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Pharmaceutical Outsourcing Trends: The Next Decade

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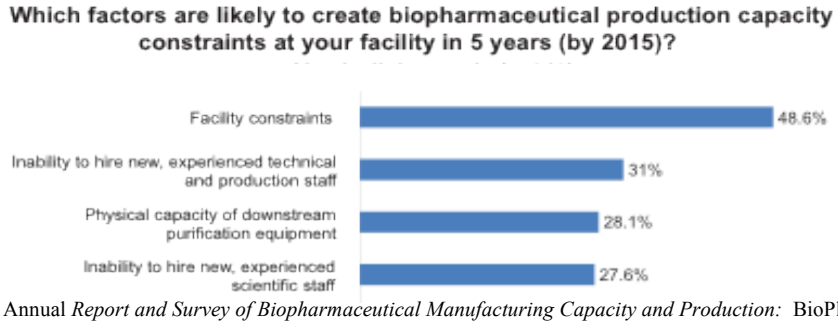
Pharmaceutical industry outsourcing, particularly for CROs and CMOs, has grown over the past ten years, and indications are that it will continue to grow through the next decade. Entire new outsourcing industry sectors, such as high-throughput screening services, have become multi-billion-dollar industries, and many functions formerly considered essential, such as in-house animal toxicology testing, now rarely exist within pharmaceutical companies. Pharmaceutical developers and manufacturers of all sizes, but particularly the largest international companies, now routinely outsource many tasks and functions formerly considered in-house core competencies. The underlying nature of the pharmaceutical industry has changed as cost management and process efficiencies become critical to survival. Outsourcing has become an industry norm, and now includes the full range of corporate activities –from screening and lead identification, to toxicology and other preclinical studies, clinical trials, marketing and manufacturing at all scales.

Outsourcing has proven effective at reducing operational and infrastructure costs. During this period, however, the pharmaceutical industry has seen a significant reduction in its R&D efforts and new product pipelines. This has caused many firms to implement further internal cut-backs and increase their outsourcing, as a way to reduce payroll and capital expenditures. This economics-driven increase in outsourcing has, in some ways, contributed to decreased long-term industry productivity. But even if outsourcing is ultimately proven not to be cost-effective in terms of supporting innovation and new product R&D, outsourcing will continue to experience growth. It is often the only option available to companies that must adapt to lower profits due to ailing R&D pipelines and products going off-patent.

Pharmaceutical outsourcing will continue to increase throughout the next decade, but at a lower rate than in the past. Our annual biomanufacturing report shows that the top factors likely to create capacity (production) constraints are economics driven, including facility constraints, inability to hire experienced technical staff, and physical capacity of equipment.

Figure 2: Selected Factors Creating Future Capacity Constraints



Source: 8th Annual *Report and Survey of Biopharmaceutical Manufacturing Capacity and Production:* BioPlan Associates, April 2011, 490 pages.

The study also evaluated 24 areas of outsourcing, with the primary outsourced activities included product characterization testing (70% of companies outsourcing at least some of this activity). Other tasks now routinely outsourced include validation services (69%), toxicity testing (65%), analytical testing (61.1%) and fill/finish operations (60.0%).

Currently, at about $25 billion annual revenue, pharmaceutical outsourcing will likely to grow at around 10% annually to over $40 billion/year in 5 years and about $60 billion in 10 years. The pharma industry now appears to be slowly recovering and is starting to invest more in R&D. Our recent annual survey has also found that budgets for R&D and manufacturing are again rather uniformly increasing at a healthy rate; and many analysts project rosy futures for CROs/CMOs as industry R&D and manufacturing activity picks up.

Much of the growth in outsourcing in the past decade, particularly the most dramatic and rapid growth, has taken place in developing countries, particularly China and India. Besides developing countries offering lower costs, these countries have their own rapidly growing domestic pharmaceutical markets and industries. Many of the largest global pharma companies invest billions in establishing their own R&D centers and/or outsourcing to CROs/CMOs in these countries. This provides access and a corporate presence in these rapidly growing markets. However, as the wage gap in these emerging economies narrow, labor and other outsourcing costs are increasing. In the future, we will shifts in outsourcing to lesser-developed countries. At the same time, Chinese and Indian firms will shift to competing more on technology and quality, rather than price.

Throughout the next decade we will continue to see a shift toward developing biopharmaceuticals rather than drugs, with these products offering increased profits and protection against eventual generic competition. Many profitable recombinant protein and antibody products are coming off-patent. Over the next decade, there will be a dramatic increase, likely a doubling, in the number of biopharmaceutical products as biosimilar, biobetter and biogeneric versions of current products enter world markets.

The Future: Much of the R&D and manufacturing of these new biosimilar products will be performed by CROs and CMOs that focus on productivity and cost-savings. Technological advances are making it easier and cost-effective to outsource manufacturing, including the use of disposable bioprocessing systems rather than more expensive fixed stainless steel systems. Advances in screening and analytical testing are also driving outsourcing to firms providing these increasingly specialized and resource-intensive services. As documented in the *Top 1000 Global Biopharmaceutical Facilities Index* (www.top1000bio.com), the increase in worldwide CMO and other bio/pharmaceutical outsourcing in the past decade will certainly continue through the next decade.

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 of numerous studies, including "Biopharmaceutical Technology in China," "Advances in Large-scale Biopharmaceutical Manufacturing", and many other industry reports. elanger@bioplanassociates.com 301-921-5979. www.bioplanassociates.com

Survey Methodology: The 2011 eighth 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 352 responsible individuals at biopharmaceutical manufacturers and contract manufacturing organizations (CMOs) in 31 countries. The methodology also encompassed an additional 186 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.