

# 2016 OUTSOURCING SURVEY



*Herein are the results of our 2016 Annual Outsourcing Survey, where we call on you, the readers, to help us benchmark the state of the pharmaceutical outsourcing industry.*

This year we had 315 industry professionals respond to *Contract Pharma's Twelfth Annual Outsourcing Survey*, which was down from 375 last year. Forty-two percent of respondents were from pharmaceutical sponsor companies, and the remaining 58% represented service providers. Survey demographics are broken down further beginning on *page 76*.

When asked if there is an increasing demand for outsourcing this year, 73% of respondents answered yes. The number one reason for

this, according to 41% of respondents, is to focus on core competencies (*Figure 1*). Pharmaceutical company sponsors say they are also outsourcing more because they are virtual (30%), while a significant number say they lack the capabilities in-house (14%).

*Figure 2* highlights the top focus areas for sponsor companies' outsourcing efforts. On *page 73* we've also compared this to last year's results to highlight where the focus of outsourcing has shifted.

FIGURE 1: Why do you outsource?

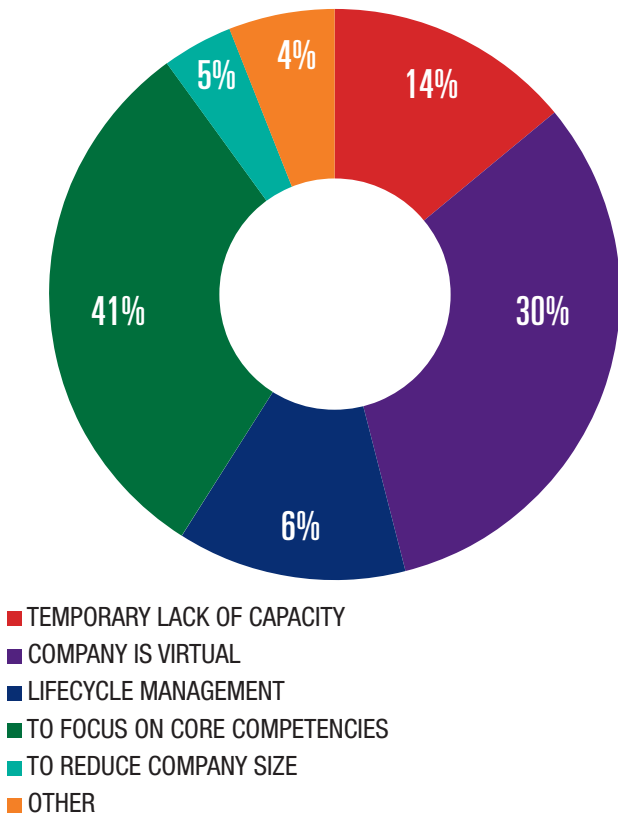


FIGURE 3: Would you describe your outsourcing as Tactical (case-by-case, based on availability) or Strategic (entire classes of functions performed out-of-house)

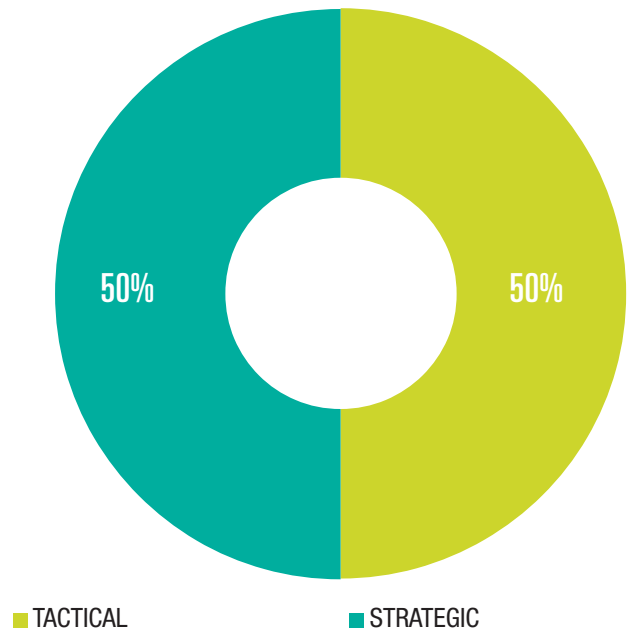


FIGURE 2: Where is your company focusing its outsourcing efforts?

