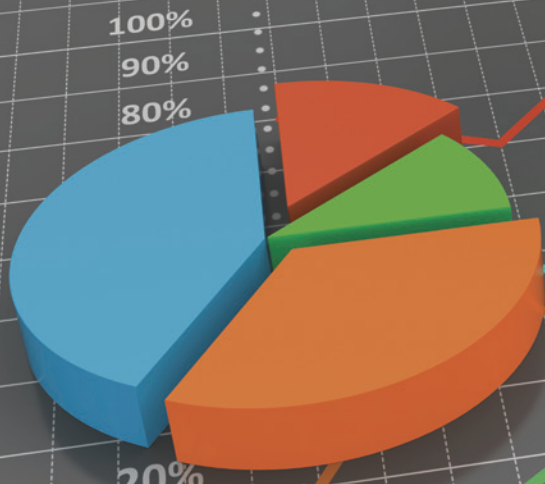


2014 OUTSOURCING SURVEY



Moving Toward STRATEGIC PARTNERSHIPS

As use of outsourcing increases, more companies see it as strategic, and relationships with service providers as partnerships. However, basic communications, vendor oversight and information transfer remain challenges.

This year, 252 industry professionals responded to *Contract Pharma's* Tenth Annual Outsourcing Survey, 36% of them from pharmaceutical sponsor companies, and roughly 64% of them from service providers (For more on demographics, see Box, p. 44). Not all respondents answered every question, but results still reflect industry trends, areas of focus, and challenges. What follows is a brief summary of results.

Survey responses suggest that use of pharmaceutical outsourcing is increasing, all along the value chain. The reasons for this growth remain the same (Figure 1). Pharmaceutical company sponsors say they are outsourcing more functions so that they can focus on their core strengths. A significant number say they are “virtual” companies and lack the capabilities in-house.

This year, sponsors say, the top six focus areas for their companies' outsourcing efforts are, in order of importance (Figure 2):

- Analytical and testing services (cited by about 35%)
- Clinical trials, Phases I-IV (roughly 25%)
- Formulation Development (about 16%)
- Solid Dosage form manufacturing (14%)
- Injectable manufacturing (approximately 10%)
- R&D services (about 10%)

API manufacturing remains a strong outsourcing focus, with 54% of sponsor company respondents this year saying that they outsource more than half their companies' API manufacturing. 37% of sponsor company respondents say that they are outsourcing more than half of their company's final dosage manufacturing and clinical manufacturing. In addition, one third of the sponsors who took this year's survey say they are outsourcing more than half of their company's analytical testing work.

Sponsors say they are also using contract service providers as secondary suppliers, with 38% saying they are using them for commercial supplies, 38%, for clinical materials, 38% for APIs. Nearly 30% say they are not using providers for any secondary supplies (Figure 10, p. 42).

MORE STRATEGIC, LESS TACTICAL APPROACH

Sponsor companies see themselves as taking a more strategic, rather than tactical, or case-by-case, project-to-project approach to outsourcing (Figure 3) with most planning to continue this approach (Figure 4, p. 38). In addition, roughly 80% of sponsor company respondents this year say that they view contract relationships as partnerships (Figure 5, p. 38). Preferred vendor lists have become important for a large percentage of respondents; roughly 45% of sponsor company respondents this year say that more than half of their outsourcing budget currently goes to preferred vendors (Figure 11, p. 42).

Service providers, meanwhile, say that they are seeing growing demand for their services, particularly from mid-sized companies. (For more insight into service provider responses, see Box, p. 40)

When selecting service providers, sponsoring pharma companies focus on the following criteria (listed in order of importance). Respondents described the following as “very important” (Figure 7, p. 41):

- Confidentiality (81%)
- Quality (81%)
- Consistency of performance (79%)
- cGMP compliance (75%)
- Regulatory inspection history (69%)

60% described timeliness as a key selection criterion for contract services provider, with 56% saying that a contract firm’s financial stability was very important, and 54% describing project cost that way.

TOP CHALLENGES: COMMUNICATION AND VENDOR OVERSIGHT

Despite growth in outsourcing, both sponsors and service providers point to ongoing challenges in outsourcing relationships. 55% of respondents from pharmaceutical sponsor companies describe communications and culture as the top challenge of the sponsor-contract services relationship. (Figure 6).

Equally pressing is suppliers’ vendor qualification, selection and oversight (45% of sponsor company respondents said this was the top challenge), with other top challenges cited as documentation (40%) and Quality Assurance (31%).

Individual comments on different aspects of communication and information sharing suggest areas where each side of the sponsor-contractor connection might improve. For instance, some sponsor company respondents describe projects being late or over budget, and complain that work is not always being carried out as they would like. In turn, service providers say that some sponsors are not giving them the information that they need to get the job done, or communicating regularly with them. They also complain that information is being given to them on a piecemeal basis, instead of at the start of a project.

Reflecting their view of contract services companies as partners, some sponsor company respondents say they would welcome more proactivity and suggestions on areas where they might improve. Writes one anonymous respondent from a sponsor company, “Try

as we might to “partner” with our CMO’s, it is hard to find examples where the CMO has taken the initiative to make an improvement.”

Writes another, “We are paying you to be our partner and to leverage your expertise. Please demonstrate your interest by suggesting improvements to our processes and methods.”

At some pharma companies, sponsor company communication and timely responses have become an important contract partner selection criterion, writes another pharmaceutical sponsor respondent. “Communications can make a project run smoothly, or can be a disaster. Our contracts are often granted based on good communication and quick replies.”

Other sponsor company respondents described lack of transparency or data sharing, or responsiveness to requests, on the part of service providers. Often, some say, the information that isn’t typically shared can prove vital to project work and success. “Share mistakes that have been made,” writes one.

