

Bio/pharma outsourcing: Strategic initiative, or just passing off low-end jobs

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Eric S. Langer
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The Shift to Strategic Outsourcing

Most companies today recognize the strategic necessity to use their internal resources more efficiently. Outsourcing as a tool has been proven to permit greater focus on core competencies. In biopharmaceutical manufacturing, outsourcing complex activities can offer advantages beyond just cost effectiveness. However, even as outsourcing increases, the activities being outsourced, according to our most recent industry study, appear to be advancing more slowly.

Our recently released 7th Annual Report and Survey of Biopharmaceutical Manufacturing[1] returned input from 327 biomanufacturers globally. This year we found evidence that companies are only now beginning to use outsourcing as a manufacturing strategy, rather than an *ad hoc* to add flex capacity, or to eliminate lower value production activities. Today, outsourced projects can cover all areas of R&D, manufacturing, testing and services, and are beginning to be used for higher end activities that focus a company's skill base on core competencies, rather than simply controlling costs, or filling temporary gaps in capacity.

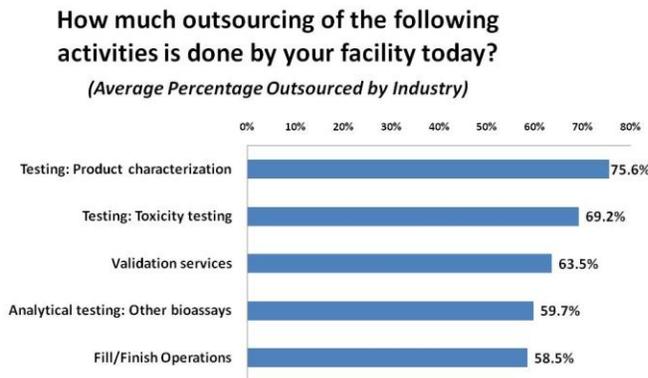
Larger pharmaceutical companies, with more flexibility, are modifying their outsourcing approach to determine which functions can realistically be outsourced. Decision factors extend beyond simply reducing costs, and now include speed, flexibility of internal operations, and internal employee placement 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.

Activities Being Outsourced

Essentially all biopharmaceutical developers sooner or later use the services of CMOs, whether for manufacture of clinical or commercial supplies, or for testing, fill-finish or other outsourced activities. However, outsourcing today continues to be dominated by relatively lower value-added services, such as fill-finish and product characterization testing. The use of biopharma CMOs has become common, particularly for mammalian cell culture, but developers are continuing to retain some manufacturing in-house, i.e., relatively few are outsourcing all of their manufacturing needs. CMOs involved in manufacturing approved products for commercial sales are also increasing, as are the activities in which they are involved. Outsourcing activities today continue to consist of relatively lower value-added services,

such as fill-finish and product characterization testing. Among the 24 areas of outsourcing testing in the study, we found that the primary outsourced activity today is product characterization testing, with biopharmaceutical companies outsourcing an average of 75.6% of this activity [See Fig. 1]. Toxicity testing (69.2%) and validation services (63.5%) were next on the list. At the other end of the scale, there appeared to be relatively low outsourcing activity, percentage-wise, for API biologics manufacturing and project management services. In some cases, CMOs are being asked to perform basic process design, scale-up, equipment selection, quality control testing and other key aspects, such as validation and support for regulatory approvals.

FIGURE 1: Selected Results: Percent Outsourcing Activities Done Today



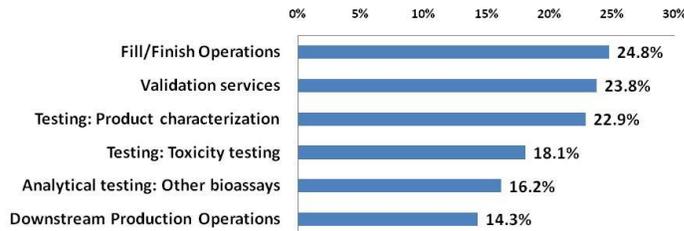
Source: 7th Annual Report and Survey of Biopharmaceutical Manufacturing, www.bioplanassociates.com

Where is Outsourcing Increasing?