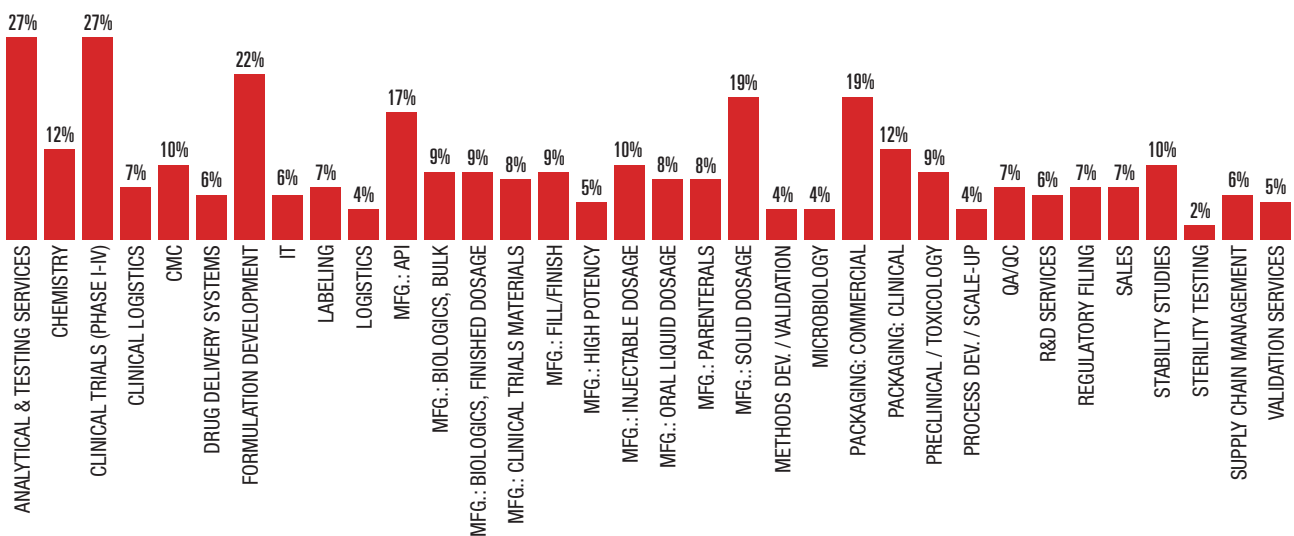


FIGURE 4: Do you see this approach changing over the next few years?

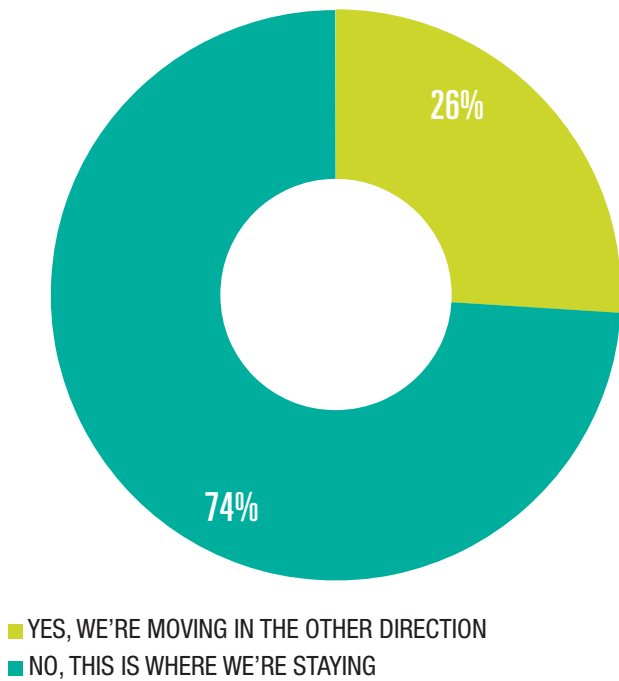


FIGURE 5: Would you use the word Partnership to describe your relationship with a Contract Service Provider?

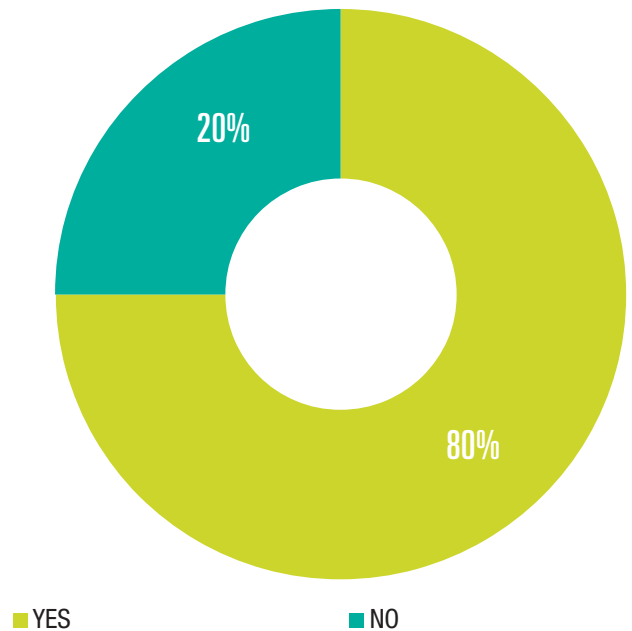


FIGURE 6: What do you find are the most challenging aspects of any outsourcing project?

