Survey Reflects Growing Maturity of CMC Outsourcing

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Chemistry, manufacturing, and controls (CMC) outsourcing is coming of age. This is the clear message from Pharmaceutical Technology and Bio/Pharmaceutical Outsourcing Report’s 2002 survey of outsourcing decision makers. The survey responses show that sponsors not only are embracing outsourcing, but also are using practices to substantially enhance the performance of contract services and increase this segment’s contribution to overall operations.

This e-mail survey was conducted in July 2002, and a total of 69 respondents participated. Respondents represented the full range of CMC and preclinical development areas, but analytical chemistry and manufacturing were the functions most heavily represented. Companies that are considered Big Pharma constituted the majority of respondents.

A strategic alternative

Survey responses confirm that the pharmaceutical industry is acknowledging outsourcing as a legitimate alternative to conducting all processes in house. More than 60% of respondents report that their companies now view outsourcing as “a strategic alternative to in-house operations,” and only 9% of respondents say their companies consider it to be “a necessary evil.” The remaining 30% still regard outsourcing as a way to supplement in-house capacity.

Even though the results show a positive response to outsourcing as a whole, significant differences exist in the perspectives of manufacturing and analytical chemistry respondents. Among manufacturing respondents, 73% view outsourcing as strategic. By comparison, only 46% of analytical chemistry respondents deem outsourcing as strategic, although an equal percentage view it as a source of supplemental capacity.

Sponsor spending on contract services is consistent with the survey respondents’ positive opinions—40% report their outsourcing spending has increased in 2002 over 2001, and 46% say their outsourcing spending in 2003 will increase over that in 2002. Half the respondents indi-
cate that their spending on outsourcing in 2002 is the same as last year, and just 9% are spending less on outsourcing than they did in 2001.

Once again, however, some significant differences are revealed in the perspectives of manufacturing and analytical chemistry professionals. Among manufacturing respondents, 60% report that outsourcing spending is up this year over last. Only 27% of analytical chemistry respondents say they are spending more on outsourcing in 2002—most are spending about the same as last year. Looking ahead to next year, all of the manufacturing decision makers expect outsourcing spending to stay the same or increase. In contrast, 12% of the analytical chemistry decision makers expect outsourcing spending to stay the same or increase. In contrast, 12% of the analytical chemistry decision makers— and 12% of all respondents—see a decline in outsourcing spending in 2003.

Dedicated outsourcing management
Survey results show how sophisticated the pharmaceutical industry’s outsourcing practices are becoming. They confirm that the industry has taken great strides toward establishing a long-term management infrastructure for CMC outsourcing.

Most sponsors see outsourcing management as a full-time job. Nearly 70% of all respondents, including 80% of those in manufacturing, report that their company has established a unit dedicated to managing outsourcing relationships. Typically, these units are multidisciplinary and are staffed by scientific and business (usually procurement and finance) professionals.

Most strikingly, these dedicated groups are spending their time managing a small number of contractors that are receiving a growing portion of the total contract services pie. More than 50% of respondents say formally designated preferred providers are receiving half or more of their company’s contract services expenditures. This trend is consistent across all survey respondent subgroups.

A major reason for funneling work to a small number of preferred providers is to reduce the costs of managing the outsourcing program. Negotiating contracts and conducting audits for a large number of vendors can be extremely expensive, and significant economies can be realized by consolidating providers.

In terms of the cost of managing their outsourcing programs, 52% of respondents say costs are running 10% or less of their total spend, and 48% indicate management costs amount to more than 10% of total spend. Manufacturing outsourcing managers seem to be spending somewhat more than their analytical chemistry counterparts to manage their vendors.

Continuous improvement
Performance improvement is another reason for sponsors to limit their outsourcing activities to a few preferred providers. These relationships are likely to last for several years, so it is worthwhile for the sponsor and contractor to invest in performance measurement ef-
forts and to establish programs and incentives to achieve performance improvement objectives. Continuous performance improvement (CPI) is a fundamental component of outsourcing relationships in other industries, but it has had limited applicability in the pharmaceutical industry because outsourcing historically has been tactical rather than strategic in nature.

The 2002 survey reveals that the tide is turning on CPI efforts—the majority of respondents either have a plan in place or are considering one. The breadth and depth of service offerings are critical. The ability to offer closely related services potentially gives a contractor advantages over smaller, more-focused competitors. This is not a return to the discredited “one-stop-shop” model—having a clinical research capability won’t help a company get more formulation business, but having a

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Implications

The consolidation of sponsor spending to a small number of preferred vendors is a trend with far-reaching implications for the pharmaceutical outsourcing industry. In particular, it is forcing vendors to look at their business models in new ways.
strong analytical chemistry business might. Furthermore, best-in-class providers of individual services (e.g., a large-scale provider of clinical packaging services with worldwide locations and sophisticated technology) will be well positioned because of their ability to meet enterprise-wide requirements.

**Acquisitions drive growth.** Large contractors are seeking acquisitions to broaden or deepen service offerings (e.g., by strengthening liquid chromatography technology, adding off-shore locations, or bringing in new therapeutic know-how). Smaller vendors may need to be acquired because their offerings and financial wherewithal may be too limited to remain competitive.

**Performance trumps capacity.** CROs and contract manufacturers must demonstrate that they can do the job better, faster, and cheaper than their clients and their competitors to remain in the preferred ranks. Simply offering flexible capacity or a one-stop-shop proposition is no longer sufficient.

The move toward preferred contractors affords sponsors the opportunity to measure their own performance against an objective benchmark. Eventually, contractors’ efforts to achieve CPI will raise the standards against which internal operations will be compared, and these efforts may drive sponsors to outsource even more.