Another respondent complains of contract service companies “relying way too much on email to resolve problems and misunderstandings.” “Pick up the phone!” he writes.

But service provider respondents echo these comments, with many describing a need for better upfront communication from sponsors regarding projects and more realistic views of the time required for key facets such as method development and tech transfer. Insufficient information was the top challenge that service provider respondents said they faced with pharma sponsors.

“Be realistic with your timelines and expectations for tech transfer,” one comments. Another suggests that sponsors “Begin inquiries for a complete program ahead of time, instead of asking for studies piecemeal.”

“If you want to succeed,” writes another, “consider the CRO as your business partner, and not a bondservant.”

SUPPLIER OVERSIGHT AND REGULATORY COMPLIANCE

Sponsors described oversight of service provider’s suppliers and vendors as another challenge. Such oversight is key to regulatory compliance and supply chain safety, but can be difficult to establish. In some cases, sponsor companies may need to improve their own oversight of contractors. 51% of sponsor respondents this year said they had verified the fact that their generic dosage form manufacturers and API suppliers had registered with FDA, under GDUFA. However, 36% said they planned to, but had not verified this yet, while another 13% said they had not verified. (Figure 13)

Although 68% of sponsors say their contract service providers hadn’t run into problems with FDA, EMA or other regulators, 17% said they had; the rest weren’t sure. (Figure 12).

OFFSHORING AND ECONOMIC CHALLENGES

Over the past few years, an increasing number of outsourcing projects have moved offshore. When asked whether they were contemplating an outsourcing project in China or India over the next year, 31% of sponsor companies described the move as “highly unlikely,” and another 13% as “rather unlikely.” Another 24% said they were “unsure.”

However, nearly 17% plan to outsource to those regions and the remaining 15% say they are already actively involved there and plan to do more work in both countries (Figure 14).

Overall, business conditions have become more competitive, with some contract services company respondents noting that they

didn't expect to be in business in a few years. However, sponsor company respondents suggest that there have been relatively few project cancellations due to economic issues. 76% of sponsor re-

spondents say they did not have to cancel or delay an outsourcing project due to economic conditions; the rest say they have had to cancel or delay such projects this year. **CP**

FIGURE 1: Why do you outsource?

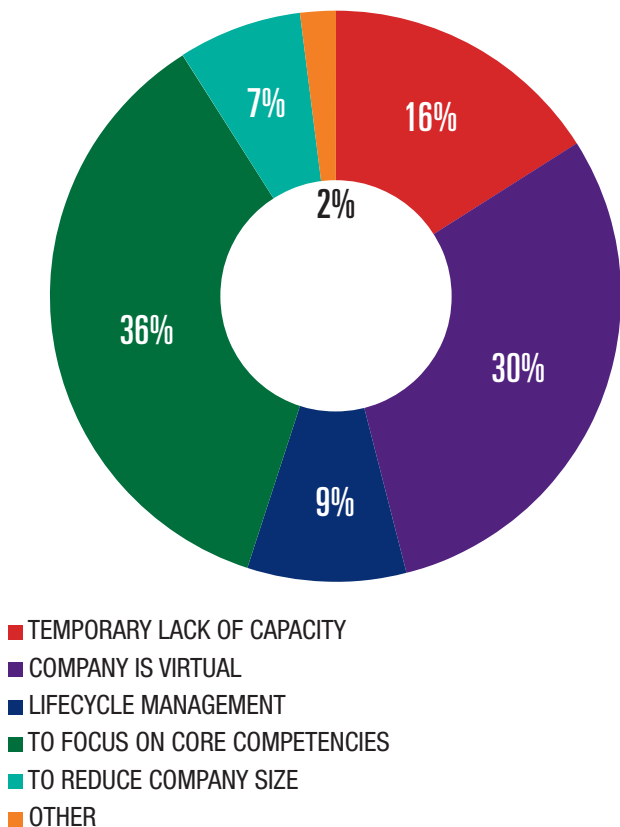


FIGURE 3: Would you describe your outsourcing as Tactical (case-by-case, based on availability) or Strategic (entire classes of functions performed out-of-house)