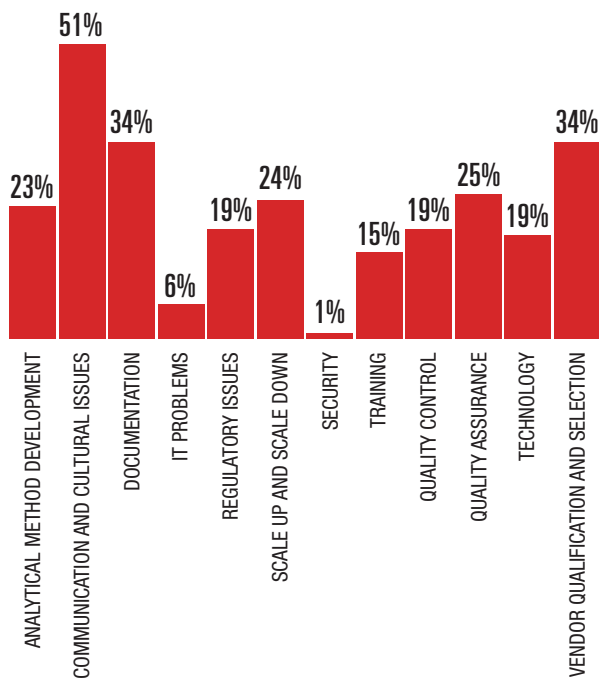
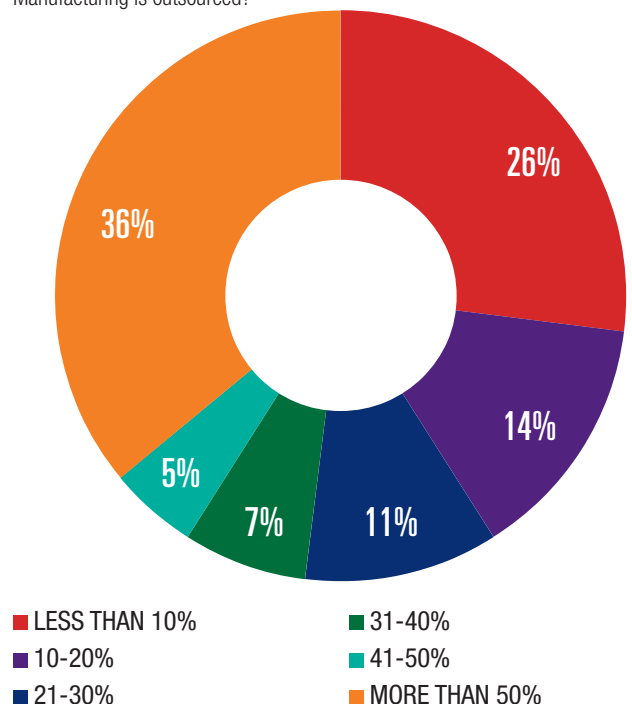


FIGURE 7: What percentage of your company's Commercial (Final Dosage) Manufacturing is outsourced?



WHERE IS YOUR COMPANY FOCUSING ITS OUTSOURCING EFFORTS?

2016

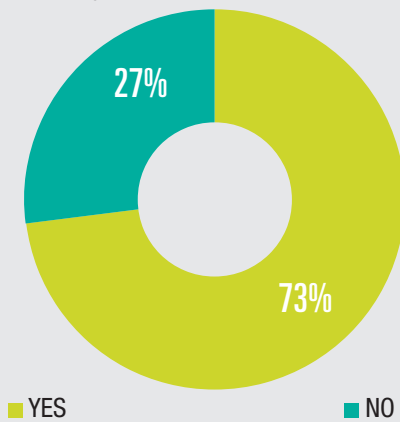
1. Analytical and testing services (27%)
2. Clinical trials, Phases I-IV (27%)
3. Formulation Development (22%)
4. Solid Dosage manufacturing (19%)
5. Commercial Packaging (19%)
6. API manufacturing (17%)

2015

1. Analytical and testing services (37%)
2. Clinical trials, Phases I-IV (34%)
3. API manufacturing (31%)
4. Solid Dosage manufacturing (28%)
5. Formulation Development (20%)
6. Clinical Trials Materials (15%)

GROWTH IN OUTSOURCING CONTINUES

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



This year, 184 professionals from contract service companies responded to the survey. Seventy-three percent of them say they are seeing an increased demand for outsourcing (Figure 1).

