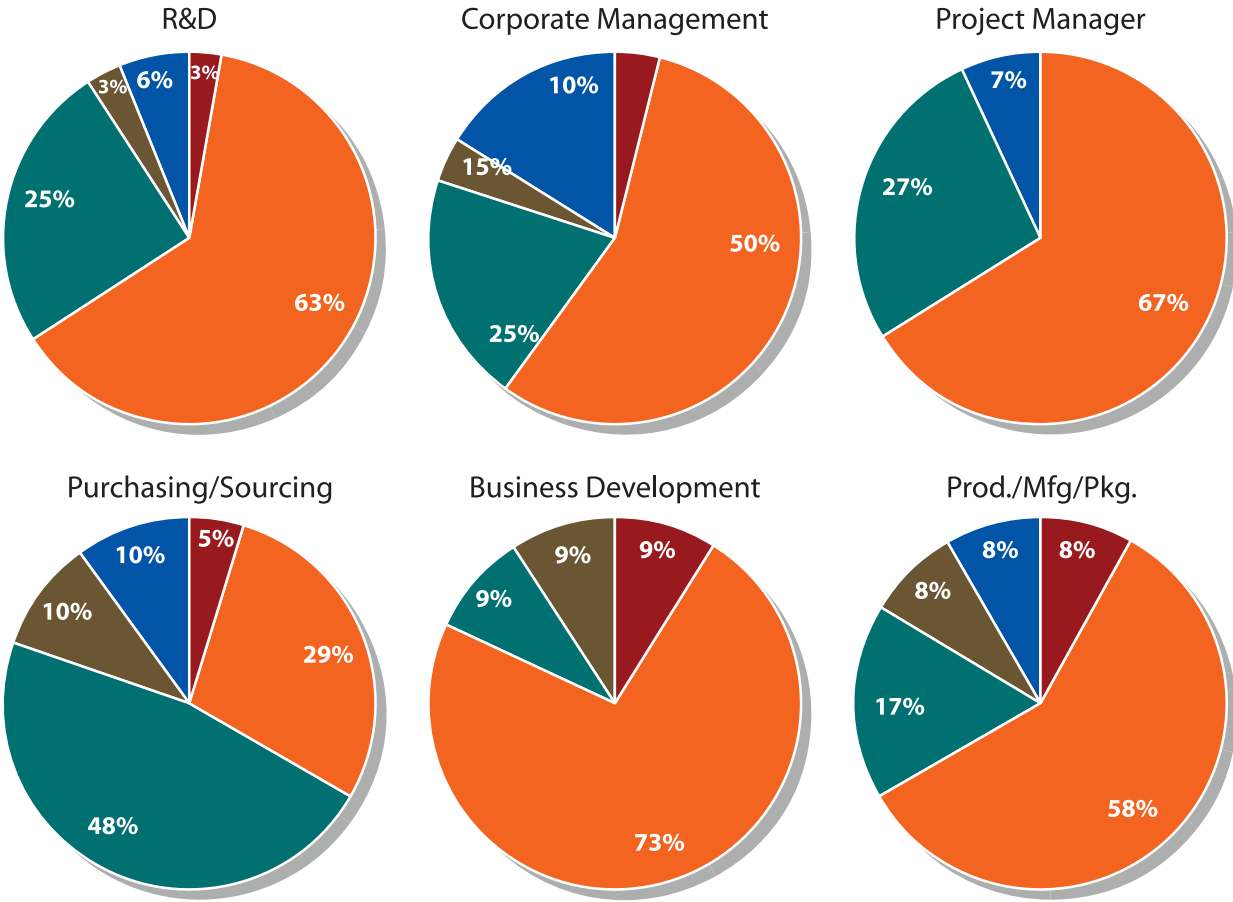
* Respondents can select multiple answers for this category

HOW MUCH DID THEIR OUTSOURCING SPENDING CHANGE FROM THE PREVIOUS YEAR?

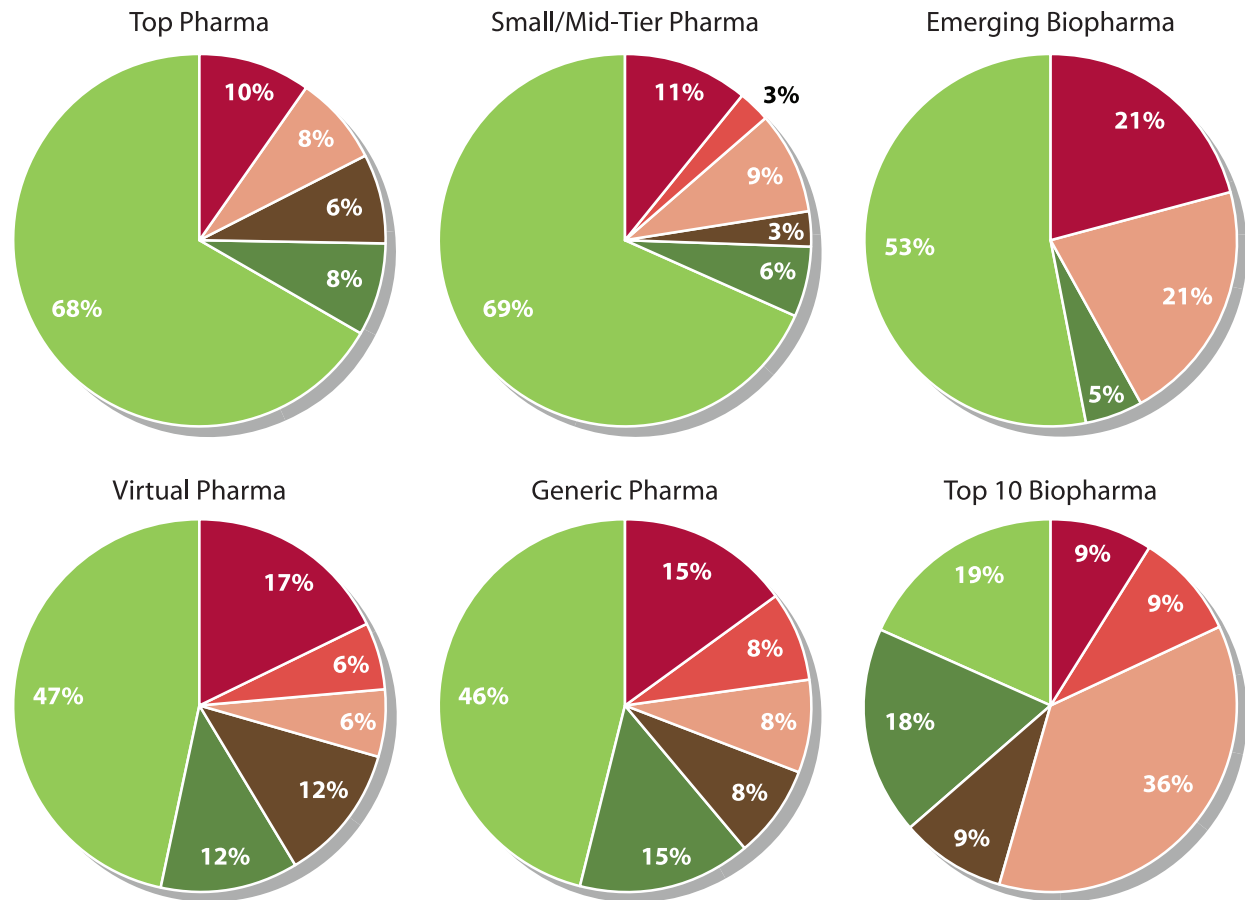
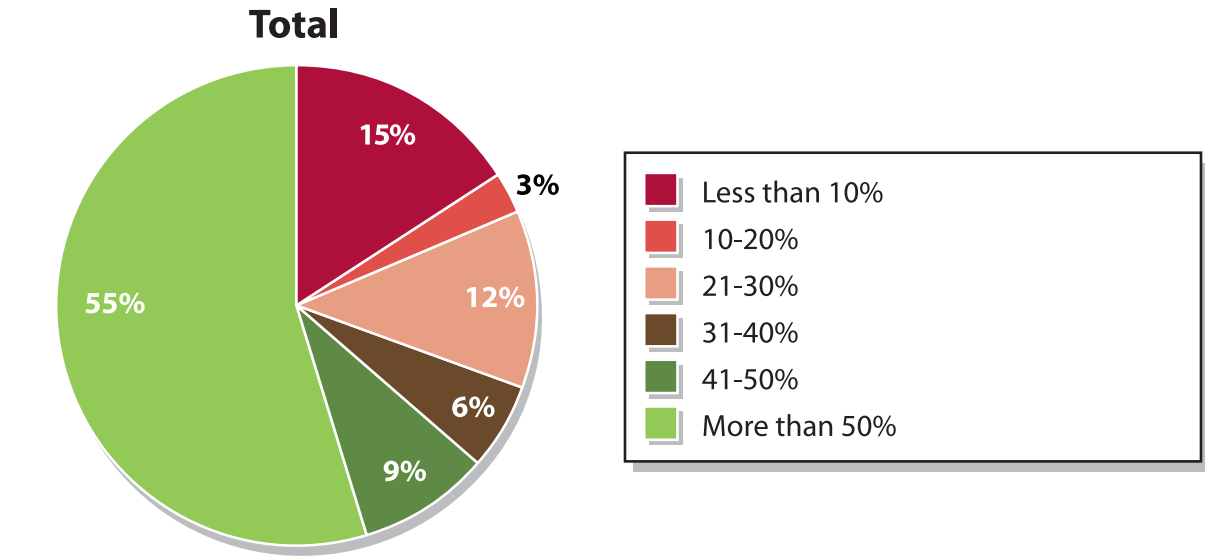
10%+ less than previous year	13.3%
6-10% less than previous year	5.6%
1-5% less than previous year	1.1%
Did not change	22.2%
1-5% more than previous year	17.8%
6-10% more than previous year	12.2%
10%+ more than previous year	27.8%

HOW MUCH DO THEY EXPECT THEIR OUTSOURCING SPENDING TO CHANGE IN THE NEXT YEAR?

