Welcome to our 9th 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:

<table>
<thead>
<tr>
<th>Company Type</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Small/Mid-Tier Pharma</td>
<td>20.1%</td>
</tr>
<tr>
<td>Top 20 Pharma</td>
<td>19.0%</td>
</tr>
<tr>
<td>Generic Pharma</td>
<td>12.3%</td>
</tr>
<tr>
<td>Specialty Pharma</td>
<td>12.3%</td>
</tr>
<tr>
<td>Emerging Biopharma</td>
<td>8.4%</td>
</tr>
<tr>
<td>Virtual Pharma</td>
<td>6.5%</td>
</tr>
<tr>
<td>Consumer/OTC</td>
<td>5.2%</td>
</tr>
<tr>
<td>Top 10 Biopharma</td>
<td>3.9%</td>
</tr>
<tr>
<td>Other</td>
<td>12.3%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Job Function</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Corp. Mgmt.</td>
<td>21.4%</td>
</tr>
<tr>
<td>R&amp;D</td>
<td>20.4%</td>
</tr>
<tr>
<td>Project Manager</td>
<td>20.4%</td>
</tr>
<tr>
<td>Purchasing/Sourcing</td>
<td>18.8%</td>
</tr>
<tr>
<td>Prod./Mfg./Pkg.</td>
<td>7.8%</td>
</tr>
<tr>
<td>QA/QC/Validation</td>
<td>6.5%</td>
</tr>
<tr>
<td>Business Development</td>
<td>5.2%</td>
</tr>
<tr>
<td>Contract Manager</td>
<td>5.2%</td>
</tr>
<tr>
<td>Marketing/Sales</td>
<td>4.5%</td>
</tr>
<tr>
<td>Clinical Research</td>
<td>3.2%</td>
</tr>
<tr>
<td>Supply Chain Manager</td>
<td>2.6%</td>
</tr>
<tr>
<td>Regulatory Affairs</td>
<td>1.9%</td>
</tr>
<tr>
<td>Engineering</td>
<td>1.3%</td>
</tr>
<tr>
<td>Other</td>
<td>3.2%</td>
</tr>
</tbody>
</table>

Plateau?
Last year, 48% of respondents believed that they will spend the same or less on outsourcing spending in the coming year; this year, that climbed to 53%. Meanwhile, 49%, told us that they spent the same or less on outsourcing in the previous year, the same as in our 2012 survey. 18% of respondents said that 2012 saw no change in outsourcing spending from 2011.

28% of respondents tell us they had cancelled outsourcing projects in the previous year due to the economy; up from 23% in our 2012 survey. Small/Mid-Tier Pharma respondents had the highest “cancellation rate” of any company type, at 59% (!).

50% of respondents said that more than half of their outsourcing dollars go to preferred providers. 74% of Corporate Management respondents said the same but most other job categories cited lower figures (43% of R&D staff, and 20% QA/QC/Validation staff cited that large a figure).

46% of the respondents said that their companies outsource generic manufacturing, but only 52% of that group said they have ascertained that their dosage form manufacturers and API suppliers have registered with FDA under GDUFA.

Thanks to all of you who took the time to respond to this year’s Outsourcing Survey. The winner of our iPad Mini drawing is Bette Monnot-Chase of Viropharma! Congratulations! — CYP
How much did your outsourcing spending change in the past year?

Total
- 10%+ less than previous year: 15%
- 6-10% less than previous year: 21%
- 1-5% less than previous year: 13%
- No change: 16%
- 1-5% more than previous year: 19%
- 6-10% more than previous year: 10%
- 10%+ more than previous year: 6%

Respondents who report that their outsourcing spending grew in the previous year: 50%
- WHAT DO THEY DO?
  - Corporate Management: 27%
  - R&D: 22%
  - Purchasing/Sourcing: 10%
  - QA/QC Validation: 9%

- WHERE DO THEY WORK?
  - Small/Mid-Tier Pharma: 26%
  - Top 20 Pharma: 19%
  - Generic Pharma: 16%
  - Specialty Pharma: 11%

Respondents who report that their outsourcing spending shrank in the previous year: 31%
- WHAT DO THEY DO?
  - R&D: 24%
  - Corporate Management: 21%
  - Contract Manager: 10%
  - Project Manager: 9%

- WHERE DO THEY WORK?
  - Top 20 Pharma: 19%
  - Specialty Pharma: 19%
  - Small/Mid-Tier Pharma: 14%
  - Virtual Pharma: 12%

WHAT TYPES OF OUTSOURCING DO THEY MANAGE?*
- Analytical & Testing Services: 46%
- Manufacturing: API: 46%
- Formulation Development: 45%
- Manufacturing: Solid Dosage: 41%
- Manufacturing: Fill/Finish: 39%
- Packaging: Commercial: 38%
- R&D Services: 36%

*RеспONDENTS can select multiple answers for this question.
How much do you expect your outsourcing spending to change in the next year?

