Issue Date: August 2012
General Area: Pharma Outsourcing
Journal: Pharmaceutical Technology
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Outsourcing Becoming More Strategic

Budgets generally flat, but increasing for key outsourcing operations

By Eric S. Langer

Planning and decision-making for the manufacture of biopharmaceuticals are becoming more complex as companies continue to implement cost-saving efforts, including outsourcing many support and even critical tasks. Increasingly, companies must make difficult strategic decisions about commercial manufacture earlier in product development. In our *9th Annual Report and Survey of Biopharmaceutical Manufacturing[1]*, we found that essentially all biopharmaceutical developers use outsourcing services of some kind, whether for manufacture of clinical or commercial supplies, for process development, R&D, assay services, or for fill-finish or a wide variety of other outsourced activities. Biopharma companies have become increasingly more comfortable with outsourcing of manufacturing. Further, as outsourcing and off-shoring become part of mainstream operations strategy, companies are becoming increasingly comfortable with their ability to model and assess the value being delivered by their outsourcing partner. As such, clients are expecting more value from their outsourcing partners.

Outsourcing Becoming More Strategic

Outsourcing, including contract manufacture, continues as a major trend. However, our study data, which includes responses from 302 global biomanufacturers in 29 countries, indicate the rate of outsourcing is slowing. Industry is running out of tasks susceptible to outsourcing that have not already been outsourced. But bright spots are growing. For example, as biosimilars and biobetters enter the major global markets, many of these developers can be expected to use CMOs for manufacture. Thus, the number of marketed products manufactured by CMOs will likely grow in coming years.

Companies that formerly eliminated in-house capabilities are now taking a more rational approach – carefully evaluating and weighing options from a longer-term perspective. Our study this year indicates that investment by companies toward rebuilding in-house manufacturing capacity is increasing.

In addition, large Chinese and Indian companies and other countries are developing commercial-scale biopharmaceutical manufacturing facilities to serve domestic and regional needs. Eventually, biopharmaceutical manufacture will start to be outsourced to developing countries,

although it will likely be many years, perhaps a decade. These countries lack the needed critical mass of facilities, knowledgeable and cGMP-experienced staff, information and quality systems, institutional know-how, and business culture required for full U.S./EU cGMP biopharmaceutical manufacture. We can expect increased use of developing country-based CROs and CMOs, but primarily to support pre-commercial R&D.

However, many developing countries are beginning to develop domestic biopharmaceutical manufacturing capabilities (see our analysis at www.top1000bio.com). This is already happening with many vaccines, with developing countries increasingly supporting development of their own vaccine manufacturing capacity. While much of this foreign expansion into biopharmaceuticals involves biogeneric versions (copies) of innovator products, some foreign companies are developing their own fully innovative biopharmaceuticals

Budgets for Outsourced Operations Flat or Declining

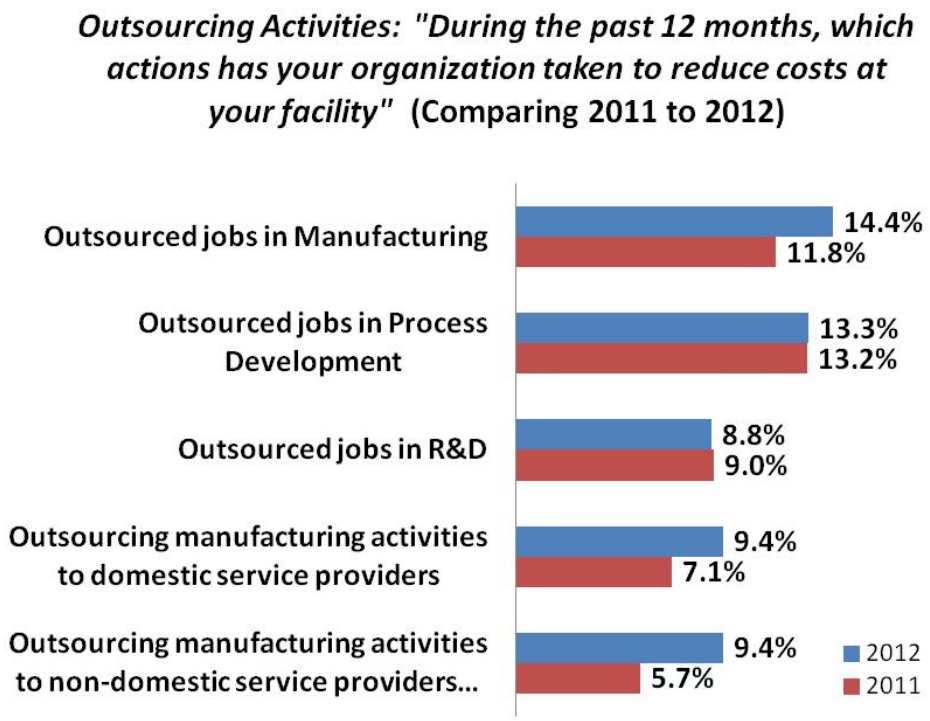
This year, we are continuing to see clear evidence that budgets are bouncing back, and all areas, except outsourced manufacturing, are increasing again this year. This is a change from two years ago where budgets showed *decreases* in areas ranging from production, hiring new scientific staff, and new facility construction.