10%+ less than last year	7.8%
6-10% less than last year	3.3%
1-5% less than last year	1.1%
Will not change	31.1%
1-5% more than last year	13.3%
5-10% more than last year	17.8%
10%+ more than last year	25.6%



What portion of your outsourcing dollars goes to preferred vendors?



Why Not Outsource?

One-quarter of respondents said that they'd cancelled outsourcing projects in past year, due to the economic climate. We asked them to describe the projects they delayed.

- CMC, GLP preclinical studies
- Sterile dosage form
- Clinical study
- Analytical study
- Second sourcing
- Development projects
- API supplies reduced
- Preclinical toxicology
- Internally funded projects at early stages without partners
- Commercial development of a new API
- Clinical trials
- Clinical studies
- Unit dose
- API process development and production
- Secondary supply (back-up manufacturers) and late-stage clinical manufacturing (delayed Phase III start)
- R&D study
- Most R&D-related budgets were slashed
- Less critical trials
- Scale up

WHAT DO THEY DO?

R&D	14.7%
Corporate Management	14.7%
Purchasing/Sourcing	14.7%
QA/QC/Validation	11.8%

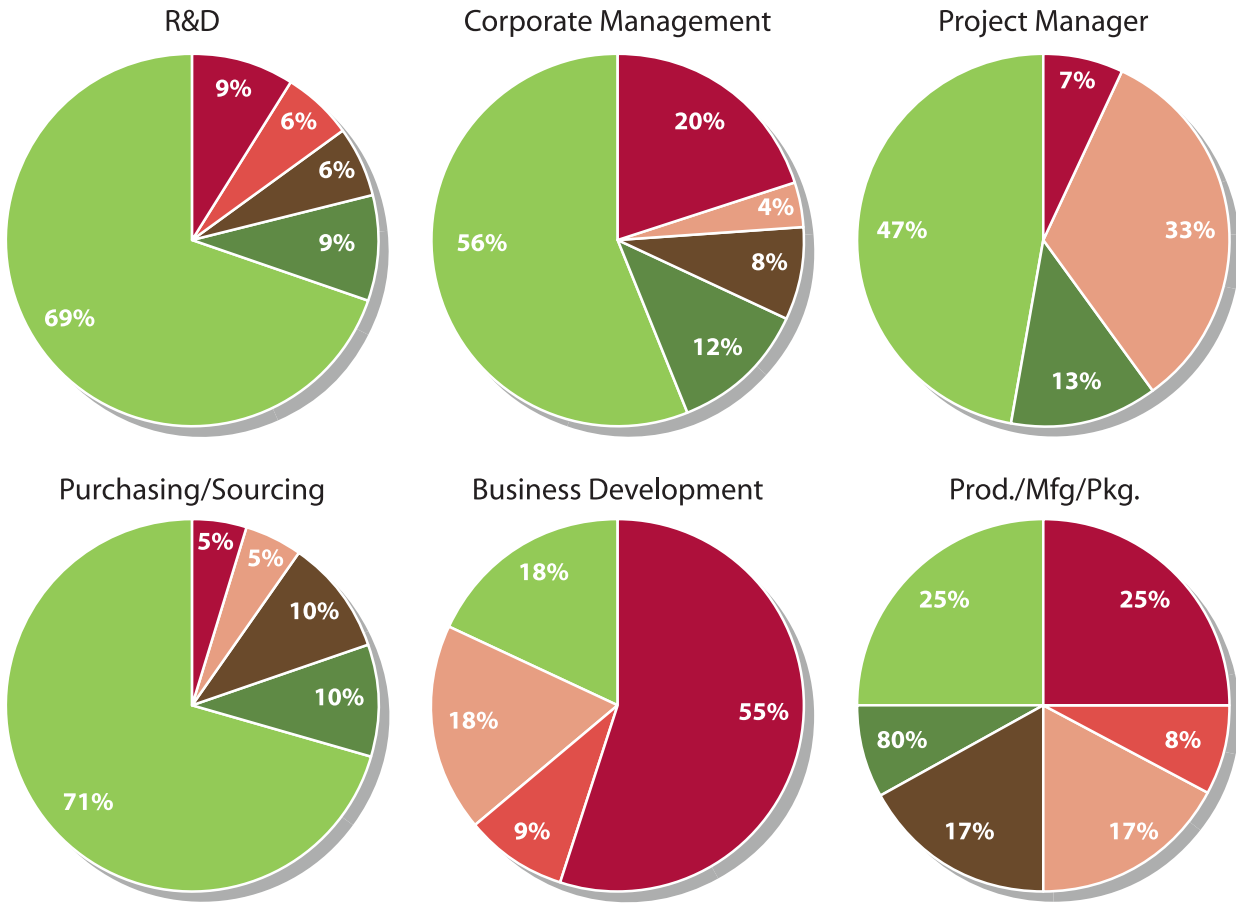
WHERE DO THEY WORK?

Top 20 Pharma	29.4%
Small/Mid-Tier Pharma	20.6%
Other	14.7%
Emerging Biopharma	11.8%

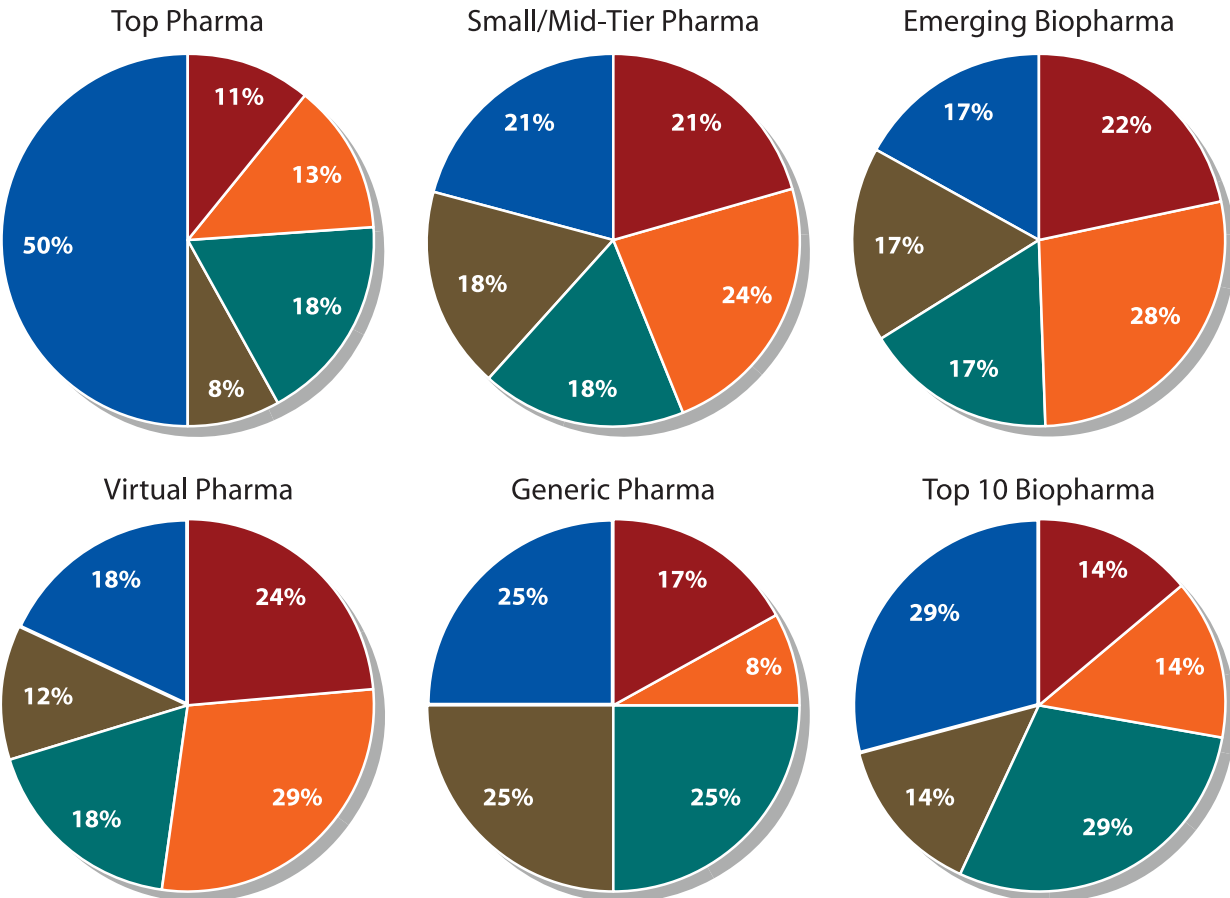
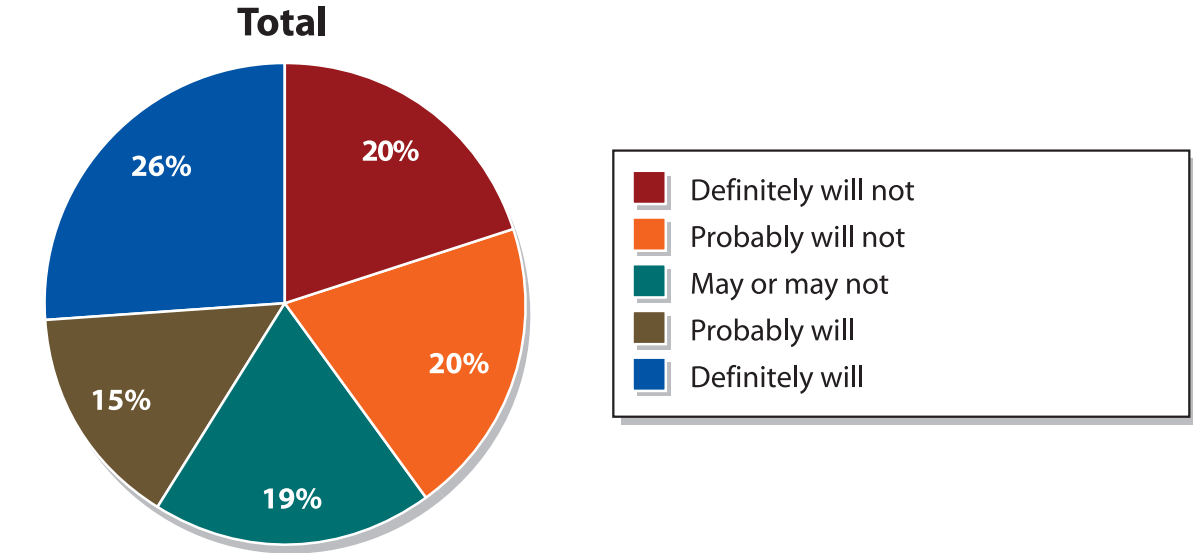
WHAT TYPES OF OUTSOURCING DO THEY MANAGE?*