- **Total**
  - 10%+ less than previous year: 15%
  - 6-10% less than previous year: 14%
  - 1-5% less than previous year: 15%
  - No change: 24%
  - 1-5% more than previous year: 7%
  - 6-10% more than previous year: 7%
  - 10%+ more than previous year: 18%

**All that Future**

Respondents who project that their outsourcing spending **WILL GROW** in the next year: 47%

**WHAT DO THEY DO?**
- Corporate Management: 29%
- R&D: 20%
- Project Manager: 11%
- QA/QC Validation: 11%

**WHERE DO THEY WORK?**
- Top 20 Pharma: 22%
- Small/Mid-Tier Pharma: 18%
- Specialty Pharma: 15%
- Generic Pharma: 14%

**WHAT TYPES OF OUTSOURCING DO THEY MANAGE?**

- Analytical & Testing Services: 49%
- Manufacturing: API: 45%
- Formulation Development: 43%
- Packaging: Commercial: 40%
- Manufacturing: Fill/Finish: 38%
- Manufacturing: Solid Dosage: 36%
- R&D Services: 37%

Respondents who project that their outsourcing spending **WILL SHRINK** in the next year: 29%

**WHAT DO THEY DO?**
- R&D: 21%
- Production/Manufacturing/Packaging: 18%
- Corporate Management: 15%
- Contract Manager: 10%

**WHERE DO THEY WORK?**
- Top 20 Pharma: 18%
- Specialty Pharma: 18%
- Small/Mid-Tier Pharma: 18%
- Virtual Pharma: 13%

**WHAT TYPES OF OUTSOURCING DO THEY MANAGE?**

- Chemistry: 44%
- CMC: 41%
- Manufacturing: API: 39%
- Analytical & Testing Services: 36%
- Process Development/Scale-Up: 32%
- Formulation Development: 31%
- Clinical Trials (Phase I-IV): 31%

*Respondents can select multiple answers for this question*
Secondhand

48% of all respondents said that they use contract service providers as secondary suppliers for commercial supply.

34% said that they use secondary suppliers for clinical materials. 44% said that they use secondary suppliers for APIs.

28% reported that they don’t use providers for any of those secondary supplies.

What do we know about the respondents who say they use no secondary suppliers?

**WHAT DO THEY DO?**

- Corporate Management ...................................... 23%
- R&D ..................................................................... 23%
- Project Manager .................................................. 13%
- QA/QC Validation ................................................. 10%

**WHERE DO THEY WORK?**

- Other ................................................................... 29%
- Top 20 Pharma .................................................... 16%
- Specialty Pharma ................................................ 16%
- Small/Mid-Tier Pharma ........................................ 13%

**WHAT TYPES OF OUTSOURCING DO THEY MANAGE?**

*Respondents can select multiple answers for this question*

- Analytical & Testing Services.......................... 39%
- Manufacturing: Injectable Dosage ................. 32%
- Clinical Trials (Phase I-IV) ............................ 26%
- Drug Delivery Systems .................................... 26%
- Formulation Development .............................. 26%
- Methods Development/Validation .................. 26%

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

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

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**Analytical & Testing Services**

- 25%
- Manufacturing: API
- Formulation Development
- R&D Services
- Chemistry
- Manufacturing: Solid Dosage
- Methods Development/Validation
- Packaging: Commercial
- Manufacturing: Injectable Dosage
2013 OUTSOURCING SURVEY

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

Total

- 10%+ less than previous year: 18%
- 6-10% less than previous year: 15%
- 1-5% less than previous year: 14%
- No change: 24%
- 1-5% more than previous year: 7%
- 6-10% more than previous year: 7%
- 10%+ more than previous year: 7%

Analytical & Testing Services
- 14%: 25%
- 18%: 14%
- 7%: 14%
- 2%: 4%

Manufacturing: API
- 18%: 29%
- 12%: 16%
- 8%: 6%
- 8%: 10%

Formulation Development
- 14%: 23%
- 19%: 16%
- 12%: 8%
- 22%: 14%

R&D Services
- 14%: 19%
- 17%: 24%
- 7%: 4%
- 19%: 24%

Chemistry
- 19%: 18%
- 16%: 13%
- 7%: 9%
- 18%: 12%

Manufacturing: Solid Dosage
- 17%: 18%
- 16%: 13%
- 4%: 7%
- 4%: 9%

We Could Put on a Show!