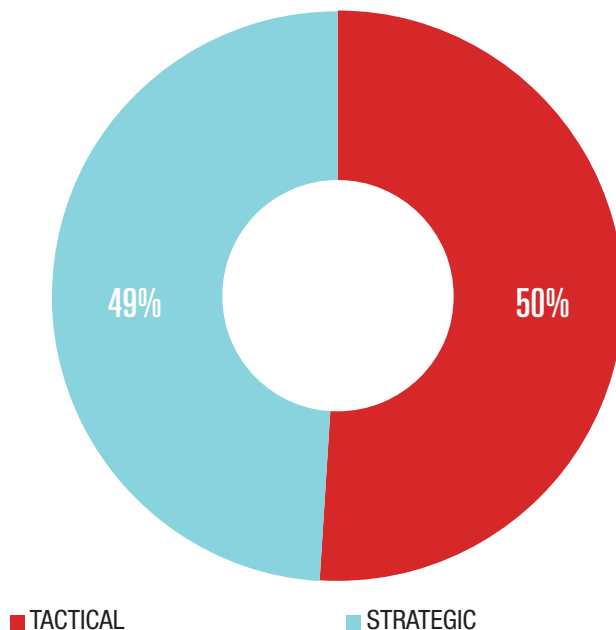
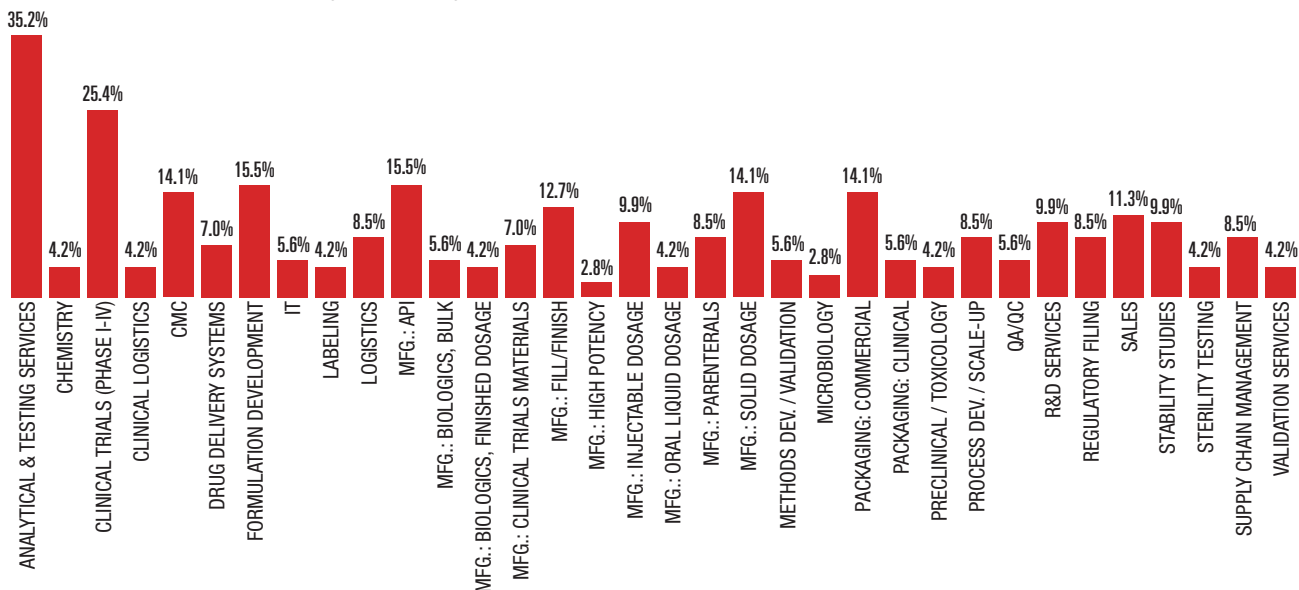
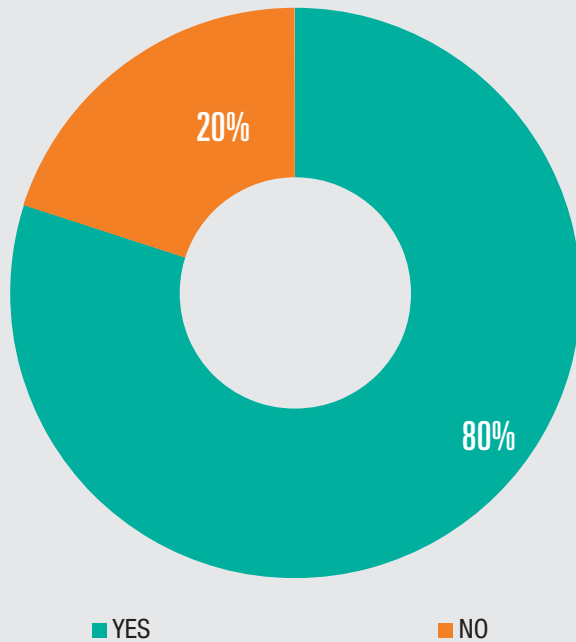


FIGURE 2: Where is your company focusing its outsourcing efforts?



CONTRACT SERVICE PROVIDERS SEE INCREASED DEMAND FOR OUTSOURCING

FIGURE 1: Are you seeing increased demand for outsourcing this year?



This year, 162 professionals from contract services companies responded to the survey. 80% of them say that they are seeing increased demand for outsourcing (Figure 1).

Most of that demand is coming from mid-sized diversified pharma companies, contract services company respondents say. 41% say that Big Pharma is responsible for most increased demand, while 33% attribute most growth to small companies (Figure 2)

When asked what their biggest challenges are in working with sponsor companies, most service provider responses mention information transfer and unrealistic deadlines (Figure 3)

FIGURE 2: Where are you seeing most increased demand for your services?



FIGURE 3: What are the top three challenges that you face in working with operating pharmaceutical companies?



FIGURE 4: Do you see this approach changing over the next few years?

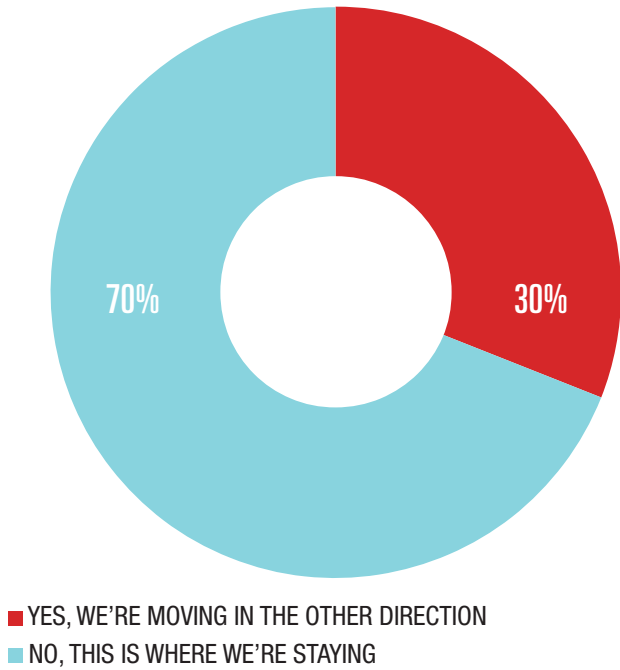


FIGURE 5: Would you use the word Partnership to describe your relationship with a Contract Service Provider?