Analytical & Testing Services	70.6%
CMC	50.0%
R&D Services	50.0%
Stability Studies	44.1%
Manufacturing: API	41.2%
Chemistry	38.2%
Process Development/Scale-up	38.2%
QA/QC	38.2%

* Respondents can select multiple answers for this category



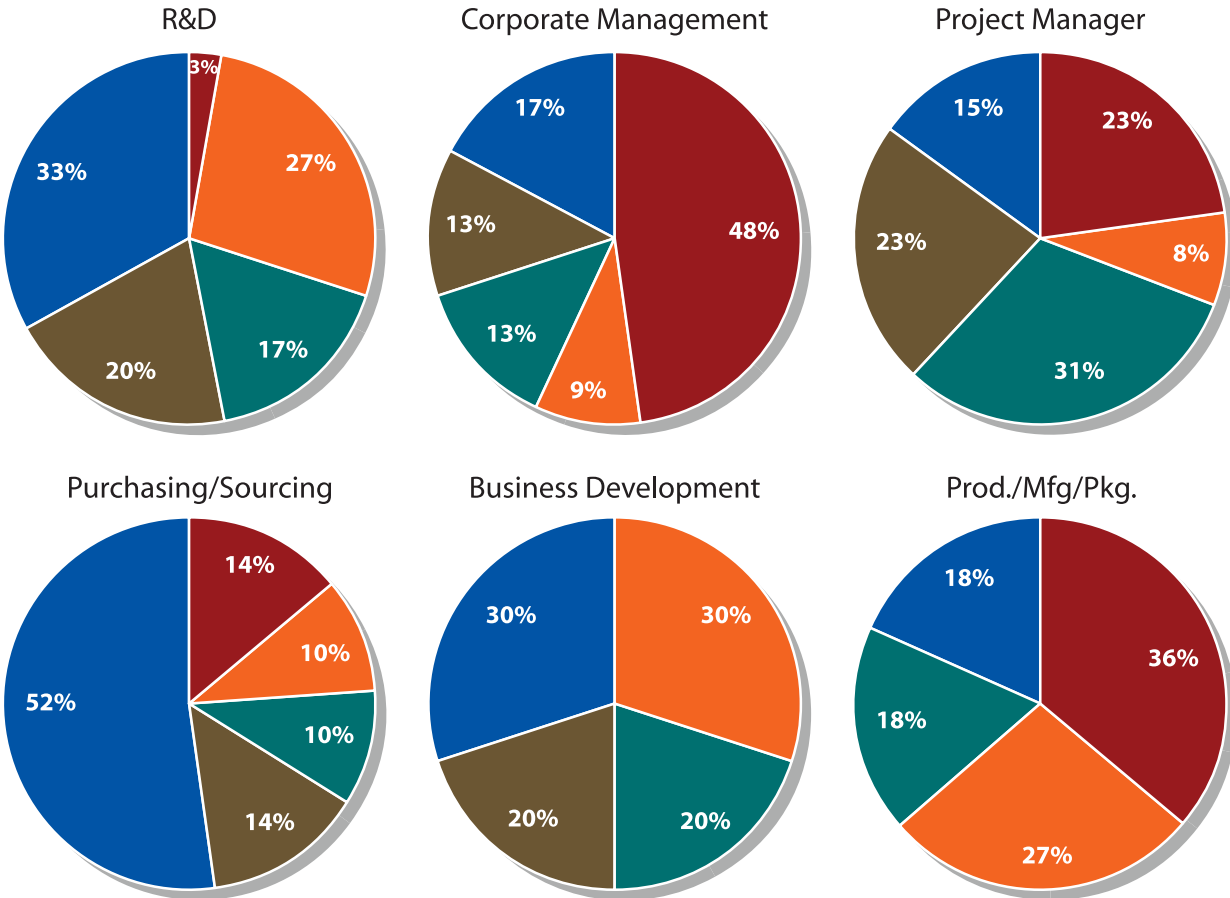
How likely are you to outsource a project to Asia (incl. India and China) in the next year?