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

OVERALL RESPONDENTS

ContractPharma Contracting & Outsourcing: 37%
INTERPHEX: 37%
CPhI/ICSE: 35%
BIO: 30%
AAPS: 28%

MORE THAN HALF OF COMMERCIAL MANUFACTURING IS OUTSOURCED

BIO: 40%
CPhI/ICSE: 32%
INTERPHEX: 32%
Contract Pharma Contracting & Outsourcing: 24%
AAPS: 20%

MORE THAN HALF OF API MANUFACTURING IS OUTSOURCED

CPhI/ICSE: 39%
Contract Pharma Contracting & Outsourcing: 36%
INTERPHEX: 36%
BIO: 28%
AAPS: 28%

MORE THAN HALF OF CLINICAL MANUFACTURING IS OUTSOURCED

AAPS: 36%
BIO: 32%
CPhI/ICSE: 32%
Contract Pharma Contracting & Outsourcing: 29%
INTERPHEX: 26%

MORE THAN HALF OF ANALYTICAL TESTING IS OUTSOURCED

AAPS: 30%
BIO: 30%
CPhI/ICSE: 26%
Contract Pharma Contracting & Outsourcing: 22%
INTERPHEX: 22%
How much did your outsourcing spending change in the past year?

More than $1 million in annual
- Bulk Manufacturing spend: 30%
- Commercial Manufacturing spend: 21%
  - 10%+ less than last year: 11%
  - 6-10% less than last year: 4%
  - 1-5% less than last year: 4%
  - No change: 17%
  - 1-5% more than last year: 10%
  - 6-10% more than last year: 28%
  - 10%+ more than last year: 7%

More than $1 million in annual R&D spend: 37%
  - 10%+ less than last year: 14%
  - 6-10% less than last year: 16%
  - 1-5% less than last year: 16%
  - No change: 14%
  - 1-5% more than last year: 7%
  - 6-10% more than last year: 5%
  - 10%+ more than last year: 7%

More than $1 million in annual Clinical Trial Materials Manufacturing spend: 22%
  - 10%+ less than last year: 14%
  - 6-10% less than last year: 14%
  - 1-5% less than last year: 16%
  - No change: 16%
  - 1-5% more than last year: 5%
  - 6-10% more than last year: 5%
  - 10%+ more than last year: 7%

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

More than $1 million in annual
- Bulk Manufacturing spend: 26%
- Commercial Manufacturing spend: 17%
  - 10%+ less than last year: 8%
  - 6-10% less than last year: 10%
  - 1-5% less than last year: 11%
  - No change: 31%
  - 1-5% more than last year: 14%
  - 6-10% more than last year: 7%
  - 10%+ more than last year: 15%

More than $1 million in annual R&D spend: 26%
  - 10%+ less than last year: 5%
  - 6-10% less than last year: 16%
  - 1-5% less than last year: 16%
  - No change: 22%
  - 1-5% more than last year: 14%
  - 6-10% more than last year: 7%
  - 10%+ more than last year: 7%

More than $1 million in annual Clinical Trial Materials Manufacturing spend: 22%
  - 10%+ less than last year: 14%
  - 6-10% less than last year: 14%
  - 1-5% less than last year: 5%
  - No change: 16%
  - 1-5% more than last year: 5%
  - 6-10% more than last year: 5%
  - 10%+ more than last year: 7%
2013 OUTSOURCING SURVEY

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

More than $1 million in annual Clinical Trials (not mfg.) spend
- 10%+ less than last year: 15%
- 6-10% less than last year: 12%
- 1-5% less than last year: 8%
- No change: 24%
- 1-5% more than last year: 20%
- 6-10% more than last year: 5%
- 10%+ more than last year: 4%

More than $1 million in annual Commercial Packaging spend
- 10%+ less than last year: 10%
- 6-10% less than last year: 13%
- 1-5% less than last year: 15%
- No change: 20%
- 1-5% more than last year: 24%
- 6-10% more than last year: 16%
- 10%+ more than last year: 5%

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
- 10%+ less than last year: 15%
- 6-10% less than last year: 16%
- 1-5% less than last year: 12%
- No change: 24%
- 1-5% more than last year: 15%
- 6-10% more than last year: 8%
- 10%+ more than last year: 4%

More than $1 million in annual Commercial Packaging spend
- 10%+ less than last year: 10%
- 6-10% less than last year: 23%
- 1-5% less than last year: 15%
- No change: 21%
- 1-5% more than last year: 15%
- 6-10% more than last year: 7%
- 10%+ more than last year: 7%
How many preferred vendors do you use?