Figure 2 shows where the demand is coming from. Most of it (51%) is coming from mid-sized diversified pharma companies, according to the service providers. Next are small pharma companies (41%).

When asked what their biggest challenges are in working with sponsor companies, most service providers (69%) say unrealistic deadlines are the biggest hurdle they face followed closely by insufficient information (67%) (Figure 3).

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

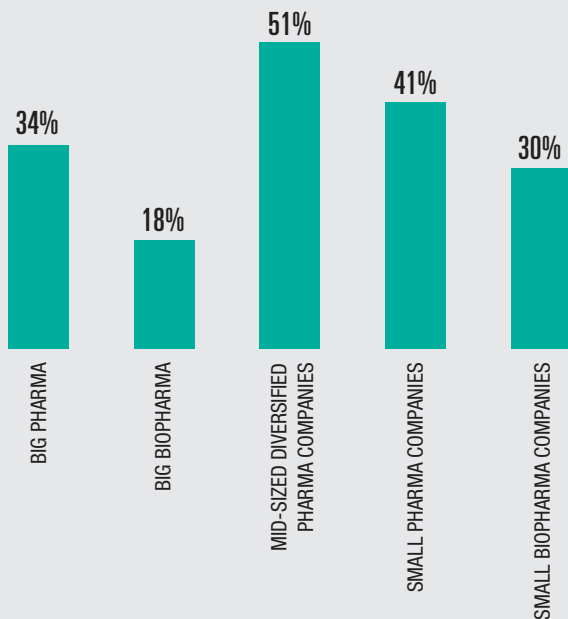


FIGURE 3: What are the top three challenges that you face in working with operating pharmaceutical companies?



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

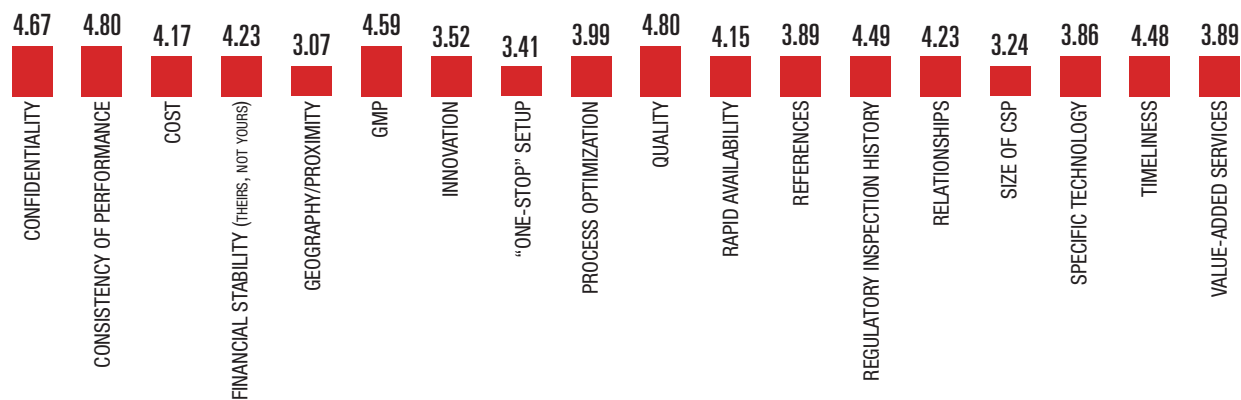


FIGURE 9: What percentage of your company's Clinical Manufacturing is outsourced?