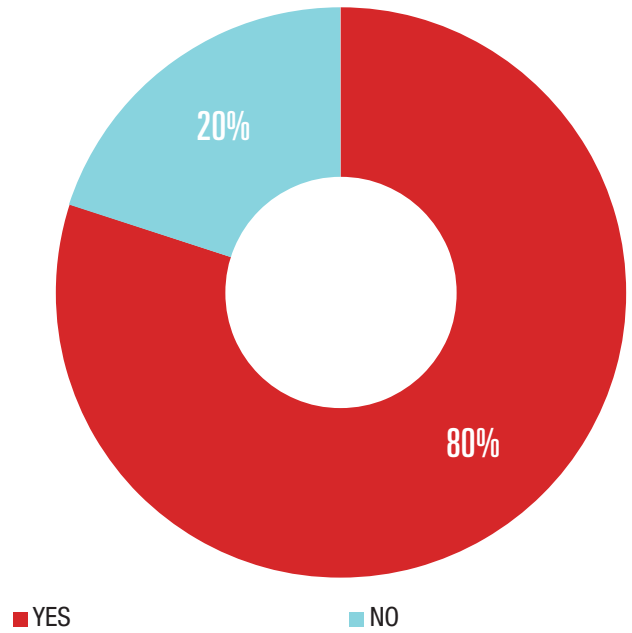


FIGURE 6: What do you find are the most challenging aspects of any outsourcing project?

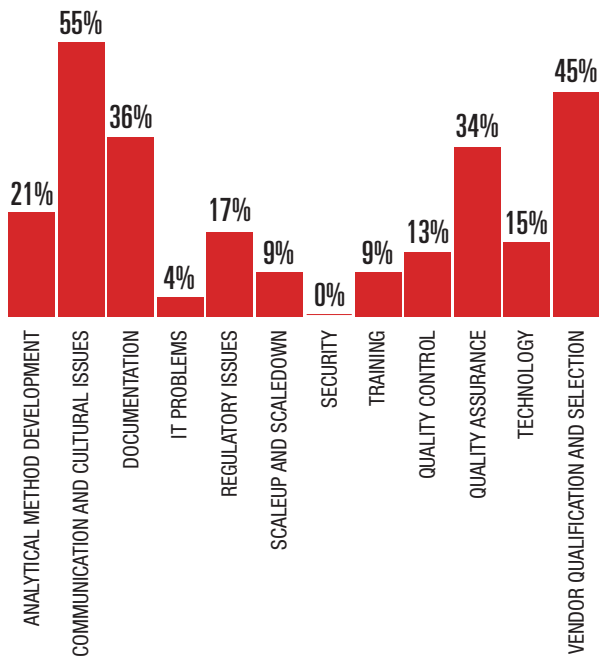


FIGURE 7: What percentage of your company's Commercial (Final Dosage) Manufacturing is outsourced?

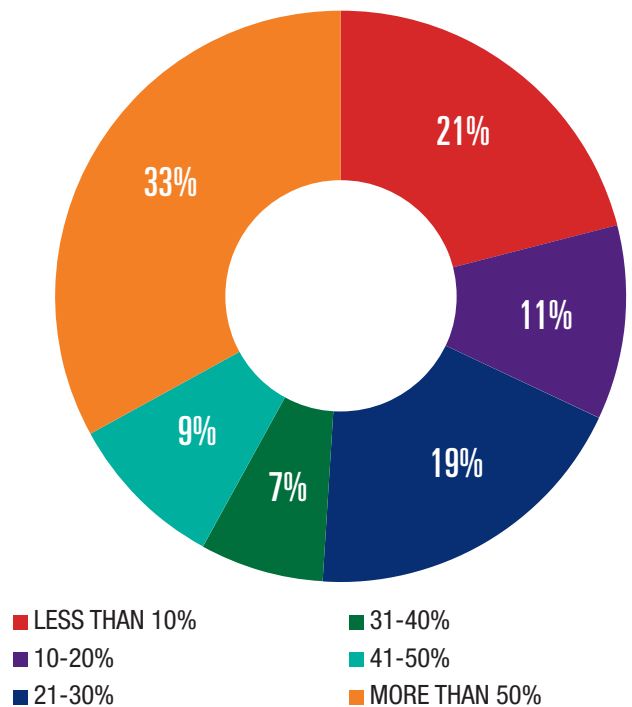


FIGURE 8: How important are the following factors in your selection of a Contract Service Provider (CSP) Ranking From 1 to 5?