Total

- None: 6%
- 1-5: 25%
- 6-10: 25%
- 11-15: 10%
- 16+: 8%

Small/Mid-Tier Pharma

- Corporate Mgmt.: 43%
- R&D: 14%
- Project Manager: 10%

Top 20 Pharma

- Corporate Mgmt.: 10%
- R&D: 14%
- Project Manager: 21%

Generic Pharma

- Corporate Mgmt.: 26%
- R&D: 27%
- Project Manager: 67%

Specialty Pharma

- Corporate Mgmt.: 21%
- R&D: 27%
- Project Manager: 53%

Emerging Biopharma

- Corporate Mgmt.: 9%
- R&D: 64%
- Project Manager: 36%

Virtual Pharma

- Corporate Mgmt.: 11%
- R&D: 64%
- Project Manager: 26%
What portion of your outsourcing dollars goes to preferred vendors?
(by company type)

I Would Prefer To

50% of respondents said that more than half of their outsourcing dollars go to preferred providers.

WHAT DO THEY DO?

Corporate Management ...................................... 23%
R&D ..................................................................... 23%
Project Manager .................................................. 13%
QA/QC Validation ................................................. 10%

WHERE DO THEY WORK?

Corporate Management ...................................... 23%
R&D ..................................................................... 23%
Project Manager .................................................. 13%
QA/QC Validation ................................................. 10%

WHAT TYPES OF OUTSOURCING DO THEY MANAGE?*

Analytical & Testing Services .............................. 39%
Manufacturing: Injectable Dosage ....................... 32%
Chemistry ............................................................ 29%
Clinical Trials (Phase I-IV) ................................... 26%
Drug Delivery Systems ........................................ 26%
Formulation Development ................................... 26%
Methods Development/Validation ....................... 26%

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

10%+ less than previous year ............................. 10%
6-10% less than previous year .............................. 8%
1-5% less than previous year .............................. 5%
Did not change .................................................... 16%
1-5% more than previous year ............................. 23%
6-10% more than previous year ............................ 12%
10%+ more than previous year ............................ 26%

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

10%+ less than last year ..................................... 12%
6-10% less than last year .................................... 12%
1-5% less than last year ..................................... 12%
Will not change .................................................... 20%
1-5% more than last year .................................... 16%
6-10% more than last year ................................. 16%
10%+ more than last year ................................. 24%

*Respondents can select multiple answers for this question.
50/50

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

- 50% report that they expect to increase their outsourcing spending in the next year
- 54% work at companies that employ a “preferred provider” model
- 71% said that more than half of their outsourcing dollars go to preferred providers
- 63% use CMOs for secondary supply for commercial products
- 30% report that they will probably or definitely outsource a project to an Asia-based provider in the next year
- 71% describe their outsourcing as strategic (as opposed to tactical)

60% outsource because their company is virtual, while 22% do so to focus on core competencies
What percentage of your company's clinical manufacturing is done by CMOs?

- Less than 10%
- 10-20%
- 21-30%
- 31-40%
- 41-50%
- More than 50%
What percentage of your company's API manufacturing is outsourced?

- Total:
  - Less than 10%: 29%
  - 10-20%: 4%
  - 21-30%: 5%
  - 31-40%: 9%
  - 41-50%: 2%
  - More than 50%: 50%

- Small/Mid-Tier Pharma:
  - 70%
  - 9%
  - 12%
  - 6%
  - 7%
  - 5%

- Top 20 Pharma:
  - 27%
  - 55%
  - 5%
  - 9%
  - 12%

- Generic Pharma:
  - 15%
  - 8%
  - 8%

- Specialty Pharma:
  - 63%
  - 50%
  - 19%
  - 6%
  - 6%

- Emerging Biopharma:
  - 25%
  - 13%
  - 12%
  - 6%

- Virtual Pharma:
  - 22%
  - 78%

- Corporate Mgmt.:
  - 63%
  - 50%
  - 20%
  - 10%
  - 10%

- R&D:
  - 25%
  - 8%
  - 8%
  - 5%

- Project Manager:
  - 20%
  - 10%

- Purchasing/Sourcing:
  - 20%
  - 20%
  - 10%
  - 10%
  - 10%

- Prod./Mfg/Pkg.:
  - 37%
  - 63%
  - 30%

- QA/QC/Validation:
  - 60%
What percentage of your company’s Analytical Testing is outsourced?

