

Pharmaceutical Online

Topic: New Single Use Devices: Trends & Demands

Editor/Contact: Lori Clapper Editor, Pharmaceutical Online

VertMarkets 5340 Fryling Rd. Suite 301 Erie, PA 16510 814-897-7700 x237

Single Use Biomanufacturing Devices in High Demand

Disposables being developed meeting industry's requirements

Single use devices are in hot demand as the biopharma industry looks for new, more innovative products. In fact, disposables make up the top 3 of 20 areas of new product development interest this year. According to our 8th Annual Report and Survey of Biopharmaceutical Manufacturers, [1] disposable product: purification, were cited by 37.9% of global biopharma respondents. This was up by nearly 10% from last year's study.

Still Time to Participate!
9th Annual Report! Be part of the bio-industry's most authoritative, comprehensive analysis! Participants contribute to industry benchmarking, are first to receive a summary, and more!

Click Here:

<http://www.surveymonkey.com/s/pharmaonline>

In addition, more than one-third of the 350 qualified global biomanufacturers we surveyed were looking for better disposable probes, sensors, etc. (37%). Disposable products: bags, connects, etc. followed with 36.5% of respondents. Improvements in disposable bioprocessing equipment are being demanded by end-users who want innovation. For example, 29.2% wanted better single use bioreactors, compared with only 6% looking for innovations in stainless steel equipment.

Figure 1: Selected New Product Development Areas of Interest, Biomanufacturers and CMOs, 2011



Source: 8th Annual Report and Survey of Biopharmaceutical Manufacturing, April 2011, BioPlan Associates, Inc. www.bioplanassociates.com

Willing to Pay for Improvements

Biomanufacturing is relatively recession-proof and budget estimates from our study show, once again, that spending is up strongly for new technologies, capital equipment, and training, among 12 other areas tested. From our study, we believe this budget bump indicates a healthy continuation of investment and spending trends seen over the previous 3-4 years.

Table 1: Selected Data: Average Change in Biomanufacturers' Budgets 2009-2011

Column1	Avg Budget Change 2009	Avg Budget Change 2010	Avg Budget Change 2011
New technologies to improve efficiencies/costs for downstream production	2.5%	4.2%	6.4%
New capital equipment	-0.6%	1.6%	6.0%
New technologies to improve efficiencies/costs for upstream production	2.4%	3.3%	6.2%
Training for operations staff	1.7%	3.7%	5.2%

Source: 8th Annual Report and Survey of Biopharmaceutical Manufacturing, Date: April 2011, BioPlan Associates, Inc. www.bioplanassociates.com

In our annual survey, responses from 100s of global, biomanufacturers/CMOs in 31 countries, and over 100 vendors to the industry show that technology, and productivity-related investments top the spending and budgets this year. The study covers new product needs, budget changes, capacity constraints, disposables, downstream purification, quality management, hiring issues, and others. This year's budgetary leader, "*New technologies to improve efficiencies/costs for downstream production*" shows average spending increases of over 6% for funding to improve capacity and break the downstream bottlenecks.

Budget for new capital equipment took one of the biggest jumps, growing from a -0.6% in 2009, to +6% in 2011. After three straight years of investment, we expect this is the result of demand for more efficient facilities, and long-term capital investments.

In addition, this year, companies are continuing to build their organizations internally, and are doing so more strategically. In fact, "*Operations staff training to improve efficiency*" ranked 4th this year, suggesting that funding for on-going staff improvements is likely to continue.

Vendors Partnering with End-Users

In addition to biopharmaceutical manufacturers, the survey separately evaluates investment in new products among 100s of biopharma vendors and suppliers. We find most vendors' budget categories will continue to grow significantly, as will their overall sales to the segment.

Further, biopharma vendors are investing in R&D for the *right* new products that are being demanded by their biopharma customers. In 2011, of the 38 new product areas that vendors are developing, the top areas include:

Table 1 Selected (of 38 Areas) of New Vendor Technology Innovations and Product Development

Area	% Vendors Researching
Disposable/single-use bioreactors/consumables	40.5%
Bioprocess development and optimization services Bioprocess modeling	40.5%
Chromatography, Disposables	34.2%
Disposable/single-use bags/films	33.5%
Disposable/single-use filtration	30.4%
Animal Free Components	27.2%

Source; 8th Annual Report and Survey of Biopharmaceutical Manufacturing, Date April, 2011, BioPlan Associates, Inc. www.bioplanassociates.com

The top New Product groupings align well with the industry’s demands, including areas associated with downstream processing, chromatography, and single use downstream devices. On the upstream side, new bioreactor technologies, disposable/single-use devices, and monitoring equipment are being invested in and developed.

Summary

Most single-use device manufacturers have the ability to innovate beyond their current product offering, but end users are pushing not only for innovation, but also for harmonization and standardization. As such, innovations in single-use equipment may be relatively slow to emerge in clinical and commercial operations, and the innovative technologies may come from small vendors rather than companies with invested, established product lines. Regardless of when they arrive, single-use innovations are en route, as both our industry vendors and end-users create demand and define requirements.

References:

1. 8th Annual Report and Survey of Biopharmaceutical Manufacturing Capacity and Production: A Survey of Biotherapeutic Developers and Contract Manufacturing Organizations, BioPlan Associates, April 2011, 490 pages.



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 biopharmaceutical 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