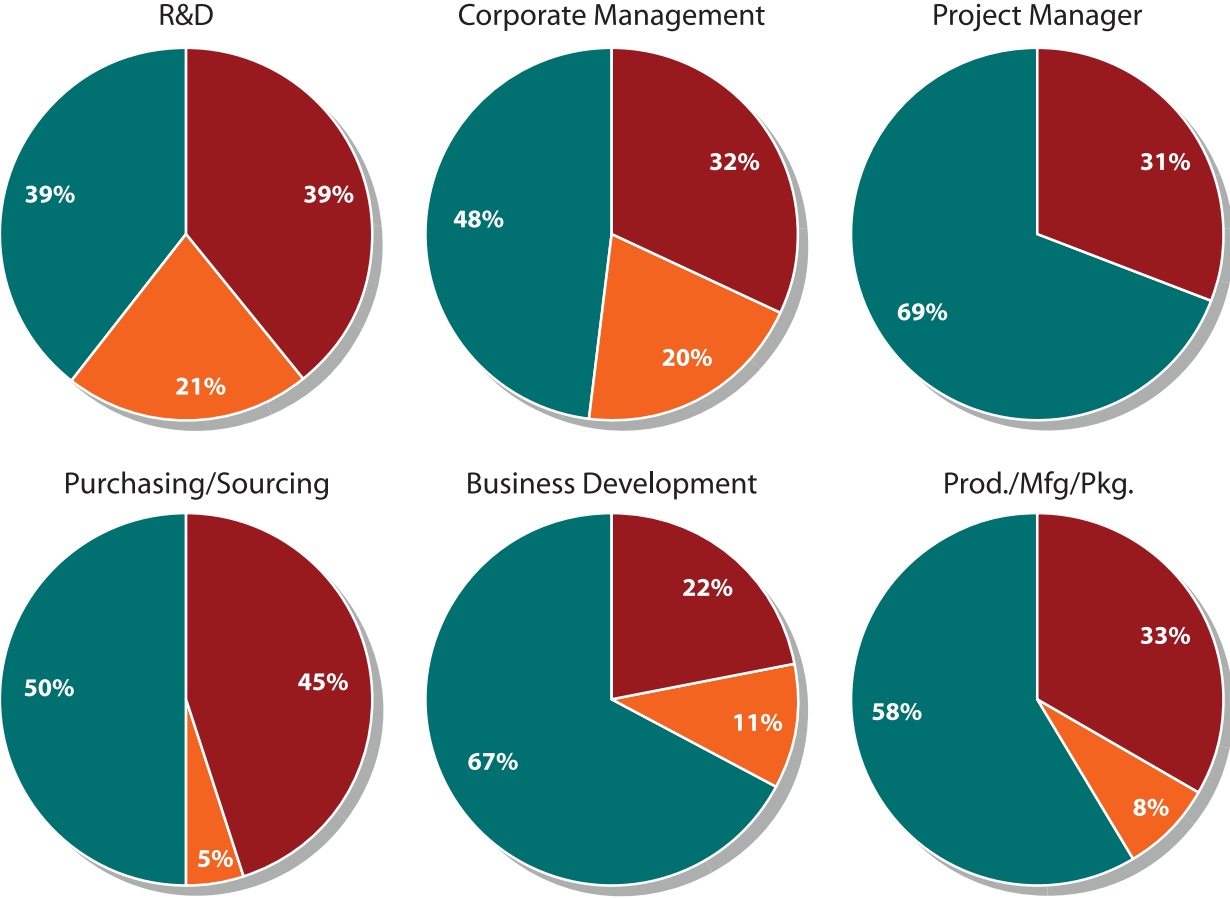
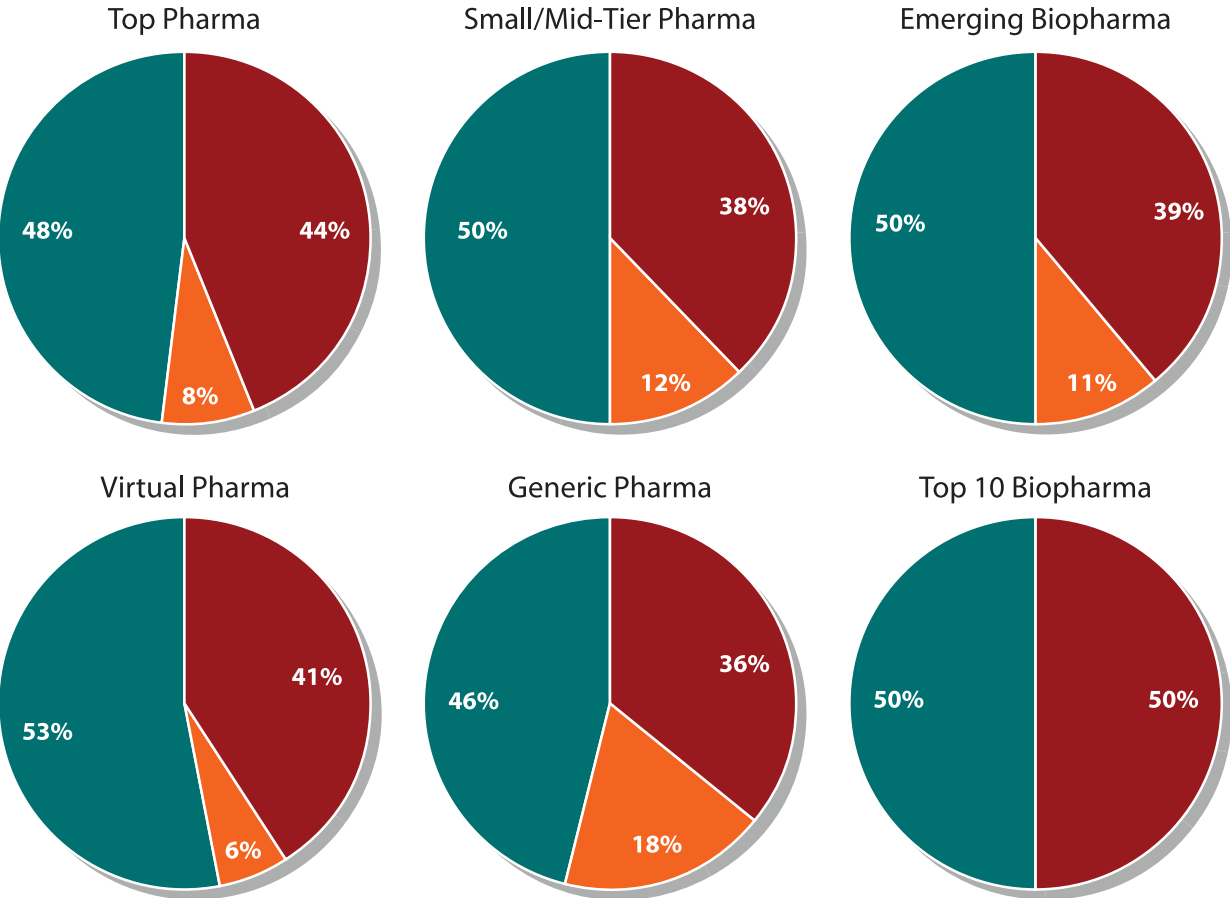
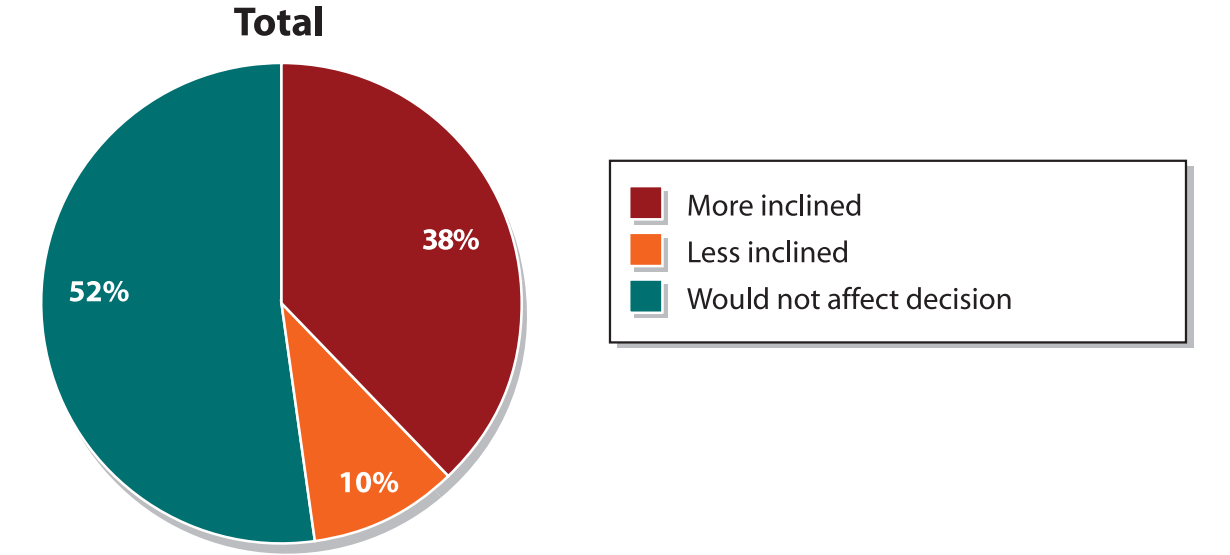
What sort of project would you be comfortable with outsourcing to Asia?

Reponses once again spanned the range from “Everything!” to “Nothing!”, with “Not sure” tossed in a few times. Here are some of the more specific answers (as usual, “API” came up a lot):