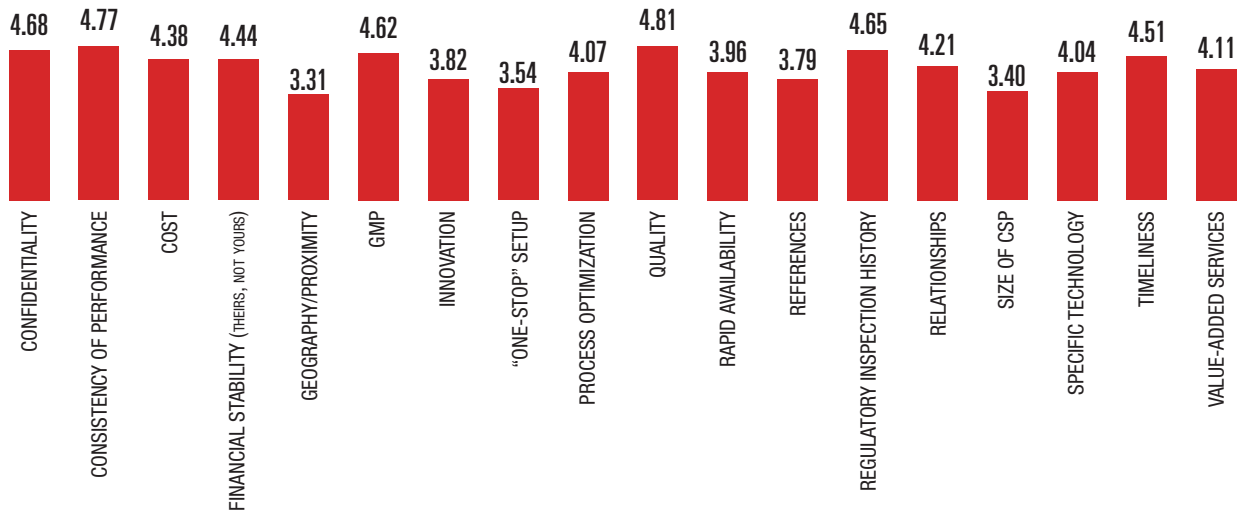


FIGURE 9: What percentage of your company's Clinical Manufacturing is outsourced?

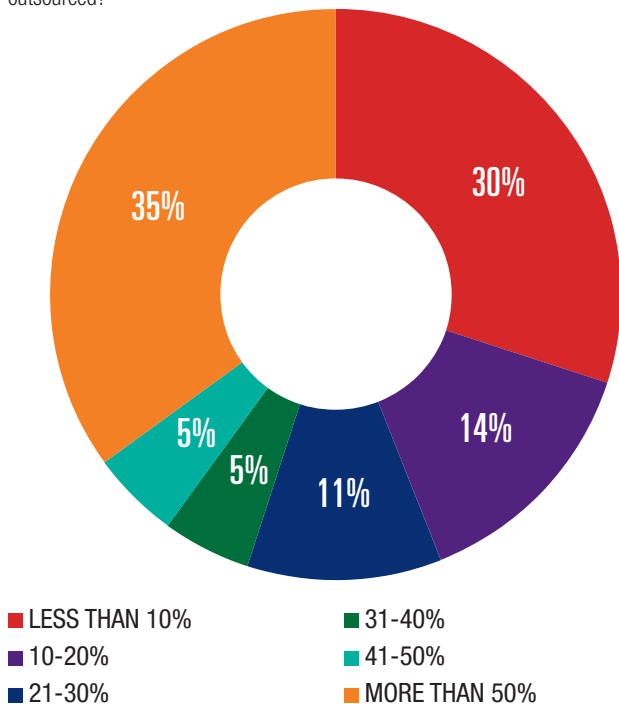
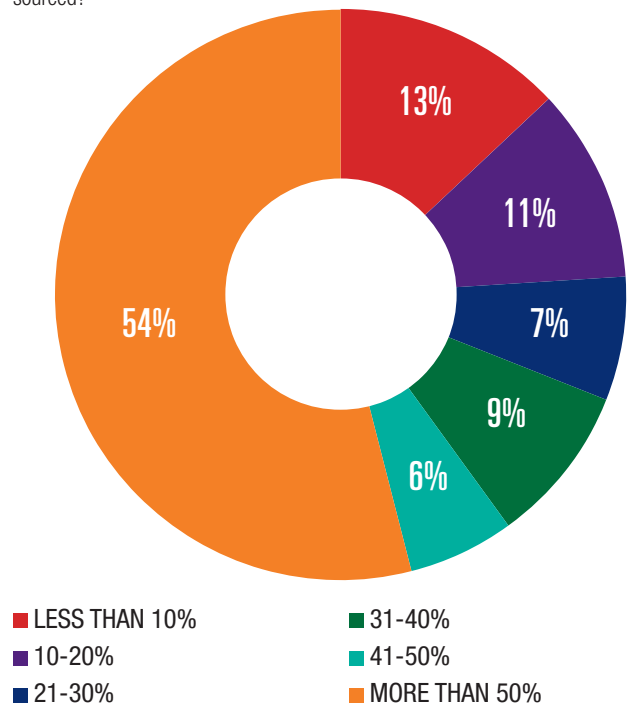


FIGURE 10: What percentage of your company's API manufacturing is outsourced?



2014 OUTSOURCING SURVEY

FIGURE 11: What percentage of your company's Analytical Testing work is outsourced?

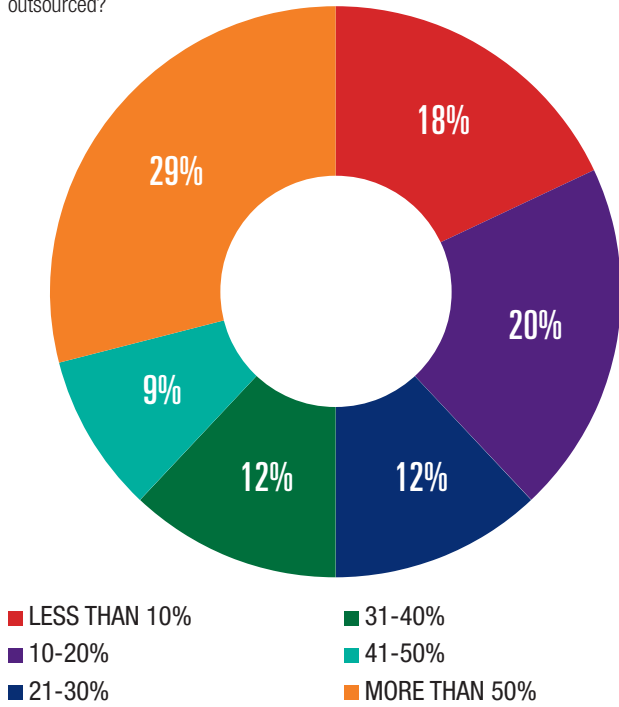


FIGURE 12: What percentage of your company's Nonclinical Work is outsourced?

