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Biopharmaceutical Manufacturing Capacity to Increase 48% by 2010 According to New Report

October 3, 2005 (Rockville, MD) – The production capacity for biopharmaceutical manufacturing will expand an average of 48% over the next five years for mammalian and microbial production systems, according to a report by BioPlan Associates. The industry's current five-year projection of production capacity expansion is now significantly lower than in 2003. In that year, the first survey's five-year projection indicated capacity would expand 69% by 2008.

The recently released report, "*3rd Annual Survey of Biopharmaceutical Manufacturing Capacity and Production,"* from BioPlan Associates, Inc. provides details and comparisons of production by biotherapeutic developers and contract manufacturing organizations (CMOs).

Capacity Expansion
"A major factor impacting production capacity expansion over the next five years will be the lack of trained and experienced production staff," according to Eric Langer, president and managing partner at BioPlan Associates. "In fact, nearly 40% of the respondents to the survey indicated this would be a critical issue."

The report found that for CMO respondents, a major factor is expected to be lack of financing for production expansion (indicated by 52% of CMO respondents). Key areas to address to avoid capacity constraints included: Optimizing cell culture systems to increase upstream performance (noted by 54.2% of respondents) and improving downstream purification performance (43.8%).

According to Howard Levine, of BioProcess Technology Consultants, a co-author of the report, "Of the respondents engaged in biopharmaceutical manufacturing using mammalian cell culture, approximately 11% indicated their production capacity was greater than 75,000 liters. In 2002-3, only three companies had greater than 50,000 liters of mammalian cell culture capacity."

Areas covered in the study include: Current and future capacity constraints; industry capacity utilization (CMO and biotherapeutic developers); production capacity, factors impacting future production; areas to address to avoid capacity constraints; capacity utilization; capacity expansions by 2010; outsourcing; disposables usage and spending on

disposables; downstream purification issues; training in biomanufacturing; suppliers' sales growth rates.

Capacity Utilization
Recently, overall capacity utilization by biopharmaceutical developers and contract manufacturers has declined. In 2005 use of existing capacity decreased 8% compared to 2003. The decrease is a result of continued industry expansion, and improvements in yield at existing facilities. Despite this, some segments of the industry, including larger biopharmaceutical developers, continue to experience capacity constraints.

"In addition to industry expansion, a significant factor reducing the demand on capacity is that biopharmaceutical developers are seeing results from efficiency-based R&D aimed at producing greater yields," notes Langer. "This has two effects. It can open existing capacity for organizations like CMOs, and it can reduce the requirements for additional capacity for producers who can expand into the extra capacity generated by the efficiencies."

Capacity utilization for all biomanufacturers using mammalian cell culture systems is currently 68.8%. Capacity utilization for microbial fermentation is 60.5%. As a comparison, the US Federal Reserve Statistical Release showed that capacity utilization for all US industries in July 2005 was 79.7%.

The annual study includes responses from 187 biopharmaceutical developers and CMOs from 23 countries. BioPlan Associates, Inc., has provided market assessment and research to biopharmaceutical, biotechnology, and healthcare companies since 1989. BioPlan Associates, Inc. 15200 Shady Grove Road, Suite 202, Rockville, MD 20850 Tel: 301-921-9074 (www.bioplanassociates.com).

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