

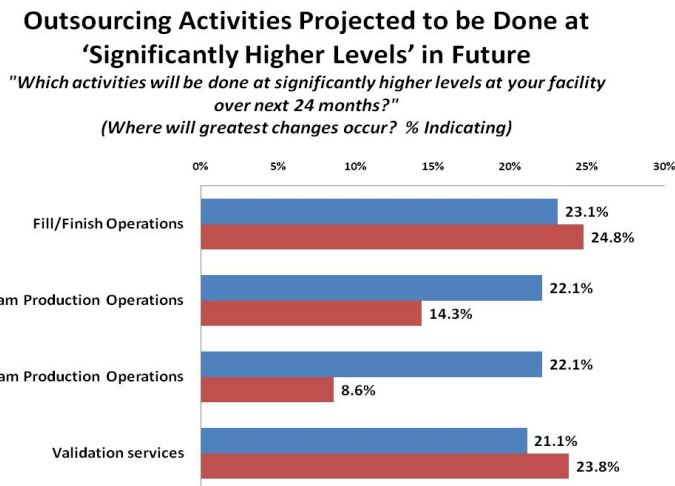
Biopharmas Doubling Critical Outsourcing Operations

By Eric S. Langer

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Outsourcing can allow companies focus on their core competencies. Until recently, however, outsourcing has tended to involve lower end, repetitive tasks. Today, outsourcing shows clear signs of integrating into much higher end, technical activities. BioPlan Associates, Inc.'s just-completed *8th Annual Report and Survey of Biopharmaceutical Manufacturing* [1] returned input from 352 global biomanufacturers. This year, among the 23 outsourcing areas we measured, we found evidence that companies are more aggressively incorporating outsourcing as a manufacturing strategy, rather than as an *ad hoc* method of adding flex capacity, or to simply eliminate overhead costs associated with lower value production activities. Data from the study show a significant spike in the percentage of biopharmaceutical companies projecting outsourcing of upstream and downstream production as an outsourcing activity over the next 24 months (Fig 1). While many manufacturers continue to consider outsourcing to reduce costs, more are considering how they can incorporate up- and down-stream operations as part of their outsourcing strategy.

Fig 1 Selected data: Outsourcing Activities Done at “Significantly Higher Levels” over 24 Months



Source: *8th Annual Report and Survey of Biopharmaceutical Manufacturing, Preliminary Data, February 2011, Publication Date April, 2011, BioPlan Associates, Inc. www.bioplanassociates.com*

Downstream production jumped from 6th place (14.3%) in 2010 to second place this year, with 22.1% expecting these activities to be done at significantly higher levels. Upstream production's leap was even more dramatic with a projected **tripling** of the percentage of companies considering outsourcing these operations, (8.6% in 2010 to 22.1% in 2011). This ties with downstream production, and now ranks near the top of the considered outsourcing activities. If biopharma companies hold to these plans, the landscape of outsourcing will change significantly over the next two years.

This may also suggest that those CMOs willing to invest in the costly expertise required to compete in technically complex outsourcing areas may have opportunities to provide higher-end services to their biopharma clients.

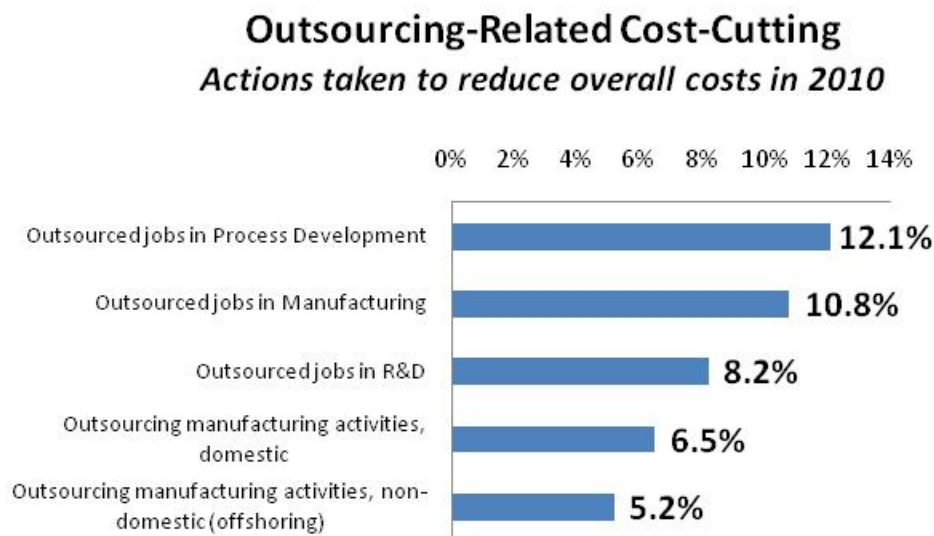
Decision factors extend beyond simply reducing costs, and include speed, flexibility of internal operations, and internal employee placement in higher value positions. Thus, outsourcing decisions, while ultimately centered on financial return on investments, are increasingly being initiated by analysis of value of full-time-employee (FTE) activities, staff allocation, and hiring.