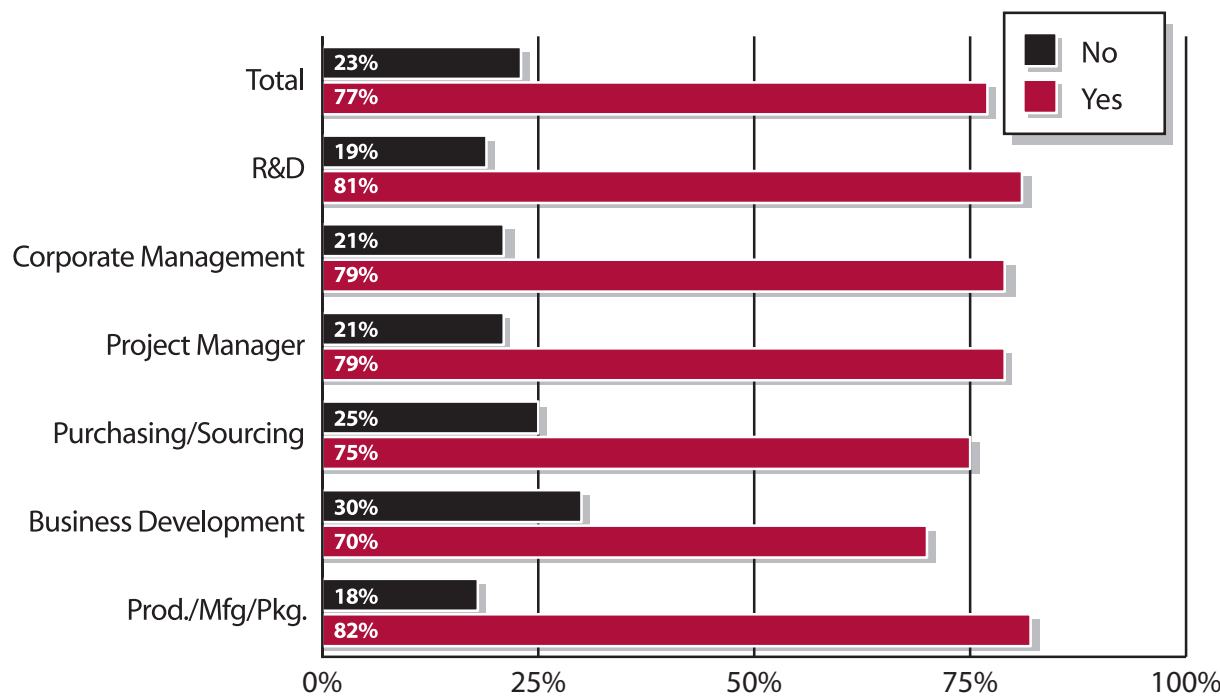
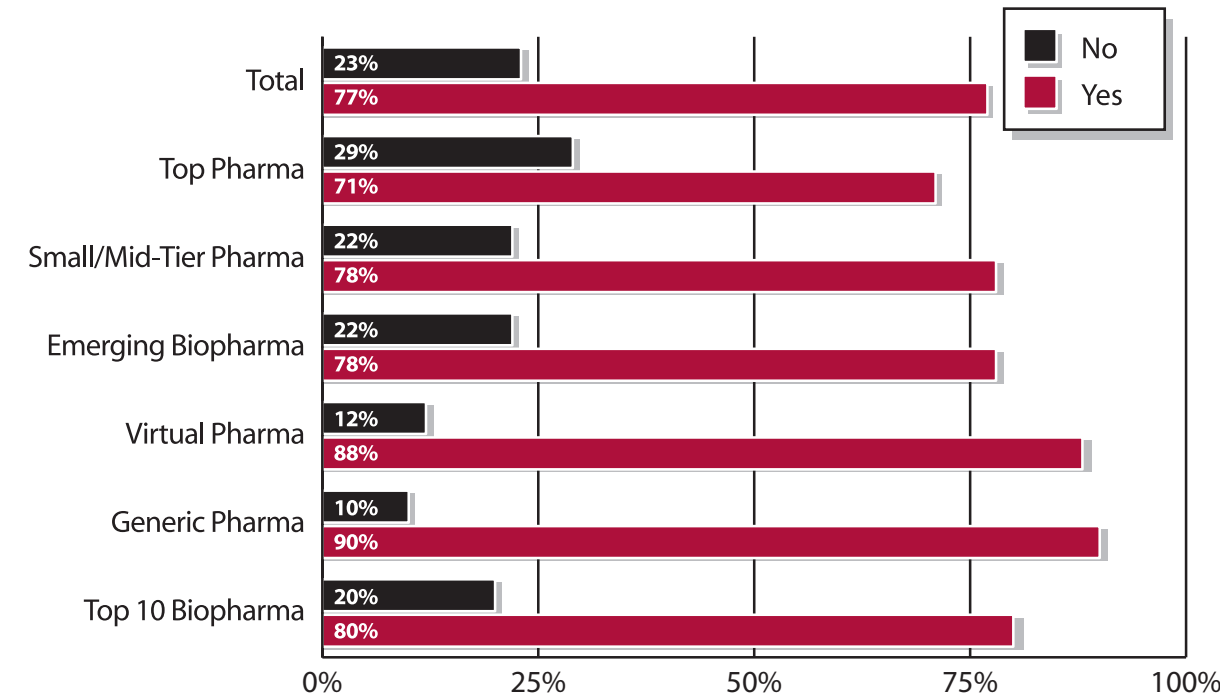
- API manufacturing, raw material
- API (from India)
- development of generics
- clinical data management, research
- Low complexity
- Blind Testing
- Medicinal chemistry
- Preclinicals, IT, R&D
- Clinical studies
- Bioequivalence study, CMO
- IT hosting, application development
- It's not the type of project, it's the quality of the CDMO
- Manufacturing biologics, preclinical and clinical studies
- Phase II clinical
- Starting material
- Back-up API supplier
- Early development work
- Synthesis
- Will not outsource a new project, but will continue to outsource a current API project to Asia
- Synthetic intermediate manufacture
- Non-IP sensitive, Non-critical raw materials, intermediates (not RSM or critical / key raw materials)
- Clinical outsourcing, SCM
- Raw materials
- Phase III study
- Generic and OTC
- Nonclinical pharmacokinetics, drug metabolism, and toxicology
- Basic chemicals and API
- Tasks that have high labor cost with relatively low regulatory risk
- Exploratory
- Phase I study
- Stability testing, method development and validation, clinical trials
- Tablet development
- Preclinical only, limited to non-GLP
- R&D late-phase project.
- Early-phase API supply could be outsourced to Asia but only to a partner we have an in-depth knowledge of and personal relationship with the upper management
- Critical Reagents
- Most discovery work, misc lab services
- CMC development, clinical development
- Scale up of non-GMP Intermediates
- R&D and PD work
- Blind preclinical testing
- As long as it is a known supplier (for example, a European supplier with their own self-managed Chinese facility), we are extremely comfortable to work with them. We would never send a new project to an unknown vetted Asian supplier.
- R&D, manufacturing (non-API)
- Preclinical non-GXP
- Clinical Research
- Steps prior to cGMP
- Only raw material, no fill/finish
- Generic drug development and commercial manufacturing
- Not the project, but comfortable outsourcing to reliable provider that has passed an FDA inspection.
- API and CTM development/manufacture for Phase I/II



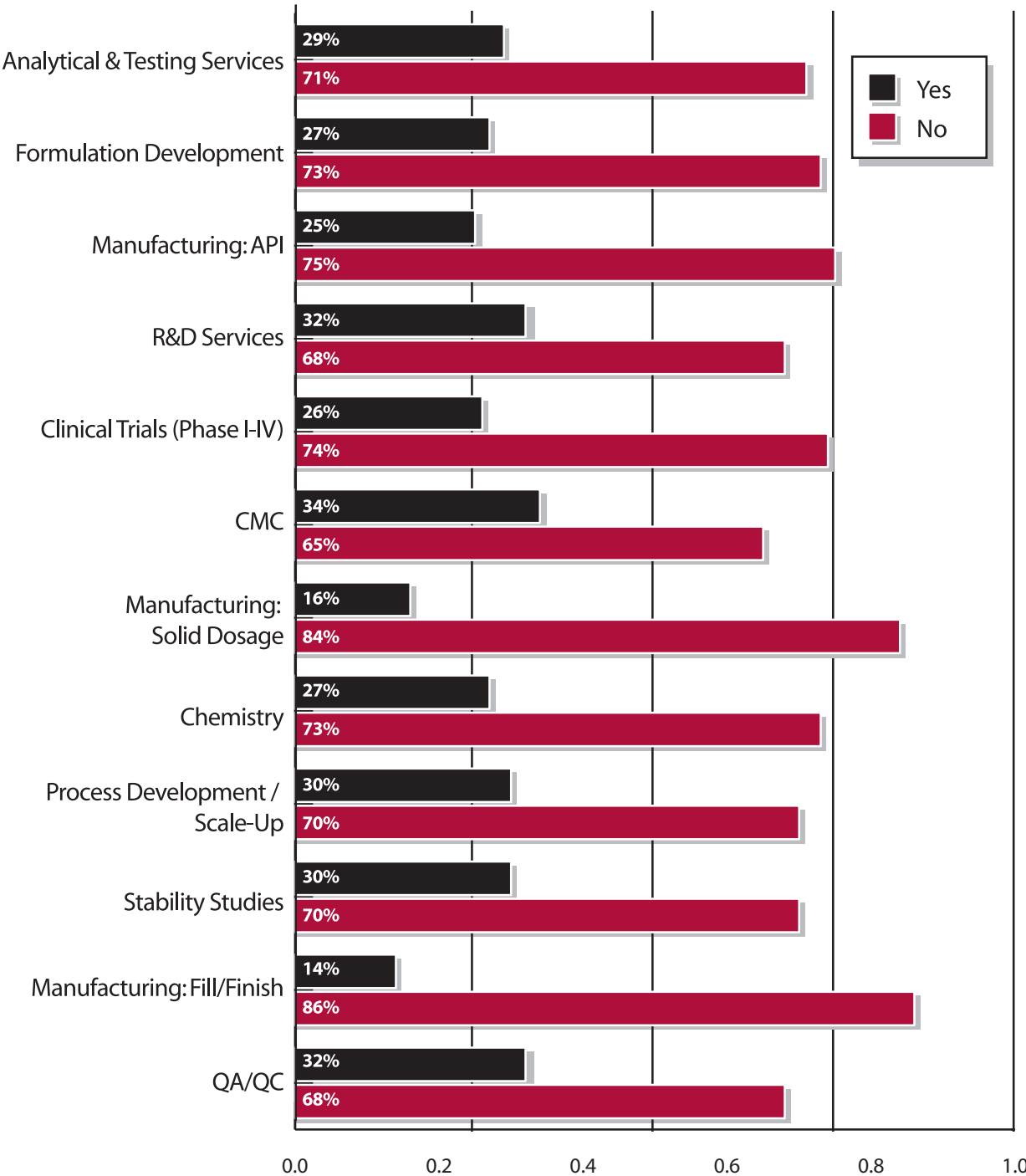
Would you be more inclined to work with a western-based contract service provider if that provider had a subsidiary or a partner company in China?



