

**GEN**

**Topic: Bioreactors**

**Due: 11 July 2012**

**BioPharma Industry Gives the Nod to Single-Use Bioreactors:  
44% Would Use Batch Fed Single-Use Bioreactors at Commercial Stage**

Improvements to bioreactors are being introduced rapidly for single-use applications, perfusion, fixed systems, and other technologies. To assess how the industry will be adopting and using some of these new technologies, at both clinical and commercial manufacturing scales, we asked more than 300 biomanufacturers their approaches to adoption of these new technologies.

The results, contained in our 9<sup>th</sup> *Annual Report and Survey of Biopharmaceutical Manufacturers*, suggest that biologics currently in the pipeline will likely be made in single-use, disposable bioreactors. Respondents indicated a clear preference for these devices and it is likely they will be overtaking fixed, stainless facilities in the near term.

One of the questions in this year's study asked respondents to specify the bioreactor types they would specify for a new facility for *clinical* or *commercial* scale biologics manufacturing, planned for operation two years from now.

Indeed, for clinical scale, two-thirds (66.9%) of our respondents would expect to implement batch-fed single use bioreactors. This compares to 31.4% who would choose batch fed stainless steel bioreactors. With single-use bioreactors already dominating many areas of pre-commercial, including clinical supplies, manufacturing market, it is no surprise that these would be predominantly specified for future clinical manufacture.

However, it is notable that only slightly more than half (53.5%) would specify batch-fed stainless steel bioreactors for commercial manufacture, as batch-fed stainless steel currently dominates the commercial stage. This result may indicate an increased willingness on the part of the industry to adopt single-use systems or otherwise abandon batch-fed stainless steel systems for commercial manufacture. In fact, a significant 44.2% said they would specify single-use batch-fed bioreactors for future commercial manufacture. This result may be impacted by the industry's general perspective, also identified in our global study, that the vendors and new product innovators of single-use devices will resolve some of the nagging problems associated with adoption. These include leachables and extractables concerns, standardization issues, and breakage problems.

**Perfusion Bioreactors**

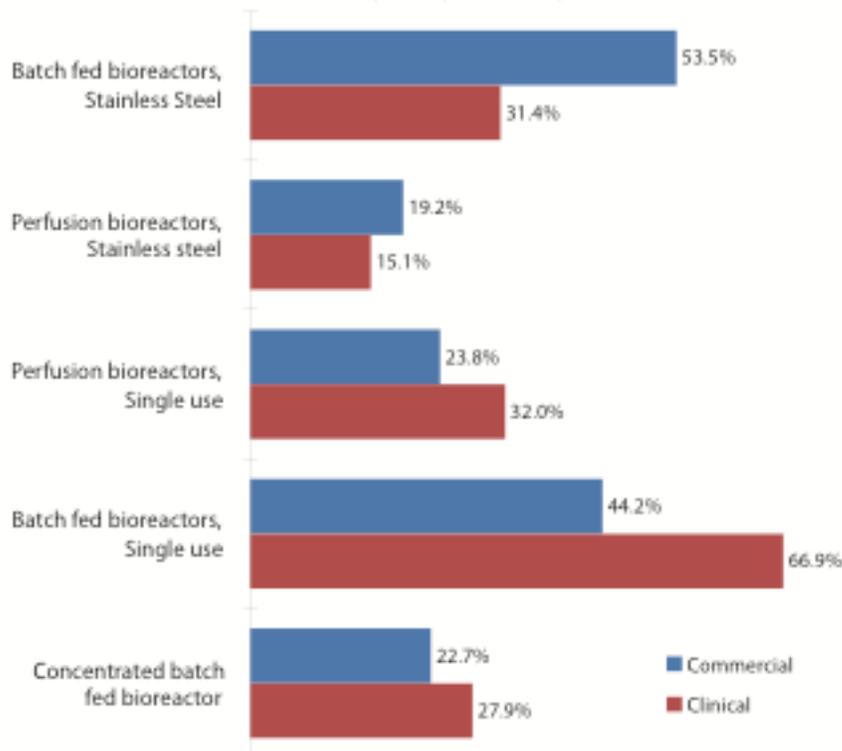
The study also found that single-use perfusion bioreactors were a more popular choice than stainless steel perfusion bioreactors, at both clinical and commercial scale. Slightly less than one-third (32%) of respondents would expect to implement single-use perfusion bioreactors at