- **Total**
  - Less than 10%: 32%
  - 10-20%: 20%
  - 21-30%: 7%
  - 31-40%: 4%
  - 41-50%: 2%
  - More than 50%: 35%

- **Small/Mid-Tier Pharma**
  - Less than 10%: 45%
  - 10-20%: 26%
  - 21-30%: 15%
  - 31-40%: 14%
  - 41-50%: 6%
  - More than 50%: 6%

- **Top 20 Pharma**
  - Less than 10%: 47%
  - 10-20%: 15%
  - 21-30%: 23%
  - 31-40%: 7%
  - 41-50%: 5%
  - More than 50%: 5%

- **Generic Pharma**
  - Less than 10%: 43%
  - 10-20%: 36%
  - 21-30%: 14%
  - 31-40%: 12%
  - 41-50%: 6%
  - More than 50%: 5%

- **Corporate Mgmt.**
  - Less than 10%: 50%
  - 10-20%: 19%
  - 21-30%: 15%
  - 31-40%: 19%
  - 41-50%: 9%
  - More than 50%: 9%

- **R&D**
  - Less than 10%: 42%
  - 10-20%: 25%
  - 21-30%: 21%
  - 31-40%: 12%
  - 41-50%: 4%
  - More than 50%: 4%

- **Project Manager**
  - Less than 10%: 28%
  - 10-20%: 27%
  - 21-30%: 11%
  - 31-40%: 9%
  - 41-50%: 9%
  - More than 50%: 27%

- **Purchasing/Sourcing**
  - Less than 10%: 33%
  - 10-20%: 17%
  - 21-30%: 33%
  - 31-40%: 17%
  - 41-50%: 17%
  - More than 50%: 11%

- **Prod./Mfg/Pkg.**
  - Less than 10%: 33%
  - 10-20%: 33%
  - 21-30%: 33%
  - 31-40%: 17%
  - 41-50%: 17%
  - More than 50%: 89%

- **QA/QC/Validation**
  - Less than 10%: 33%
  - 10-20%: 33%
  - 21-30%: 33%
  - 31-40%: 17%
  - 41-50%: 17%
  - More than 50%: 11%
What percentage of your company's Nonclinical Work is outsourced?

<table>
<thead>
<tr>
<th>Total</th>
<th>Less than 10%</th>
<th>10-20%</th>
<th>21-30%</th>
<th>31-40%</th>
<th>41-50%</th>
<th>More than 50%</th>
</tr>
</thead>
<tbody>
<tr>
<td>34%</td>
<td>36%</td>
<td>5%</td>
<td>6%</td>
<td>17%</td>
<td>2%</td>
<td>17%</td>
</tr>
</tbody>
</table>

- Small/Mid-Tier Pharma:
  - Corporate Mgmt.: 54%
  - R&D: 30%
  - Project Manager: 18%

- Top 20 Pharma:
  - Corporate Mgmt.: 25%
  - R&D: 17%
  - Project Manager: 36%

- Generic Pharma:
  - Corporate Mgmt.: 46%
  - R&D: 8%
  - Project Manager: 6%

- Specialty Pharma:
  - Corporate Mgmt.: 9%
  - R&D: 9%
  - Project Manager: 13%

- Emerging Biopharma:
  - Corporate Mgmt.: 8%
  - R&D: 4%
  - Project Manager: 6%

- Virtual Pharma:
  - Corporate Mgmt.: 46%
  - R&D: 30%
  - Project Manager: 14%
How much did your outsourcing spending change in the past year?
(by how much COMMERCIAL manufacturing is outsourced)

Less Than 10%
10%-50%
more than 50%

- 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 COMMERCIAL manufacturing is outsourced)

Less Than 10%
10%-50%
more than 50%

- 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 did your outsourcing spending change in the past year?
(by how much CLINICAL manufacturing is outsourced)

Less Than 10%
10%-50%
more than 50%

- 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 CLINICAL manufacturing is outsourced)

Less Than 10%
10%-50%
more than 50%

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

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 Analytical Testing is outsourced)

How much do you expect your outsourcing spending to change in the next year?
(by how much Analytical Testing is outsourced)
2013 OutSourcing Survey

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

- Less Than 10%
  - 15% 15%

- 10% - 50%
  - 26% 26%

- More than 50%
  - 32% 32%

Key:
- 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)

- Less Than 10%
  - 14% 14%

- 10% - 50%
  - 10% 10%

- More than 50%
  - 38% 38%
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?