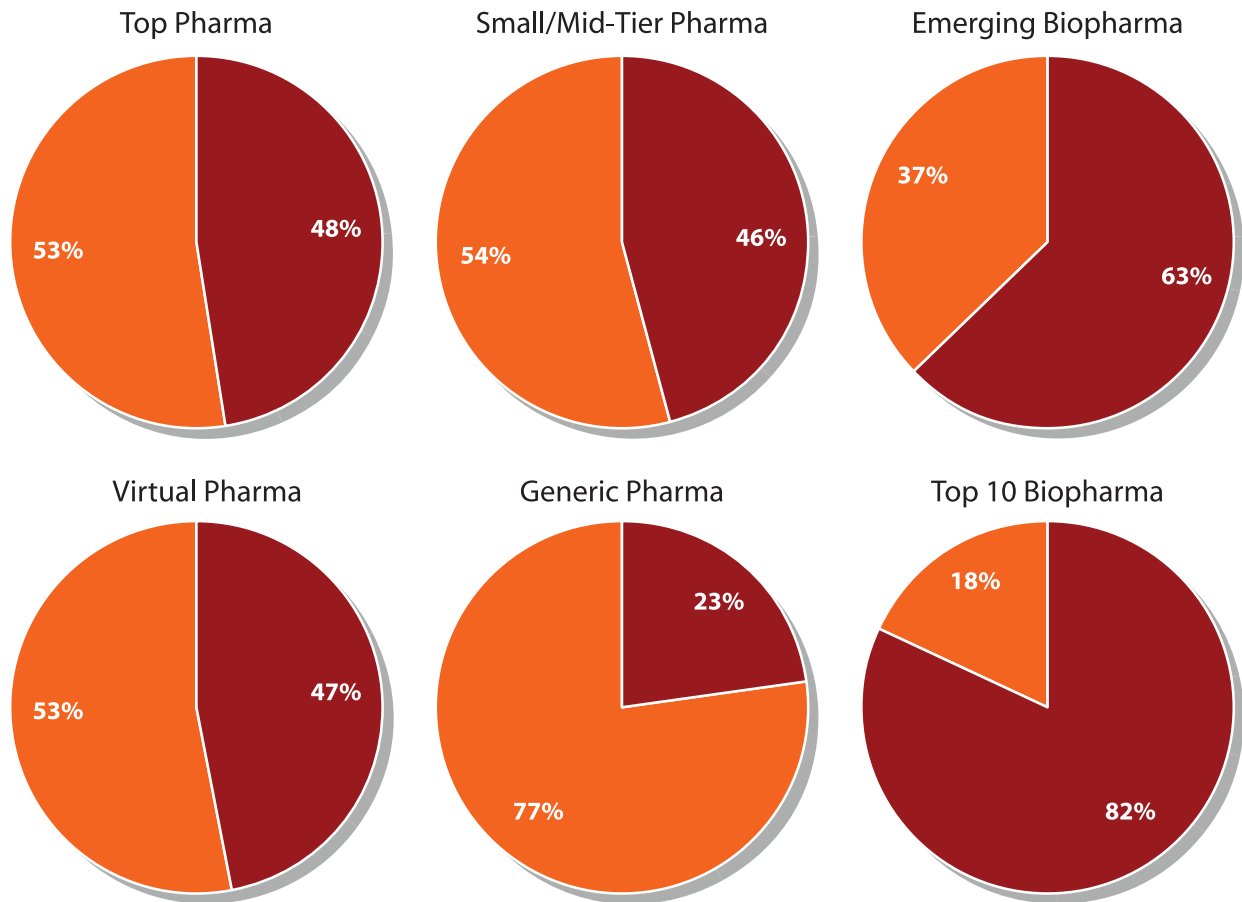
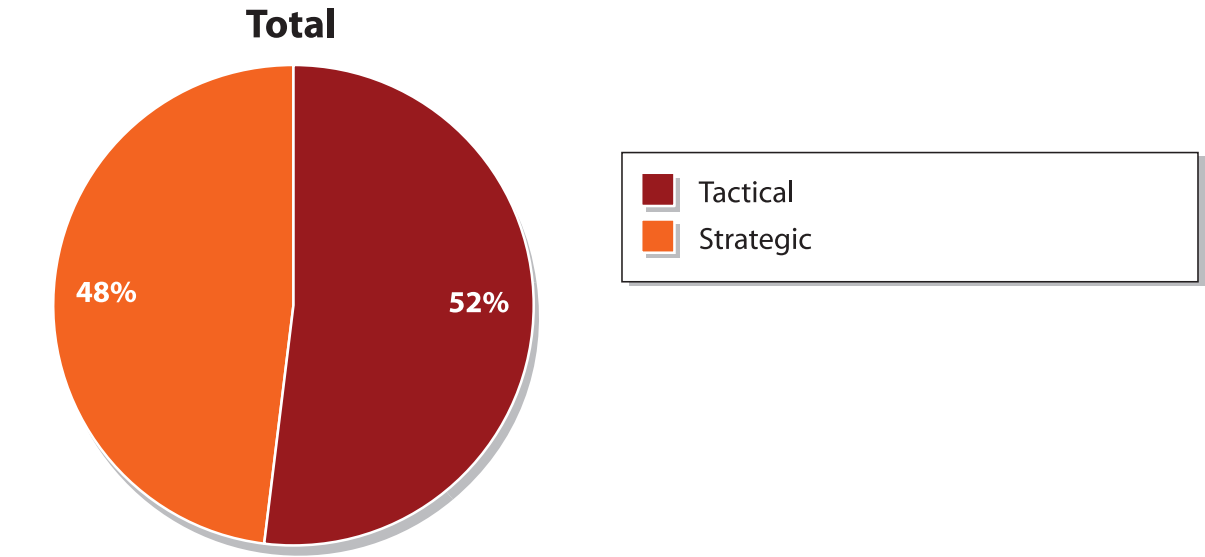
Have you canceled projects
(due to the current economic climate)
that you would have outsourced?



Have you canceled projects
(due to the current economic climate)
that you would have outsourced?



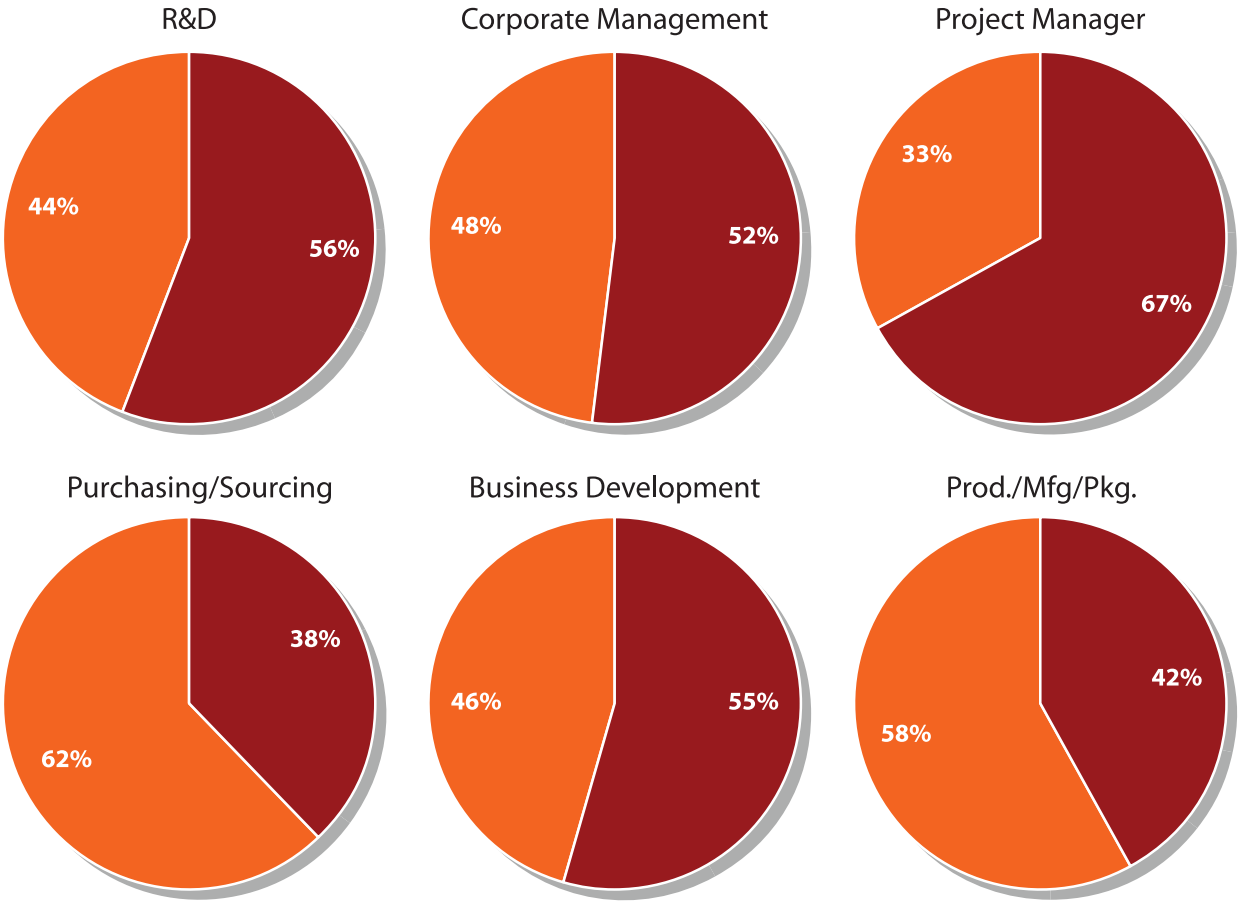
Would you describe your outsourcing as Tactical or Strategic?