In our global study, we tested 24 different areas of outsourcing today. We found that manufacturers are evaluating and planning to outsource an increasing number of operations tasks to maintain productivity. This is especially true for current activities typically outsourced. For example, 25% of respondents to the study will be outsourcing significantly more ‘Fill/finish operations’ over the next 24 months than is currently done (Figure 2). Following are ‘validation services’ and ‘product characterization testing’ (24%, and 23% of respondents, respectively) indicated this is where the greatest changes will occur in their outsourcing. Other areas of substantial growth include toxicity testing and downstream production operations, (where 18% and 14% of facilities, respectively, will see substantial changes).

Figure 2: Selected Outsourcing Activities Projected to be Done at ‘Significantly Higher Levels’.

FUTURE OUTSOURCING GROWTH
 Which outsourcing activities will be done at *significantly higher* levels at your facility over next 24 months? (*Where will greatest changes occur?*)
 (Percent Indicating)



Source: 7th Annual Report and Survey of Biopharmaceutical Manufacturing; Other areas tested include: Downstream Process Development, Testing: Lot release, Media optimization, Cell line development, API biologics manufacturing, Contract manufacturing of biologics, Upstream Process Development, Regulatory services, Testing: Cell line stability, Environmental monitoring services, Design of Experiments (DoE), Testing: Host cell protein analysis, Plant maintenance services, Upstream Production Operations, GMP Training, Contract Research (laboratory), QbD Services

Virtually all areas of R&D and manufacturing are now being considered as options for outsourcing and the impact of this is being felt on a global basis, with emerging markets ranking favorably alongside established markets as outsourcing destinations.

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.

Risk Analysis for Outsourcing Activities

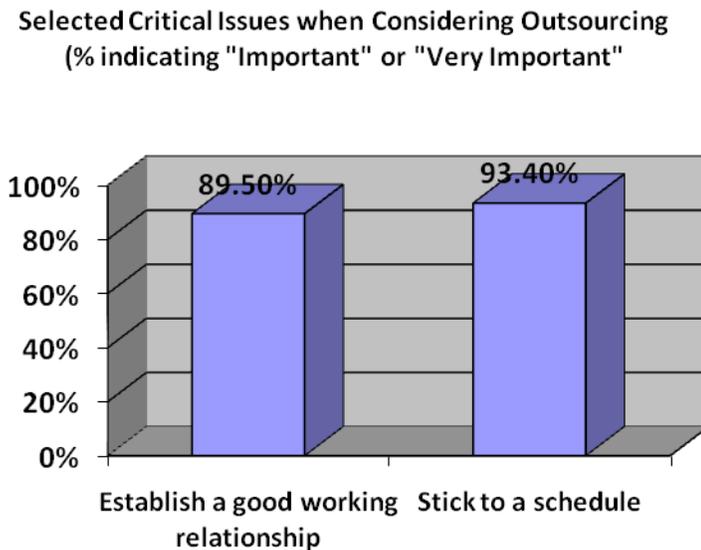
Outsourcing is on the rise, and the same reasons companies have always outsourced still apply, notably saving costs and time, increased flexibility, convenience, and relying on specialists with needed expertise and infrastructure in place. Biomanufacturers are evaluating their outsourcing relationships based on more rigorous risk analysis. Today, most expect to work more efficiently and establish CMO relationships that allow this. Companies are creating internal models to evaluate the thousands of different items involved in manufacturing and operations, and assessing risks of working with an external service provider. Some major companies today use a rating system to assess the risk of outsourcing. This approach can help funnel the decision making to a relatively few items that may ultimately be outsourced. As companies attempt to assess more than the monetary expenses, they are including the overall risks of working with a CMO. Using in-house rating systems, risks can be measured and weighed, quality standards can be compared, and decisions can be increasingly made on relationship management and overall probabilities of successful outcomes.