Most frequent responses were “None,” followed by “API.”

- API manufacturing
- Finished product manufacturing
- Non-sensitivework
- Intermediate synthesis
- Sterile fill, ophthalmics
- PK or necessary tasks for local registration
- Monitoring, stats, data cleaning
- Parenteral, injectable products, onco-products
- Custom starting material manufacture
- Purchase of API, validated
- Nutrition
- Oral Solid Dose
- Distribution
- IP protection is a concern.
- Phase II or III clinical study
- Development
- Something that I can have great oversight of quality and timelines, such as an IT project
- Non-GLP preclinical studies
- Bulk chemical
- Commercial (final dosage) manufacturing
- Preclinical work
- Anything that is not API or Drug Product
- Research, early development only
- A non-IP protected project — one using their process.
- One that’s likely to have few issues
- Formulations manufacturing
- API for commercial generics
- Clinical trials (BE/BA)
- BE study
- Intermediate supply for APIs
- Softgels and OSD products
- API, RSM, raw materials, critical raw materials
- Commercial API
- Preclinical, non-regulatory projects; chemistry
- Chemical libraries
- non-GXP discovery
- Acetylated polysaccharides and anthraquinone profiles in plant extracts
- API Manufacturing
- Materials for tox studies, intermediates for GMP manufacturing (Phase I-II)
Why Not Outsource?

28% of respondents said that they’d cancelled outsourcing projects in the past year, due to the economic climate. We asked them to describe the projects they delayed.

- Clinical manufacturing and scale-up
- CMC clinical supplies with lower probability of success (and/or higher risks)
- Distribution got short cycled
- The company delayed a development program for a difficult biologic
- Clinical studies
- Product Development
- Portfolio re-prioritization
- Formulation, stability
- Histology
- DP transfers based on slow CMO tech transfer performance
- CMC, Preclinical
- New business development
- Delay manufacture due to slow acquisition of funding
- Formulation development
- Transfer to new CMO
- Pending completion of dissolution profile matching
- Transgenic animal
- API manufacture
- Phase I materials
Would you describe your outsourcing as Tactical or Strategic?

Total

- Tactical: 50%
- Strategic: 50%

- Small/Mid-Tier Pharma: 57% Tactical, 43% Strategic
- Top 20 Pharma: 57% Tactical, 43% Strategic
- Generic Pharma: 53% Tactical, 47% Strategic
- Specialty Pharma: 58% Tactical, 42% Strategic
- Emerging Biopharma: 55% Tactical, 45% Strategic
- Virtual Pharma: 56% Tactical, 44% Strategic
- Corporate Mgmt.: 59% Tactical, 41% Strategic
- R&D: 66% Tactical, 34% Strategic
- Project Manager: 45% Tactical, 55% Strategic
- Purchasing/Sourcing: 55% Tactical, 45% Strategic
- Prod./Mfg/Pkg.: 55% Tactical, 45% Strategic
- QA/QC/Validation: 80% Tactical, 20% Strategic
Would you use the word Partnership to describe your relationship with a Contract Service Provider?

Total

- Yes: 30%
- No: 70%

By Industry:

- Small/Mid-Tier Pharma: 19% Yes, 81% No
- Top 20 Pharma: 19% Yes, 81% No
- Generic Pharma: 47% Yes, 53% No
- Specialty Pharma: 10% Yes, 90% No
- Emerging Biopharma: 27% Yes, 73% No
- Virtual Pharma: 56% Yes, 44% No

By Function:

- Corporate Mgmt.: 41% Yes, 59% No
- R&D: 21% Yes, 79% No
- Project Manager: 45% Yes, 55% No
- Purchasing/Sourcing: 45% Yes, 55% No
- Prod./Mfg/Pkg.: 25% Yes, 75% No
- QA/QC/Validation: 30% Yes, 70% No
Why does your company outsource?