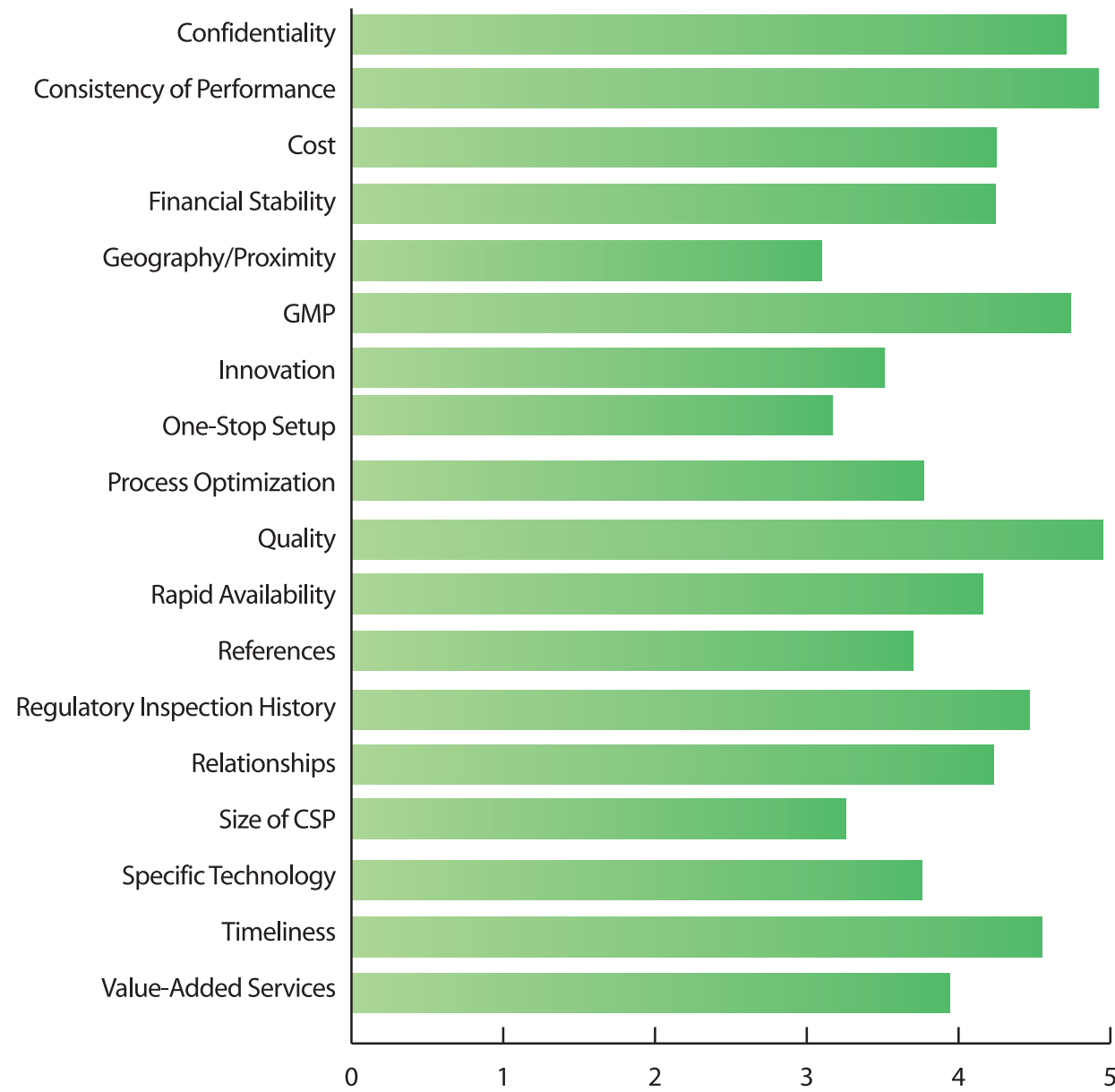
SHOWTIME!

What conferences have our respondents attended in the past three years?

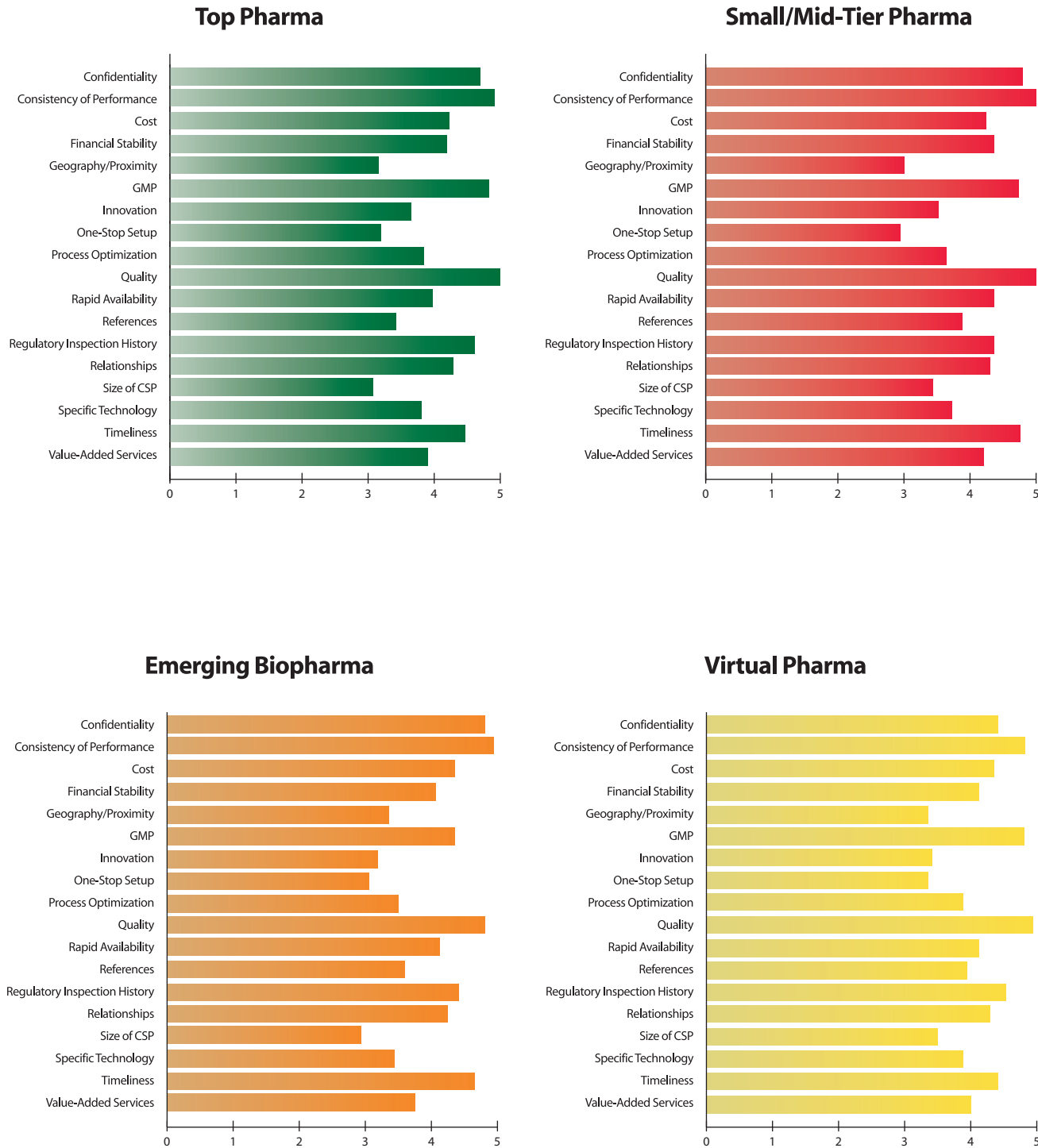
OVERALL RESPONDENTS	
AAPS	31.2%
Interphex	28.0%
Contract Pharma Contracting & Outsourcing	24.8%
CPhI/ICSE	24.0%
BIO	20.8%
RESPONDENTS PREDICTING 10+% GROWTH IN OUTSOURCING SPENDING IN THIS YEAR	
AAPS	42.9%
Interphex	42.9%
Contract Pharma Contracting & Outsourcing	38.1%
BIO	28.6%
Informex	23.8%
MORE THAN HALF OF COMMERCIAL MANUFACTURING IS OUTSOURCED	
Contract Pharma Contracting & Outsourcing	34.2%
CPhI/ICSE	28.9%
AAPS	26.3%
BIO	26.3%
Interphex	26.3%
MORE THAN HALF OF CLINICAL MANUFACTURING IS OUTSOURCED	
Contract Pharma Contracting & Outsourcing	34.9%
Interphex	32.6%
AAPS	27.9%
BIO	27.9%
Informex	25.6%
MORE THAN HALF OF API MANUFACTURING IS OUTSOURCED	
Interphex	33.3%
Contract Pharma Contracting & Outsourcing	31.4%
CPhI/ICSE	29.4%
AAPS	25.5%
Informex	21.6%
MORE THAN HALF OF ANALYTICAL TESTING IS OUTSOURCED	
AAPS	31.0%
Interphex	31.0%
CPhI/ICSE	28.6%
Contract Pharma Contracting & Outsourcing	21.4%
PDA	14.3%