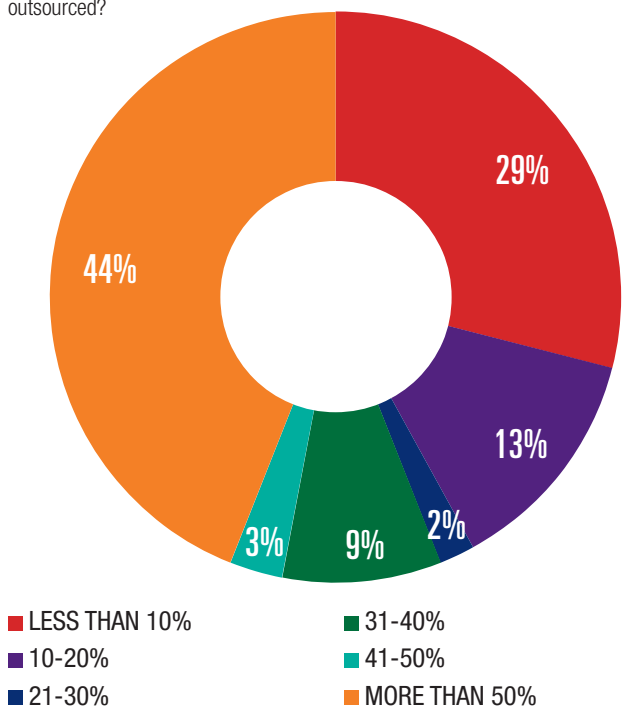
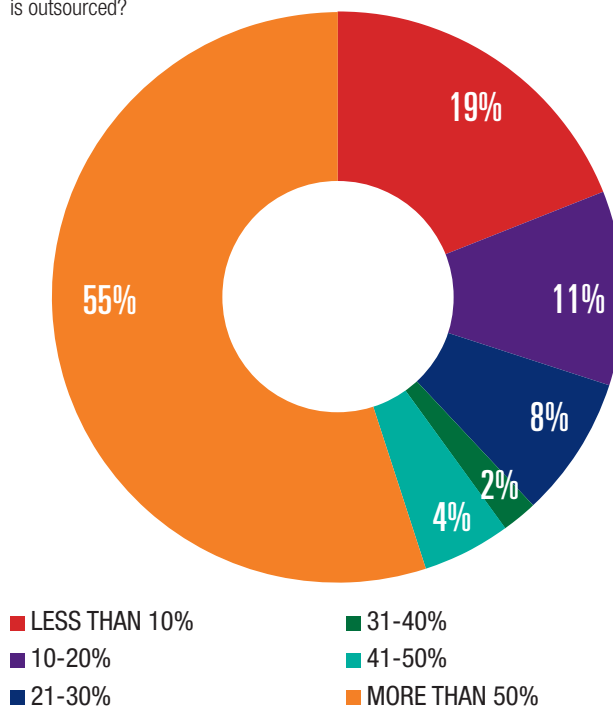


FIGURE 10: What percentage of your company's API manufacturing is outsourced?



Sponsors say they are also using contract service providers as secondary suppliers, with 46% saying they are using them for APIs, 39% for commercial supply, 37% for clinical materials. Twenty-three percent say they are not using providers for any secondary supplies (Figure 13).

Sponsor companies report they are continuing to take strategic (50%), as well as tactical (50%), or case-by-case, project-to-project approaches to outsourcing (Figure 3). Change is not likely in the wind as most (74%) are planning to continue this approach (Figure 4). In addition, 80% of sponsor company respondents this

year say that they view contract relationships as partnerships (Figure 5). Preferred vendor lists have become less important for respondents this year; roughly 33% of sponsor company respondents say that more than half of their outsourcing budget currently goes to preferred vendors, which is down from 38% last year (Figure 14).

Mid-sized and big pharma companies were tied, leading the pack in terms of seeking service providers (17%) followed by generic pharma (13%); specialty pharma (11%); consumer/OTC (10%); and big biopharma (9%).

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

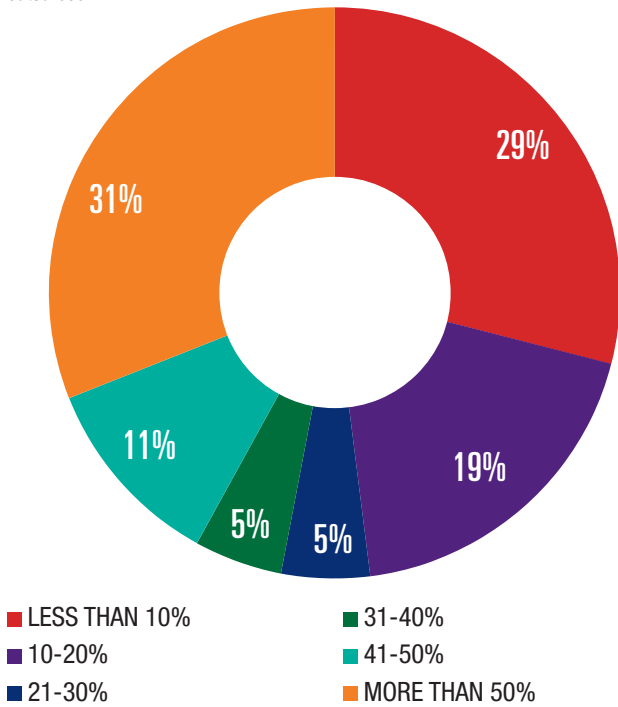


FIGURE 12: What portion of your company's Nonclinical Work is outsourced?