However, in a separate question, we asked respondents to indicate how their spending on outsourcing will change over the *next* 12 months, in both R&D and for manufacturing. On average, budgets for future outsourcing at individual facilities will see a moderate overall increase (9.3% over the next 12 months). These budget increases may be focused on the key outsourcing areas (see below), rather than broadly across all operations. While a majority indicated no change in budgets, only 7.1% reported expecting any decrease in outsourcing spending.

Cost Cutting Not a Factor in Outsource Decision Making

We evaluated how companies are addressing cost issues in biopharmaceutical manufacturing. When we break out the data and focus on how outsourcing has played a role in cost containment, we found that virtually all outsourcing activities ranked in the bottom quarter of measured factors. There was a reported increase in outsourcing jobs in manufacturing, 14.5% this year, up from 11.8% last year. And 13.3% of respondents reported that outsourcing jobs in process development was one action taken over the past 12 months that resulted in reduced costs. This was followed by outsourcing jobs in R&D (indicated by 8.8%). Outsourcing manufacturing activities to both domestic and non-domestic service providers (offshoring) had an impact on the smallest percentage of respondents, 9.4%, during the past year.

Fig 1: Selected Cost-Cutting Changes, Outsourced Jobs, by Segment, and Geography



Source: 9th Annual Report and Survey of Biopharmaceutical Manufacturing, April 2012, BioPlan Associates, Inc. www.bioplanassociates.com

Critical Outsourcing Operations

Outsourcing can allow companies to focus on their core competencies by removing lower end, repetitive tasks from their operations. Today, some outsourcing is also being integrated into higher end, technical activities. This year, our study evaluated the 23 key outsourcing areas in biomanufacturing. We found evidence that companies are 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 also show a spike in the percentage of biopharmaceutical companies projecting outsourcing of analytical testing, validation services, and fill-finish.

Increased Outsourced Activities, 24-month Projections

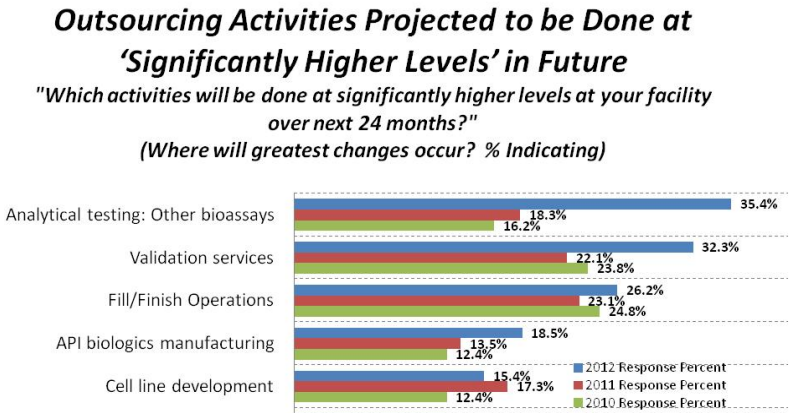
We evaluated 24 different areas associated with outsourced operations and asked respondents which activities will be outsourced "more often" over the next 24 months. We found, for example, that 35.4% expect to increase outsourcing of analytical testing/bioassays. Following are 'validation services' (32.3% this year, 22.1% last year and 23.8% in 2010) indicated this to be where increases will occur in their outsourcing. Also, 26.2% of biomanufacturers will be outsourcing significantly more 'Fill/finish operations' over the next 24 months than is currently done (compared to 23% last year and 25% in 2010). Other areas of substantial growth include API biologics manufacturing, cell line development, testing for lot release, and toxicity testing.