This is consistent with industry CMO experience. According to Dr Michiel Ultee, Chief Scientific Officer at Laureate Biopharmaceutical Services, Inc., “We’ve seen a significant increase in inquiries for higher-end activities such as full-scale development and clinical production of antibodies and fusion proteins. Companies are relying on established CMOs with a track record...and deep scientific understanding.”

Relating Outsourcing to Workforce Reduction

Our study shows that biopharmas see outsourcing as a useful cost-reduction tool that will have direct impact on their overall business strategy. We researched how companies are reducing costs, and found that a significant percentage have been using outsourcing of operational areas during the past 12 months to cut costs.

Figure 2: Cost-cutting Changes (selected areas)



The fact that 12% of the industry outsourced process development activities in 2010 to cut costs is an indication that companies are willing to let go of some of their more critical tasks. Outsourcing of process development, typically an in-house core capability, can be a harbinger of increased integration of outsourced services. Careful selection of an effective CMO with the requisite know-how and observation of industry standards and process can increase the value of outsourcing, and potentially mitigate risks of outsourcing high-level activities.

Although only 6.5% of companies last year actually outsourced or off-shored manufacturing activities, the 24 month projection for increases in higher end manufacturing jobs indicates that the market for these contract activities is likely to expand in the near future.

Outsourcing of manufacturing jobs is a by-product of tightened budgets due to the global economic situation. However, as biomanufacturers use this approach as an economic tool, they also appear to be establishing deeper alliances with their outsourcing partners. The changes reported above and numerous other changes shown in our survey indicate not only growing reliance on outsourcing but growing expectations for what these relationships yield.

According to Morten Munk, VP Business Development at CMC Biologics, a contract manufacturing organization in Copenhagen, Denmark, and Bothell, WA, “More companies are considering outsourcing increasingly more complex production operations, not only during the development phases but also after commercialization of their innovative pharmaceutical products. This is a long-term trend that is creating opportunities, particularly for CMOs with experience in regulatory areas, and those able to perform

technical operation at a high quality level.” This is supported by our report which shows that industry outsourcing for biopharmaceutical manufacture is a long-term trend, with increases expected to continue as the industry adopts project management processes, and establishes the skills needed to manage external relationships. The industry and, particularly client-contractor relationships will continue to mature and become more complex. With these changes will come a more cooperative management and maintenance of outsourcing relationships, which will increase the ability to partner on technically complex projects.

Increasingly, contract management organizations are attempting to position themselves with capabilities in upstream production, downstream purification improvements, and other changes. As a result, outsourcing itself is maturing and positioning itself to become an increasingly essential part of R&D and manufacturing strategies.

Additionally, biopharmaceutical manufacturers are looking to outsourcing to address chronic issues that have been growing in importance over nearly a decade, including the costs of downstream operations, the need for real-time process monitoring.

Strategic Planning, Not a Band-aid Approach

Hiring a CMO can provide a strategic advantage, particularly if the task requires specialized expertise, equipment and infrastructure maintained by the contractor. For small companies, outsourcing the manufacture of biologics may be the only way to get their drugs to market. In some areas adoption of the use of biodisposables has expanded CMOs’ capabilities to provide advantages and options not available in-house. Therefore, drug manufacturers are tending to view contract manufacturing and outsourced services more as an asset to drive strategic decisions than as simply a way to save money.

The rise of outsourcing has resulted in many companies establishing centralized contracting groups to handle the complex and time-consuming business of selecting and managing partners. This allows a greater consistency in evaluating the progress on projects and reduces start-up times. As the use of outsourcing partners becomes more embedded into the strategy of companies, effective management of the contract by pharmaceutical companies will become a more critical issue.

In summary, incentives that point to more technical outsourcing include:

- Need for access to enabling technology (e.g. expression systems, downstream processing)
- Lack of internal expertise (available staff or specialized expertise)
- Need to control budgets and funding
- Increased capacity needs
- Response to competitive pressures
- Urgency: time-to-market (smaller companies)

Companies are increasingly turning to outsourcing to control costs and to manage their internal staff and resources. Although economic conditions today are easing, organizations continue to evaluate their core competencies and decide how they will direct their R&D and manufacturing resources. The outsourcing of processes enables focus on a company’s skill base and its core competencies, as well as yielding economic benefits. As CMOs offer expertise, tools and capacity that biopharma companies don’t have in-house—or that they elect to outsource as part of their strategic planning--it will increasingly become less about direct cost savings, and more about doing things better and more competitively.

[1] 8th Annual Report and Survey of Biopharmaceutical Manufacturing, Preliminary Data, Publication Date April, 2011, BioPlan Associates, Inc.
www.bioplanassociates.com