

**For Immediate Release**

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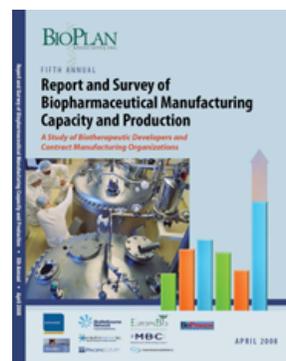
## **Biopharmaceutical Manufacturing Capacity to Increase 66% in Europe by 2012, According to New Report**

Recent Study Provides Analysis of Worldwide Biomanufacturing

May 2008 (Rockville, MD) – Production capacity for biopharmaceutical manufacturing will expand an average of 46% over the next five years for mammalian production systems, according to a new report by BioPlan Associates.

The jump will be even more significant in Europe, where the average increase will reach 66% over the next five years. In comparison, US manufacturers will increase capacity only 36%.

The recently released report, *“5th Annual Report and Survey of Biopharmaceutical Manufacturing Capacity and Production,”* from BioPlan Associates, Inc. provides an on-going analysis of worldwide biomanufacturing, with data from 434 biopharmaceutical developers & contract manufacturing organizations from 32 countries.



In addition, 126 industry suppliers provided supporting data, and eight Subject Matter Experts provided in-depth analysis. The quantitative trend analysis provides details and comparisons of production by biotherapeutic developers and contract manufacturing organizations (CMOs). It also evaluates trends over time, and assesses differences in the world’s major markets in the US and Europe.

### *Capacity Expansion*

“A major factor impacting production capacity expansion over the next five years will be the need for improved downstream purification performance,” according to Eric Langer, president and managing partner at BioPlan Associates. “In fact, over 54% of European respondents and 46% of US respondents to the survey indicated this would be a critical issue.”

The report also found that for CMO respondents, the need for downstream improvements was an even greater factor than for the drug innovators (downstream bottlenecks were indicated as a major capacity constraint by 46% of CMO’s compared with 28% of drug innovators). In addition, other key areas to address to avoid capacity constraints included: the need for better disposable products, optimizing upstream performance, and standardizing international regulatory processes.

This year’s report coverage includes:

- Capacity, production, and outsourcing
- Downstream purification problems and issues
- Current industry bottlenecks
- Capacity utilization and current production levels
- How capacity bottlenecks are being resolved
- Projected capacity bottlenecks
- Production trends and implications for industry
- Outsourcing trends
- Disposables: Spending growth; applications; reasons for increasing/ restricting use; budgets; vendor satisfaction
- Range of titres in biomanufacturing
- Batch failure rates
- Selecting a CMO
- PAT implementation issues
- Hiring and employment growth
- Industry supplier growth rates

### *Capacity Utilization*

Overall capacity utilization by the biopharmaceutical industry has continued to decline since 2003. The decrease is a result of continued industry expansion, improvements in yield at existing facilities, and efficiencies associated with production. Despite this, the report indicates that some segments of the industry, including larger biopharmaceutical developers, continue to experience capacity constraints.

“Over the past four years, the percent of operating capacity at which respondents’ facilities are operating has declined by 9% annually for mammalian cell culture systems, and by 13% for microbial fermentation.” notes Langer. “Capacity utilization has been particularly weak for US manufacturers using microbial fermentation systems. As a comparison, the US Federal Reserve Statistical Release showed that capacity utilization for all US industries in March 2008 was 80.5%.”

### *About BioPlan*

BioPlan Associates, Inc., is a life sciences publishing and market research organization and has provided market studies and research to biopharmaceutical, biotechnology, and healthcare companies since 1989. For more information about BioPlan Associates, Inc., please visit our website at <http://www.bioplanassociates.com>.

Please call 301-921-9074 to arrange interviews with Eric Langer or for graphics related to this report and data.

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