When we compare prior years' projections, and outsourcing trends where respondents believed they would be outsourcing *significantly more* projects, we see an increasingly large jump in

"analytical testing: other bioassays". We believe much of this increase relates to product characterization, including for biosimilars, for example.

Significant recent increases are seen with analytical testing/bioassays, validation services and to a lesser extent, fill-finish and toxicology testing. Significant recent *decreases* are seen with many more activities, including downstream production operations; testing/product characterization; media optimization; upstream production operations; regulatory services; upstream process development; and testing cell line stability.

Fig 2: Selected Outsourcing Activities Projected to be Done at 'Significantly Higher Levels' in 2 Years, 2010 - 2012 Trends



Future Projections

The biopharma industry continues to focus on productivity, efficiency, getting more out of existing internal resources, and maximizing performance from their provider relationships. Outsourcing plays a role in this equation as companies recognize the strategic necessity of using internal resources more efficiently, while outsourcing activities that are not part of their core competencies. While outsourcing can improve overall efficiency and reduce costs, the management of relationships continues to be challenging, and necessitates CMO/CRO flexibility to meet clients' shifting needs. This change in relationship management will likely require time as the industry settles in to the current economic, hiring, and budgetary realities.

Today, most areas of R&D and manufacturing are at least being considered for outsourcing and the impact of this is being felt on a global basis. Emerging markets are becoming increasingly favorably evaluated alongside established markets as potential outsourcing destinations. And while developing country destinations may not find substantial growth in the short term, their long term future is fairly clear. With huge domestic populations, for example, India and China will need to produce biologics for their local populations. Some of this experience, at some point in the near future will find outsourced operations making inroads into Western markets.

Data from this study shows that biopharma CMOs are expanding their manufacturing competence through the use of novel technologies, single-use/disposable bioreactors and other differentiated bioprocessing services. Expansions are resulting in increased adaptability, lower costs, faster turnaround and higher yields. For clients, this means that more CMOs will likely meet their needs (more competition, more choice) and the costs for using CMOs for product manufacturing are becoming at least slightly more competitive. Biologics manufacturing is inherently very complex, and companies are becoming more aware of the value of experienced CMOs as a provider of expertise, as well as a back-up manufacturer, with 'flex' capacity.

References:

1. 9th Annual *Report and Survey of Biopharmaceutical Manufacturing Capacity and Production*, April 2012, Rockville, MD www.bioplanassociates.com

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Survey Methodology: The 2012 Ninth Annual Report and Survey of Biopharmaceutical Manufacturing Capacity and Production in the series of annual evaluations by BioPlan Associates, Inc. yields a composite view and trend analysis from 302 responsible individuals at biopharmaceutical manufacturers and contract manufacturing organizations (CMOs) in 29 countries. The methodology also included over 185 direct suppliers of materials, services and equipment to this industry. This year's survey covers such issues as: new product needs, facility budget changes, current capacity, future capacity constraints, expansions, use of disposables, trends and budgets in disposables, trends in downstream purification, quality management and control, hiring issues, and employment. The quantitative trend analysis provides details and comparisons of production by biotherapeutic developers and CMOs. It also evaluates trends over time, and assesses differences in the world's major markets in the U.S. and Europe.

NOTE: IMPORTANT TO INCLUDE THIS SO READERS UNDERSTAND HOW THE STUDY WAS CONDUCTED