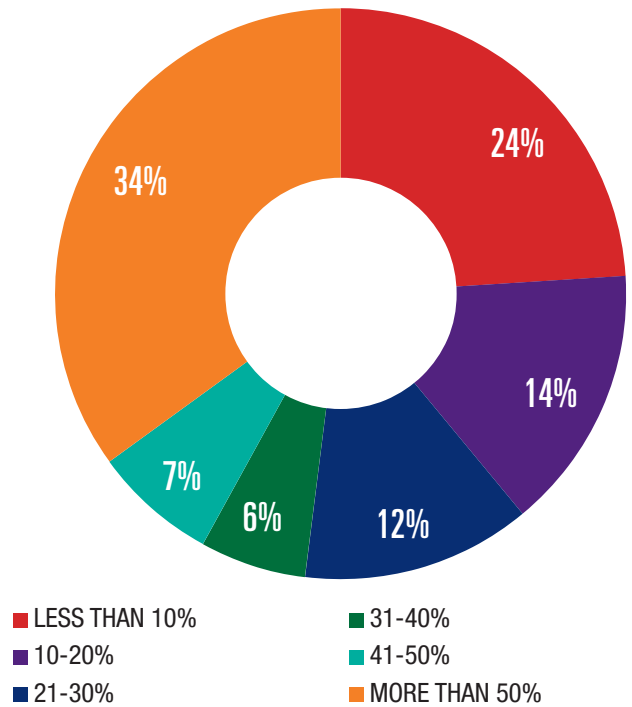


FIGURE 13: Do you use Contract Service Providers as secondary suppliers for any of the following?

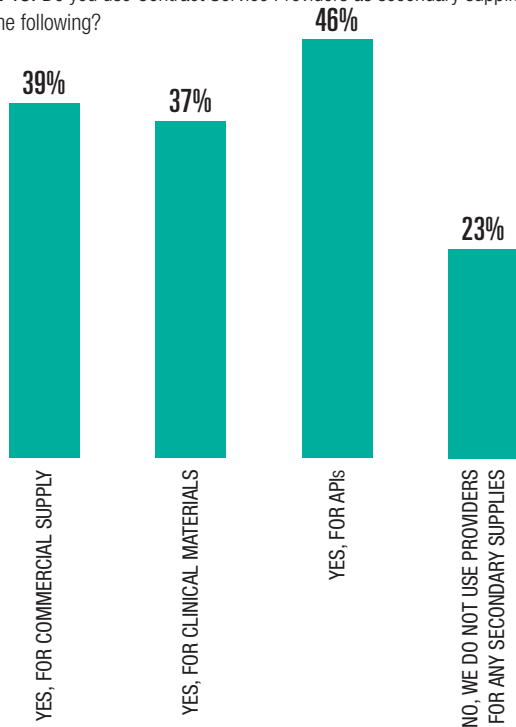
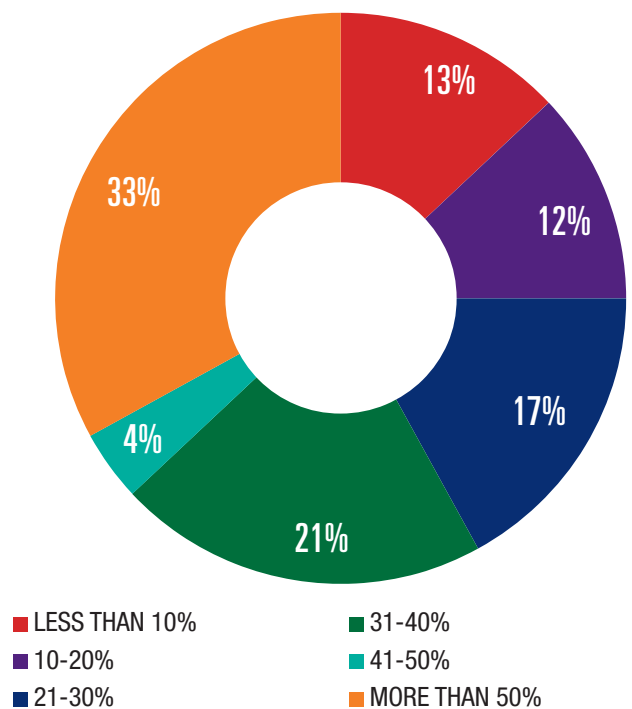


FIGURE 14: What portion of your outsourcing dollars goes to preferred vendors?



Despite growth in outsourcing, both sponsors and service providers point out ongoing challenges in outsourcing relationships. The top issue continues to be communication and culture (Figure 6). One respondent from the sponsor side said, "Only commit to what you can deliver with quality and integrity. Do a good due diligence of the scope of work, maintain transparency and communicate."

Fifty-one percent of respondents this year cited this as the top challenge of the sponsor-contract services relationship, which was down from 46% last year. Hopefully this is not a sign that

communication paths are getting cloudier. Documentation and vendor qualification/selection were tied for the next top challenge cited (34%) followed by quality assurance (25%), scale up and scale down (24%), and regulatory issues, quality control and technology (19%).