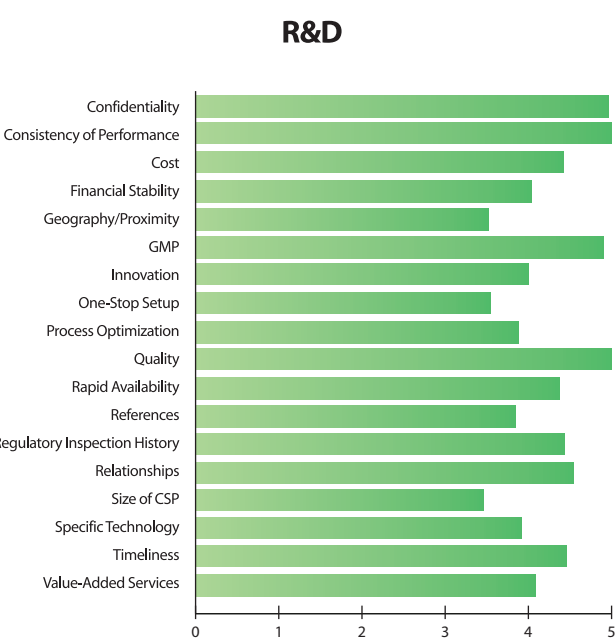
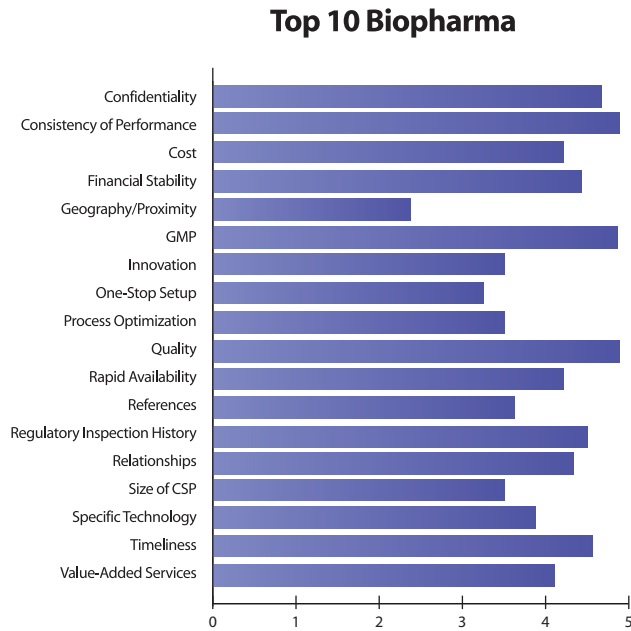
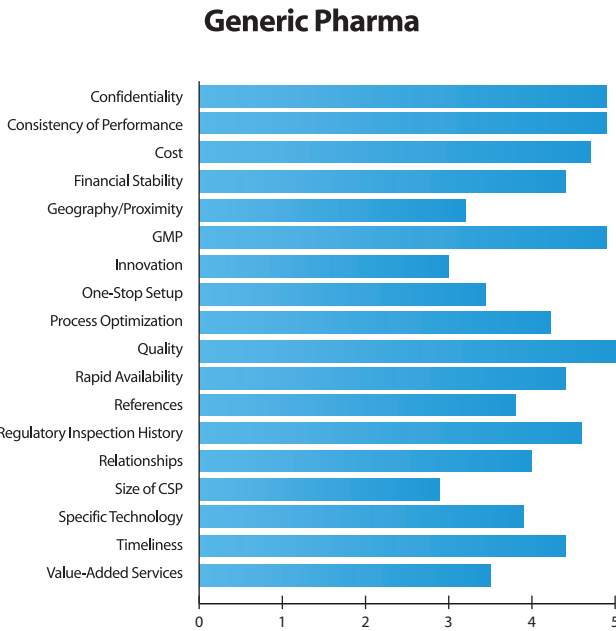
How important are the following factors in your selection of a Contract Service Provider (CSP)?
(all respondents)



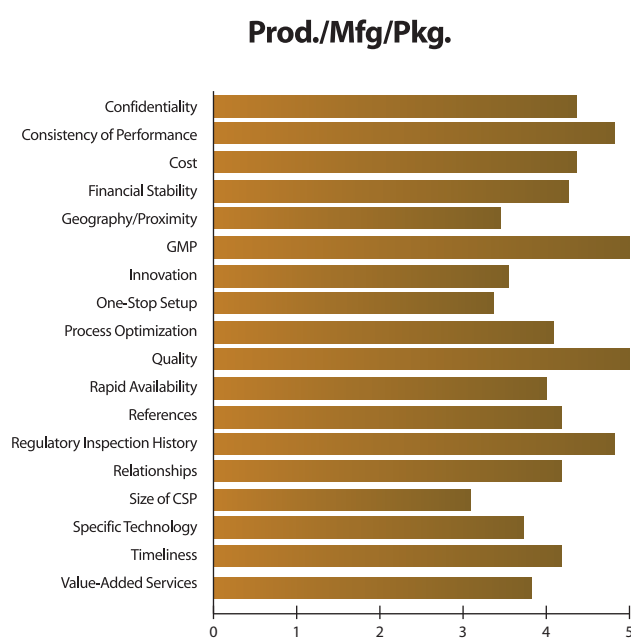
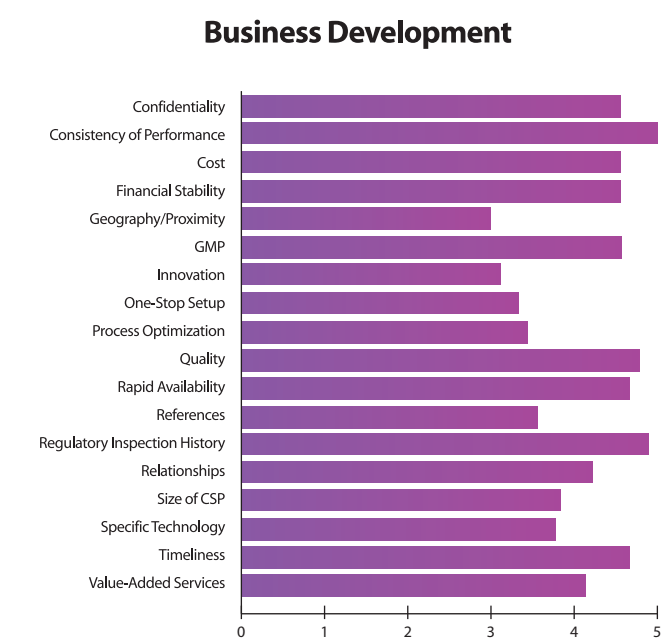
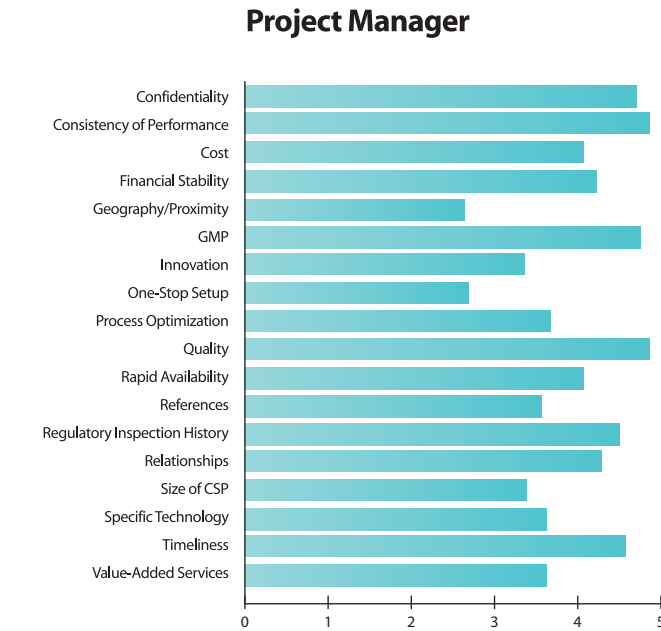
Factors involved in making outsourcing decisions



Factors involved in making outsourcing decisions



Factors involved in making outsourcing decisions



What is your biggest complaint about Contract Service Providers you've worked with in the past?

Here's an edited selection of what our respondents had to say. "Timeliness" remained the top complaint, with "Quality" and "Communication" at show and place.

- Getting them to call me back.
- Quality of resources
- Timeliness
- Slow final reports
- Poor communication at times from CMOs
- Scheduling
- Quality of work
- Poor responsiveness when issues arise
- Not delivering what they promise
- Quality of services and costs
- Bad performance
- Turnaround time
- The quality of their work is not always where we need it to be
- Nickel & dime-ing
- Completeness of investigations
- Taking responsibility when something happens that is clearly within their control. When you lose an API or components due to something you did, you should replace that API and not make it a fight to recoup the cost.
- Too high a turnover rate of employees within CROs
- Not informing the client immediately when there is a problem; we generally lose several weeks timing because of this.
- Timeliness of communication particularly when data or information is not positive
- High price
- No complaints! I have a pretty good relationship with my CSP. They are pretty responsive to my inquiries.
- Communication
- Unreliability
- Over-committing and under-delivering
- Lack of ability to execute consistently
- Unable to meet timelines they have put in place. Turnover of CSP personnel on project team.
- Lack of consistency re attention to detail
- Over-selling their service, resulting in change orders
- Not meeting target timeline
- Not reading submitted study designs before preparing time and cost proposals.
- Insufficient human resources to meet our needs in a timely manner.
- Inconsistent service
- Adherence to scheduling commitments
- Reneging on quotes or commitments
- Not delivering what was contracted and lack of understanding of drug early development
- Losing focus and drop off of delivery/quality after the honeymoon is over. Not working hard enough to keep me as a customer. Taking me for granted.
- Change in personnel
- Cannot meet timelines
- Many times, the difference in the SOPs and practices creates issues.
- Failure to take ownership of clinical data quality and to clean proactively, per documented sponsor expectations
- Most of our outsourcing is in the training area and a lack of quality by [certain big-named training groups and associations] has led us to choose another provider as our sole source of external training, which helps us control the quality
- Not being able to lead a project.
- Overselling of capabilities and/or capacity
- Contract mods increasing price
- Inflexibility; nickel-and-dimed to death; not being forthright on capabilities and what they have actually done in the past.
- Lack of technical expertise that caused problems at the 12th hour for the use of the material in the clinic, and the lack of engagement on their part to fix the problems.
- Stability of products
- An honest presentation of their capabilities.
- Cost expectations too high, slow to start projects, hard to keep projects moving along
- Reporting deviations
- Little focus / investment on Continuous Improvement / Innovation
- Completely reactive, rather than proactive
- We no longer work with CMOs that over-promise and under-deliver. We prefer to work with CMOs that provide us value. There are numerous smaller CMOs that have significant value with the types of molecules they handle and the experience they bring giving us a huge advantage in the drug development race vs. our competitors. Also, we dislike traders or companies that tend to represent a variety of vendors but act as a sourcing agent.

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