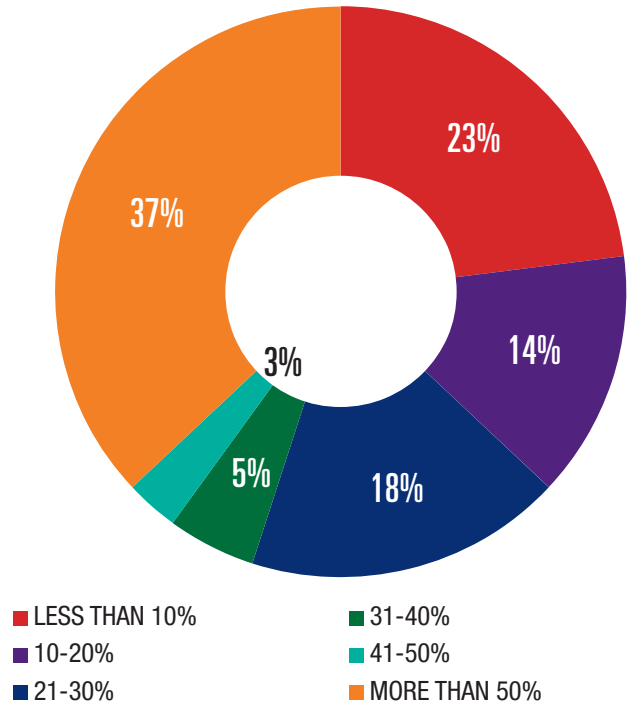


FIGURE 13: Do you use Contract Service Providers as secondary suppliers for any of the following?

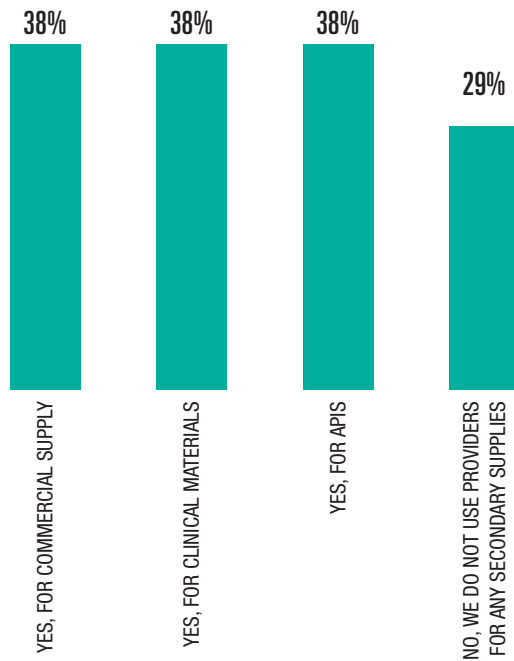
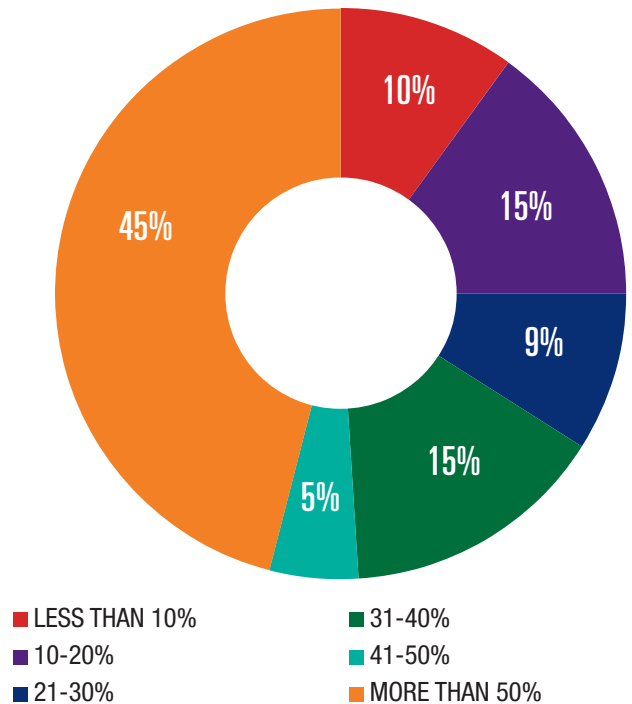


FIGURE 14: What portion of your outsourcing dollars goes to preferred vendors?