Total
- Temporary lack of capacity: 16%
- Company is virtual: 32%
- Lifecycle management: 16%
- To focus on core competencies: 13%
- To reduce company size: 13%
- Other: 6%

Small/Mid-Tier Pharma
- Temporary lack of capacity: 44%
- Company is virtual: 11%
- Lifecycle management: 28%
- To focus on core competencies: 11%
- To reduce company size: 25%
- Other: 6%

Top 20 Pharma
- Temporary lack of capacity: 10%
- Company is virtual: 50%
- Lifecycle management: 5%
- To focus on core competencies: 10%
- To reduce company size: 25%
- Other: 7%

Generic Pharma
- Temporary lack of capacity: 36%
- Company is virtual: 29%
- Lifecycle management: 14%
- To focus on core competencies: 14%
- To reduce company size: 7%
- Other: 10%

Corporate Mgmt.
- Temporary lack of capacity: 44%
- Company is virtual: 54%
- Lifecycle management: 4%
- To focus on core competencies: 11%
- To reduce company size: 4%
- Other: 11%

R&D
- Temporary lack of capacity: 23%
- Company is virtual: 54%
- Lifecycle management: 8%
- To focus on core competencies: 8%
- To reduce company size: 25%
- Other: 9%

Project Manager
- Temporary lack of capacity: 18%
- Company is virtual: 55%
- Lifecycle management: 8%
- To focus on core competencies: 9%
- To reduce company size: 9%
- Other: 9%

Emerging Biopharma
- Temporary lack of capacity: 27%
- Company is virtual: 37%
- Lifecycle management: 27%
- To focus on core competencies: 13%
- To reduce company size: 25%
- Other: 18%

Virtual Pharma
- Temporary lack of capacity: 88%

Purchasing/Sourcing
- Temporary lack of capacity: 18%
- Company is virtual: 12%
- Lifecycle management: 9%
- To focus on core competencies: 9%
- To reduce company size: 25%
- Other: 22%

Prod./Mfg/Pkg.
- Temporary lack of capacity: 33%
- Company is virtual: 50%
- Lifecycle management: 13%
- To focus on core competencies: 9%
- To reduce company size: 25%
- Other: 22%

QA/QC/Validation
- Temporary lack of capacity: 45%
- Company is virtual: 22%
- Lifecycle management: 22%
- To focus on core competencies: 9%
- To reduce company size: 9%
- Other: 11%
2013 OUTSOURCING SURVEY

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

- Total: 24% No, 76% Yes
- Small/Mid-Tier Pharma: 59% No, 41% Yes
- Top 20 Pharma: 65% No, 35% Yes
- Generic Pharma: 28% No, 72% Yes
- Specialty Pharma: 73% No, 27% Yes
- Emerging Biopharma: 50% No, 50% Yes
- Virtual Pharma: 42% No, 58% Yes

- Total: 28% No, 72% Yes
- Corporate Mgmt: 27% No, 73% Yes
- R&D: 27% No, 73% Yes
- Project Manager: 27% No, 73% Yes
- Purchasing/Sourcing: 27% No, 73% Yes
- Prod./Mfg/Pkg: 85% No, 15% Yes
- QA/QC/Validation: 69% No, 31% Yes
How important are the following factors in your selection of a Contract Service Provider?

- Confidentiality
- Consistency of Performance
- Cost
- Financial Stability
- Geography/Proximity
- GMP
- Innovation
- One-Stop Setup
- Process Optimization
- Quality
- Rapid Availability
- References
- Regulatory Inspection History
- Relationships
- Size of CSP
- Specific Technology
- Timeliness
- Value-Added Services

2013 Outsourcing Survey
How important are the following factors in your selection of a Contract Service Provider?

**Emerging Biopharma**

- Confidentiality
- Consistency of Performance
- Cost
- Financial Stability
- Geography/Proximity
- GAP
- Innovation
- Overall Setup
- Process Optimization
- Quality
- R&D
- Rapid Availability
- Reputation
- Regulatory/Compliance History
- Relationships
- Size of CSP
- Specific Technology
- Timeliness
- Value Added Services

**Virtual Pharma**

- Confidentiality
- Consistency of Performance
- Cost
- Financial Stability
- Geography/Proximity
- GAP
- Innovation
- Overall Setup
- Process Optimization
- Quality
- R&D
- Rapid Availability
- Reputation
- Regulatory/Compliance History
- Relationships
- Size of CSP
- Specific Technology
- Timeliness
- Value Added Services