From the service providers' perspective the top challenges cited when working with pharmaceutical companies (see box on page 73) are unrealistic deadlines (69%), insufficient information (67%), infrequent communication (41%), incomplete technology platforms (35%), and inadequate tech support (28%). **CP**

### RESPONDENT DEMOGRAPHICS

This year, 58% of respondents came from contract service provider companies, the rest from sponsor companies (Figure 1).

Of sponsor company respondents, 17% came from small/mid-tier pharma and another 17% from Big Pharma (Figure 3).

Top sponsor company respondent job functions were Corporate Management (18%), R&D (17%), Quality and Validation (10%). Figure 2 below breaks out respondent job functions further.

FIGURE 2: What is your job function?

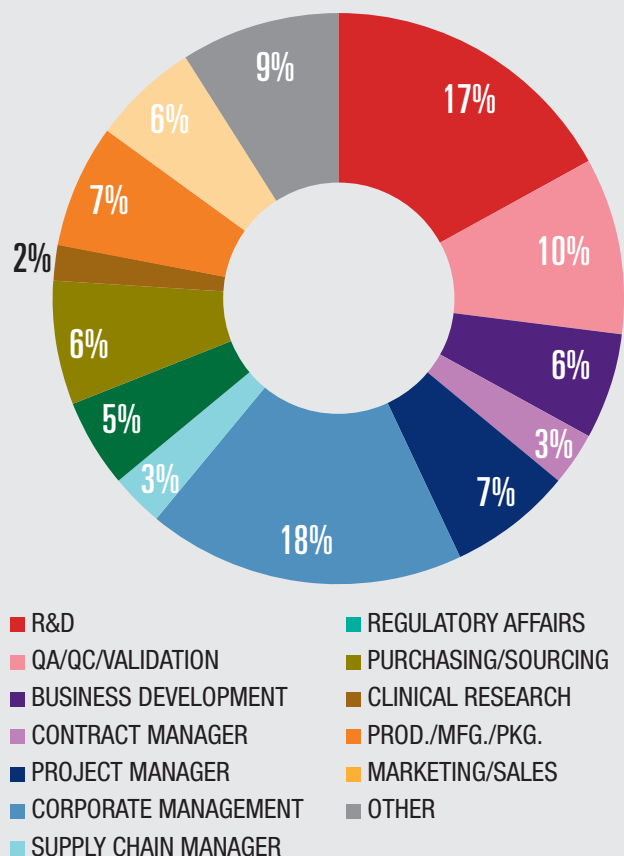


FIGURE 1. MY COMPANY IS A:

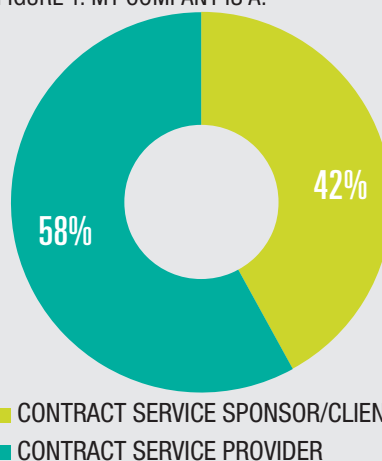


FIGURE 3: What type of company do you work for?