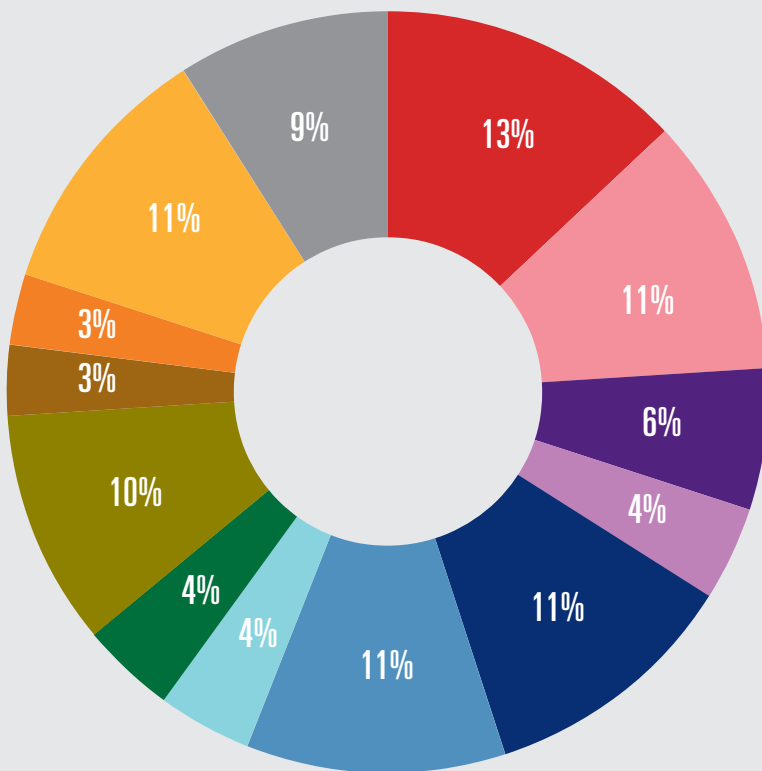
RESPONDENT DEMOGRAPHICS

This year, roughly 65% of respondents came from contract service provider companies, and the rest from sponsor companies. (Figure 1).

Of sponsor company respondents, 22% came from Big Pharma and nearly 20% came from small or mid tier pharma companies (Figure 3)

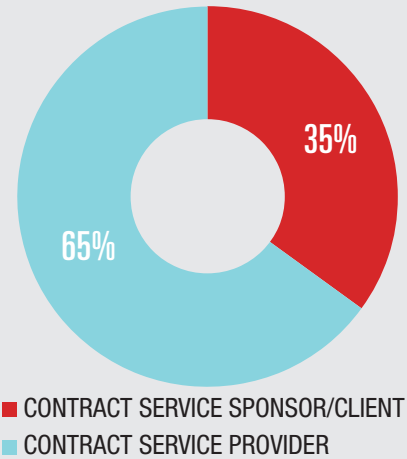
Top sponsor company respondent job functions were R&D, Quality and Validation, Project Management, Corporate Management and Marketing and Sales (Figure 3).

FIGURE 2: What is your job function?



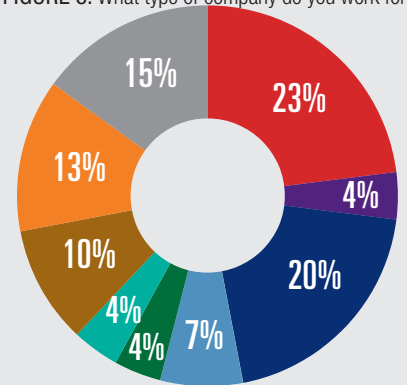
- R&D
- QA/QC/VALIDATION
- BUSINESS DEVELOPMENT
- CONTRACT MANAGER
- PROJECT MANAGER
- CORPORATE MANAGEMENT
- SUPPLY CHAIN MANAGER
- REGULATORY AFFAIRS
- ENGINEERING
- PURCHASING/SOURCING
- CLINICAL RESEARCH
- PROD./MFG./PKG.
- MARKETING/SALES
- OTHER

FIGURE 1. MY COMPANY IS A:



- CONTRACT SERVICE SPONSOR/CLIENT
- CONTRACT SERVICE PROVIDER

FIGURE 3: What type of company do you work for?



- TOP 20 PHARMA
- TOP 10 BIOPHARMA
- SMALL/MID-TIER (NOT TOP 20) PHARMA
- VIRTUAL PHARMA
- EMERGING BIOPHARMA
- SPECIALTY PHARMA
- GENERIC PHARMA
- CONSUMER/OTC HEALTHCARE
- OTHER

FIGURE 15: Has your company ever received a Warning Letter from FDA, EMA or other regulatory agency due to an inspection at a CMO?

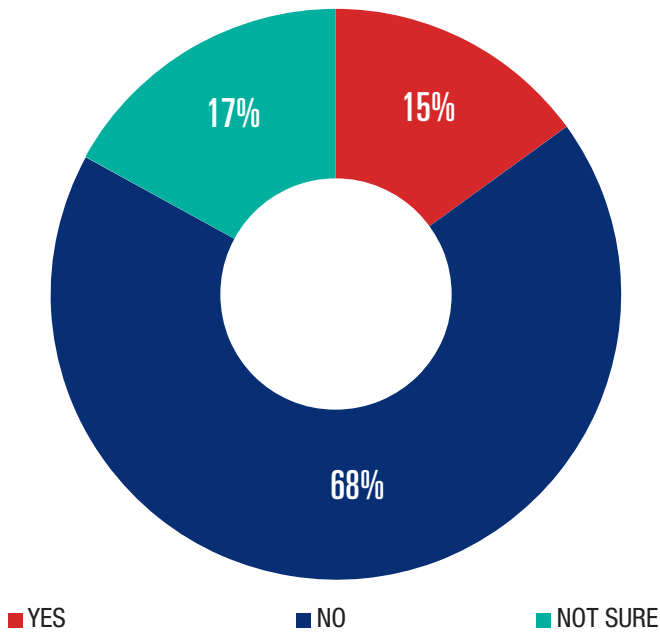


FIGURE 16: If you outsource generic manufacturing, have you ascertained that your dosage form manufacturers and API suppliers have registered with FDA under GDUFA?