**Project Manager**

- Confidentiality
- Consistency of Performance
- Cost
- Financial Stability
- Geography/Proximity
- GAP
- Innovation
- Overall Setup
- Process Optimization
- Quality
- R&D
- Rapid Availability
- Reputation
- Regulatory/Compliance History
- Relationships
- Size of CSP
- Specific Technology
- Timeliness
- Value Added Services

**Purchasing/Sourcing**

- Confidentiality
- Consistency of Performance
- Cost
- Financial Stability
- Geography/Proximity
- GAP
- Innovation
- Overall Setup
- Process Optimization
- Quality
- R&D
- Rapid Availability
- Reputation
- Regulatory/Compliance History
- Relationships
- Size of CSP
- Specific Technology
- Timeliness
- Value Added Services

**Corporate Management**

- Confidentiality
- Consistency of Performance
- Cost
- Financial Stability
- Geography/Proximity
- GAP
- Innovation
- Overall Setup
- Process Optimization
- Quality
- R&D
- Rapid Availability
- Reputation
- Regulatory/Compliance History
- Relationships
- Size of CSP
- Specific Technology
- Timeliness
- Value Added Services

**R&D**

- Confidentiality
- Consistency of Performance
- Cost
- Financial Stability
- Geography/Proximity
- GAP
- Innovation
- Overall Setup
- Process Optimization
- Quality
- R&D
- Rapid Availability
- Reputation
- Regulatory/Compliance History
- Relationships
- Size of CSP
- Specific Technology
- Timeliness
- Value Added Services

**Prod./Mfg./Pkg.**

- Confidentiality
- Consistency of Performance
- Cost
- Financial Stability
- Geography/Proximity
- GAP
- Innovation
- Overall Setup
- Process Optimization
- Quality
- R&D
- Rapid Availability
- Reputation
- Regulatory/Compliance History
- Relationships
- Size of CSP
- Specific Technology
- Timeliness
- Value Added Services

**QA/QC/Validation**

- Confidentiality
- Consistency of Performance
- Cost
- Financial Stability
- Geography/Proximity
- GAP
- Innovation
- Overall Setup
- Process Optimization
- Quality
- R&D
- Rapid Availability
- Reputation
- Regulatory/Compliance History
- Relationships
- Size of CSP
- Specific Technology
- Timeliness
- Value Added Services
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, followed “Quality” and “Communication.”

- Quality issues
- Communication and consistency
- Unable to meet obligations
- Waiting too long to communicate a problem
- Contract negotiations from legal perspective (one model does not fit all) and in a few cases inability to meet timelines or technical challenges
- Consistency
- Inflated bills, effectively pressing for unnecessary, out-of-scope work
- Not being forthcoming with bad news as soon as it was known
- Inconsistency and over-billing
- Color change in some finished product in vial packs
- Understaffing, which impacts quality
- Contingency planning
- Closing site that we awarded business to
- Change order requests
- Lack of information
- Not delivering what was promised
- Lack of responsiveness
- Promising more than they can deliver
- They never said “no” even when they were unable to perform services, causing quality or timing issues.
- Transparency
- Delay of final report
- Delays on new product introductions
- Schedule for compliance and Quality and Technical Excellence
- Inability to deliver what was agreed upon
- They over commit and under-deliver; they don’t communicate enough
- Being deceptive regarding how much real experience they have in a particular area
- Response time
- Focus
- Unwilling to work with start ups
- Not delivering on time
- Scheduling
- Quality issues, missed deliveries
- Lack of independent, technical problem-solving skills
- Payment process too slow
- Many do not effectively use provided study designs in preparation of proposals
- Failure to meet timelines
- Maintenance of equipment and facility
- Incomplete documentation
- Non-compliance with timelines
- Compound quality
- Turnover of personnel
- Timeline not met, unprofessional in study design and execution
- Cost and location
- Bandwidth in the quality area
- Frequent change orders
- Lack of commitment to develop a true partnership; their priorities shift to other clients after ensuring they will stand by us
- Poor responsiveness / timeliness
- Cost
- Problems not communicated in a timely manner
- Continuity of contact
- Scheduling
- Occasional lack of insight about the process being performed.
- Timeliness of delivering bad news.
- Not meeting our timelines.
- Consistency
- Falling short on quality and GMP aspects
- I have been extremely happy with the companies we worked with in the past
- When they say, “We are improving our methods/equipment to give you more accurate results,” and don’t mention how inaccurate they were before