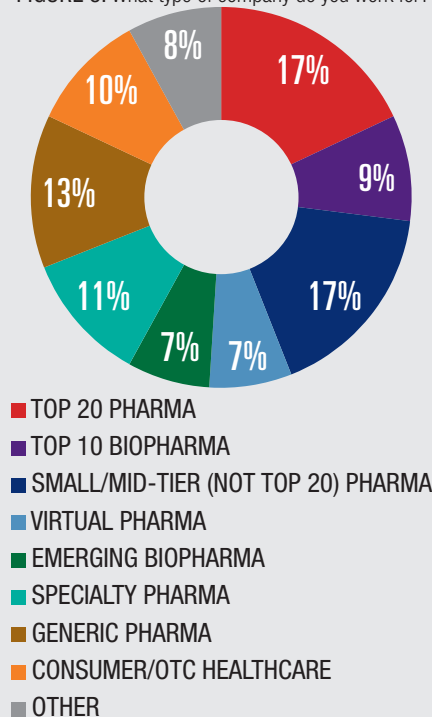
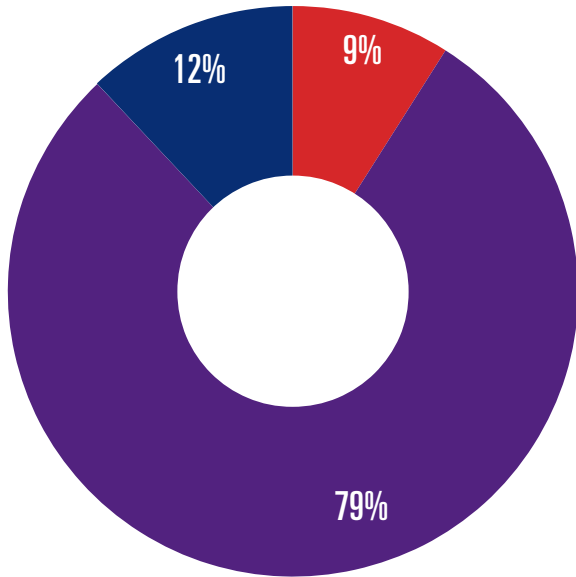
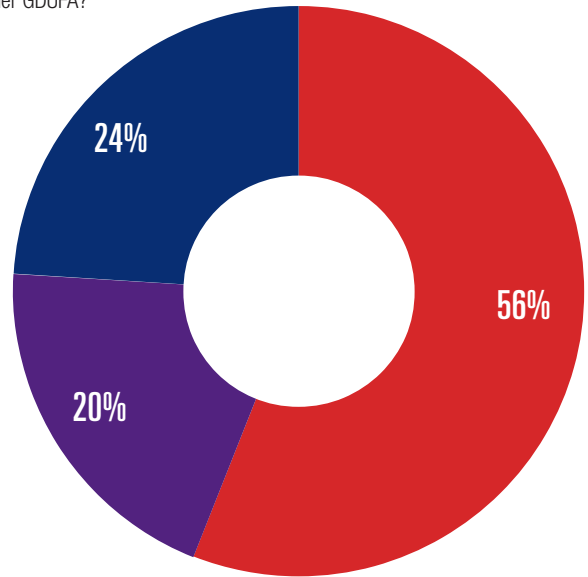


FIGURE 15: Has your company ever received a Warning Letter from FDA, EMA or other regulatory agency due to an inspection at a CMO?



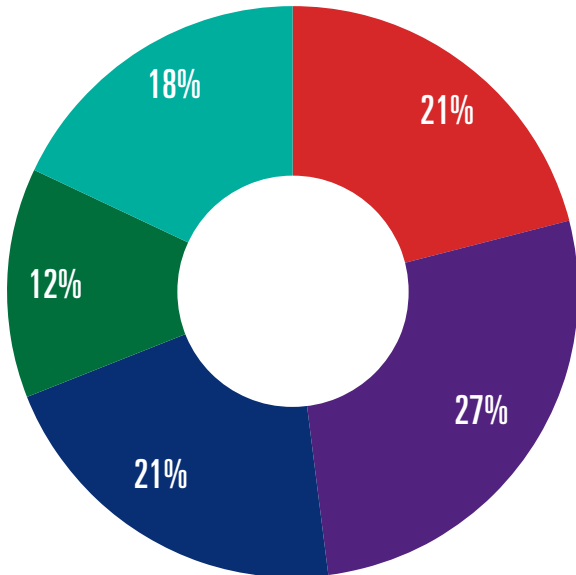
■ YES      ■ NO      ■ NOT SURE

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



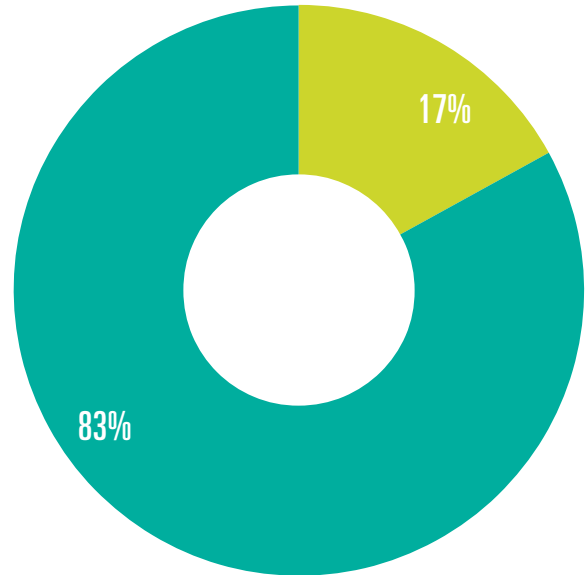
■ YES      ■ NO      ■ NOT SURE

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?



■ HIGHLY UNLIKELY  
 ■ RATHER UNLIKELY  
 ■ NOT SURE; WE'RE EVALUATING POTENTIAL PARTNERS  
 ■ WILL OUTSOURCE PROJECTS TO THOSE REGIONS  
 ■ WE'RE ALREADY ACTIVELY INVOLVED THERE AND PLAN TO OUTSOURCE MORE WORK TO THOSE REGIONS

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



■ YES      ■ NO