Clients' Outsourcing Problems

Biomanufacturers (clients) this year continue to be stressed over the issues that have concerned them the past 7 years that we have been measuring these factors. Among the 25 factors we evaluated, relationship issues continue near the top of the lists. And although the relationship trend improved slightly this year, they are far from optimal. CMOs have moved the "Establishing a good working relationship" factor from

63% seeing it as “Very Important” last year, to 58% this year (Fig 1 shows % indicating factor as “Important” or “Very Important”).

**Figure 3: Top 2 “Critical Issues” when Outsourcing
Respondents indication factor “Important” or “Very Important”**



Source: 7th Annual Report and Survey of Biopharmaceutical Manufacturing Capacity, April 2010, BioPlan Associates, Inc. Rockville, MD www.bioplanassociates.com

According to Mark Mazzie, Managing Director at Center for Professional Innovation and Education, (Malvern, PA), “The recent increase in pharmaceutical outsourcing activities is creating headaches at pharma companies. This is especially true for companies that haven’t trained their managers to manage these new relationships, or to understand how time-consuming and difficult offsite managing can be. With the current economic crunch, everyone is being asked to do more with less, so these problems are likely to increase unless personnel are given the requisite skills to manage these tasks.”

In addition to the relationship issues, we are seeing operational concerns. For example, this year concerns about compliance with quality standards jumped to 64% from 59% last year (% respondents indicating the factor as “Very Important”). These quality issues may be the result of worries about possible cost-cutting and service reductions on the part of CMO vendors. Biologics manufacturers may not yet be sufficiently confident that their outsourcing partners can guarantee quality standards.

“Protecting intellectual property” was also seen as critical by 60% of respondents this year. These IP concerns may be showing up due to increased interest in offshore (international) outsourcing. Worries about handling cross-contamination issues, again this year, jumped significantly, from 20% in 2007, to 52% last year, and 58% this year.

CMO Industry Shifts

This year, nearly one-half (48.2%) of surveyed biopharmaceutical manufacturers noted that they expect to increase their budgets for biopharma CMO outsourcing. As more companies outsource, the need for effective project management will grow. In times when there was less available capacity, CMOs with better technologies, expertise, and facilities, would have simply been too busy and pre-booked, to handle new clients. Many of these shifts are the result of financial pressures. Outsourcing drivers are changing, and financial pressures are creating real concerns over hiring and staff allocation. Not only do outsourcing service providers need to justify the cost benefits, now they need to evaluate the impact of outsourcing on FTEs, staff allocations, and speed to project completion.

Conclusions

Pharmaceutical companies continue to define their own internal core capabilities. As the global economic situation continues to keep purse strings tight, outsourcing will become more embedded as a strategic manufacturing consideration. Low-level activities will continue to be outsourced, but as biomanufacturers evaluate what they should and shouldn't keep in-house, they will establish deeper alliances with their outsourcing partners, and will continue to expect more out of these relationships. Our Report 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 mature approach to managing the outsourcing relationship.

Survey Methodology: This seventh in the series of annual evaluations by BioPlan Associates, Inc. yields a composite view and trend analysis from over 327 responsible individuals at biopharmaceutical manufacturers and contract manufacturing organizations (CMOs) in 35 countries. The methodology also encompassed an additional 117 direct suppliers of materials, services and equipment to this industry. This year's survey covers such issues as: current capacity, future capacity constraints, expansions, use of disposables, trends and budgets in disposables, trends in downstream purification, quality management and control, hiring issues, employment and training. The quantitative trend analysis provides details and comparisons of production by biotherapeutic develops and CMOs. It also evaluates trends over time, and assesses differences in the world's major markets in the U.S. and Europe.

References

[1] 7th Annual Report and Survey of Biopharmaceutical Manufacturing Capacity and Production, BioPlan Associates, Inc, Rockville, MD, 2010 Preliminary Data

About the Author:

Eric S. Langer is president and managing partner at BioPlan Associates, Inc., a biotechnology and life sciences marketing research and publishing firm established in Rockville, MD in 1989. He is editor numerous studies, including "Advances in Large-scale Biopharmaceutical Manufacturing, 2nd Ed", and publisher of industry reports. elanger@bioplanassociates.com 301-921-5979.
www.bioplanassociates.com