clinical scale, more than double the 15.1% who would implement stainless steel perfusion bioreactors. And while the disparity is not as great at the commercial scale (23.8% specifying single-use perfusion bioreactors vs. 19.2% specifying stainless steel perfusion bioreactors), the trend clearly favors the disposable solution.

**Fig. 1: Likelihood of Implementing Bioreactor, by Type**

**"When specifying bioreactor types for a new [Clinical] or [Commercial] scale biologics facility, how likely are you to specify:"**

**% "Very Likely" or "Likely"**



Source: 9<sup>th</sup> Annual Report and Survey, Biopharmaceutical Manufacturing and Capacity, www.BioPlanAssociates.com, April 2012

*FOR YOUR LAYOUT PERSON TO PASTE INTO YOUR OWN GRAPHIC FORMAT*

| <b>Answer Options</b>                  | <b>Commercial</b> | <b>Clinical</b> |
|--|-------------------|-----------------|
| Batch fed bioreactors, Stainless Steel | 53.5%             | 31.4%           |
| Perfusion bioreactors, Stainless steel | 19.2%             | 15.1%           |
| Perfusion bioreactors, Single use      | 23.8%             | 32.0%           |
| Batch fed bioreactors, Single use      | 44.2%             | 66.9%           |
| Concentrated batch fed bioreactor      | 22.7%             | 27.9%           |

**Focus on Disposable Bioreactors**

Although it is noteworthy that single-use batch-fed bioreactors were chosen by a significant proportion of respondents for commercial scale manufacturing in 2 years, this result becomes less surprising when viewed from the perspective of new product development demands.

Identifying new product development areas of focus is a worthy indicator of which way the industry is headed, and the data from our study confirms that biopharmaceutical manufacturers are demanding more and more innovation in disposable solutions, and seem to be less motivated by advances in stainless steel equipment. In other words, data show that the industry sees disposable solutions differently, and they are pushing vendors to develop enhanced solutions to meet their needs.

This year, of the 21 different *new product development* areas of interest evaluated, disposable solutions accounted for 3 of the top 5 areas of interest, led by demand for new and better disposable bags and connectors. Following were disposable probes and sensors, and disposable bioreactors, in the #4 spot. Interest in disposable bioreactor innovation has grown from last year, though it remains behind levels from 2010.

For comparison's sake, of the new product development areas we identified, stainless steel occupied the 19<sup>th</sup> spot. Just 1 in 10 respondents consider this to be an area they want their suppliers to focus their development efforts on. Certainly, this is in part because stainless steel equipment is more mature than many of the other newer areas we identified. However, it also illustrates that the industry may be less concerned with refining this existing equipment, and far more interested in developing new areas.

Whether or not traditional processes are converted to fully single-use, a hybrid system, or not converted at all (and simply replaced post-depreciation), our report's results certainly appear to support this trend towards increased single-use adoption. And, at least when it comes to bioreactor types, it appears that this move may come at the expense of traditional stainless steel systems.

#### **References:**

1. 9<sup>th</sup> Annual Report and Survey of Biopharmaceutical Manufacturing Capacity and Production: A Survey of Biotherapeutic Developers and Contract Manufacturing Organizations, BioPlan Associates. [www.bioplanassociates.com](http://www.bioplanassociates.com)



#### **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](mailto:elanger@bioplanassociates.com) 301-921-5979. [www.bioplanassociates.com](http://www.bioplanassociates.com)

**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 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*