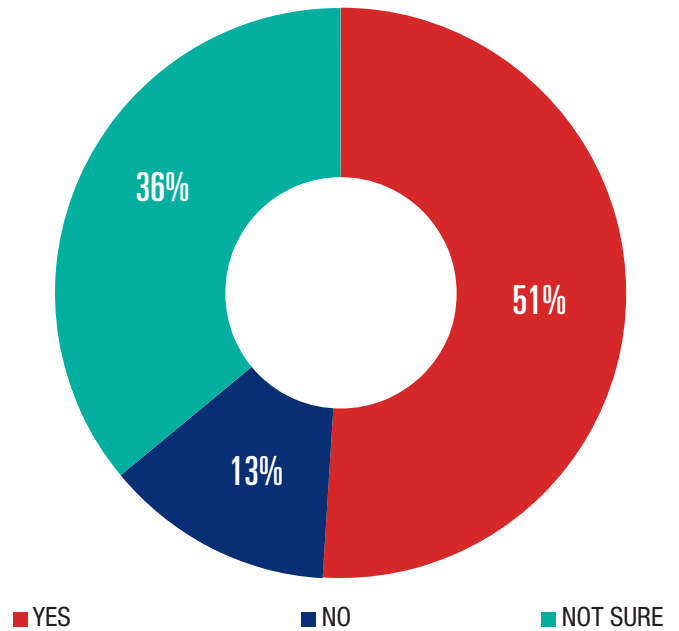


FIGURE 17: On a scale of 1-5, how likely are you to outsource a project to a company in India or China in the next year?

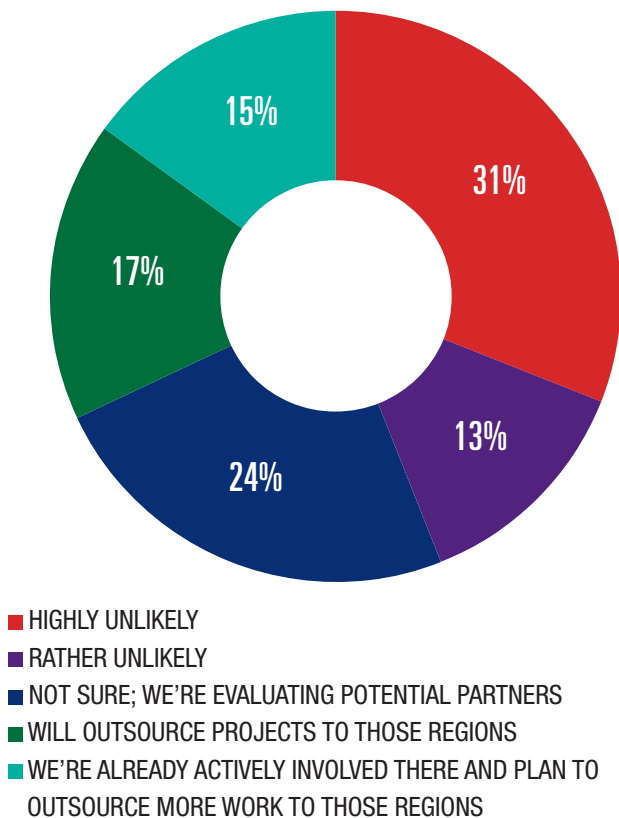


FIGURE 18: In the past year, have you canceled or delayed outsourcing projects (due to the current economic climate) that you would have outsourced?

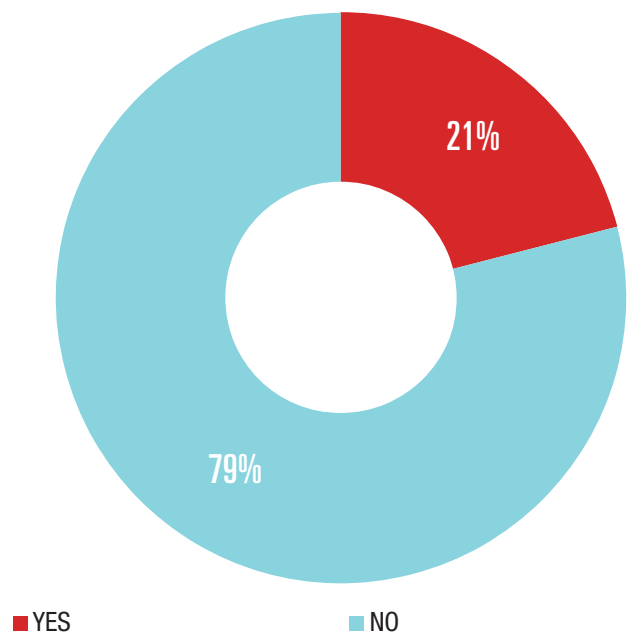


FIGURE 19: Have you canceled or do you plan to cancel plans to attend or exhibit at conferences or exhibitions that you attended in previous years?

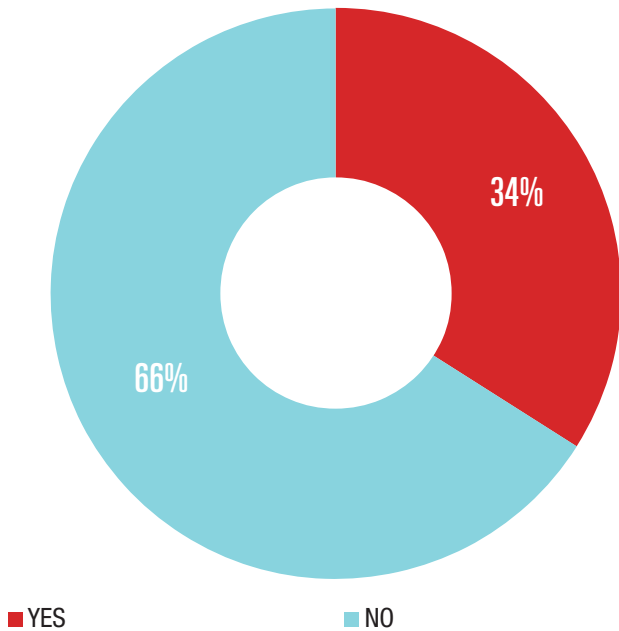


FIGURE 20: Which of the following conferences or annual meetings have you attended in the past 3 years?

