

Life Science Leader

Topic: New Product (NPD) Trends & Demands

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Biopharma Manufacturers Looking for Product Innovation

CMOs demanding better sensors; drug innovators demanding better assays

Biopharma manufacturers are increasingly vocal about the new product development areas they need to increase productivity and improve quality. The top three areas of NPD interest among biomanufacturers and contract manufacturing organizations this year were related to single-use solutions. This was led by “disposable product: purification”, cited by almost 2 in 5 respondents, according to our 8th *Annual Report and Survey of Biopharmaceutical Manufacturers*. [1] Within this area, slightly more CMOs are demanding new products. Of the 21 New Product Areas we measured, the next hottest, with more than one-third of the 350 qualified respondents, were improved disposable products: bags, connects, etc., and disposable product: probes, sensors, etc.

But single use devices are not the only hot items. Also on the list of nearly two dozen opportunities, and showing up in fourth position, was “analytical assays”. This is partly due to increased interest in monitoring process improvements, but also as a means to develop biosimilars, and demonstrate biologic comparability at different facilities. Disposable bioprocessing equipment is in high demand partly because innovation in these products has been slow in coming. For example, 29.2% also noted a desire for improvements in bioreactors. By comparison, only 6% sought innovations in fixed stainless steel bioprocessing equipment.

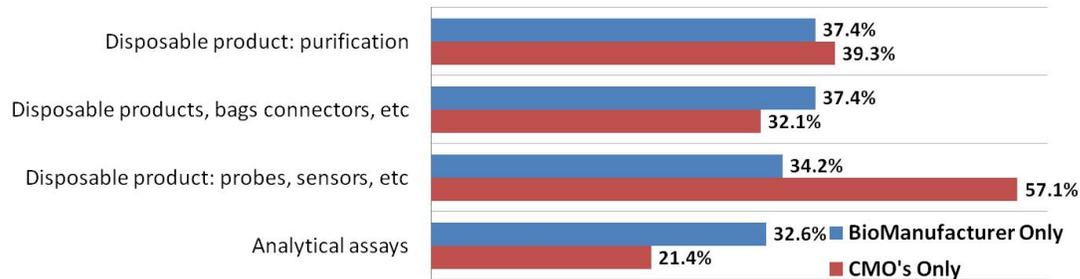
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Figure 1: New Product Development Areas of Interest; Biomanufacturers vs CMOs, 2011

**New Product Development
Areas of Interest
"Biotherapeutic Developers vs CMOs"**



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

FOR YOUR OWN GRAPHICS

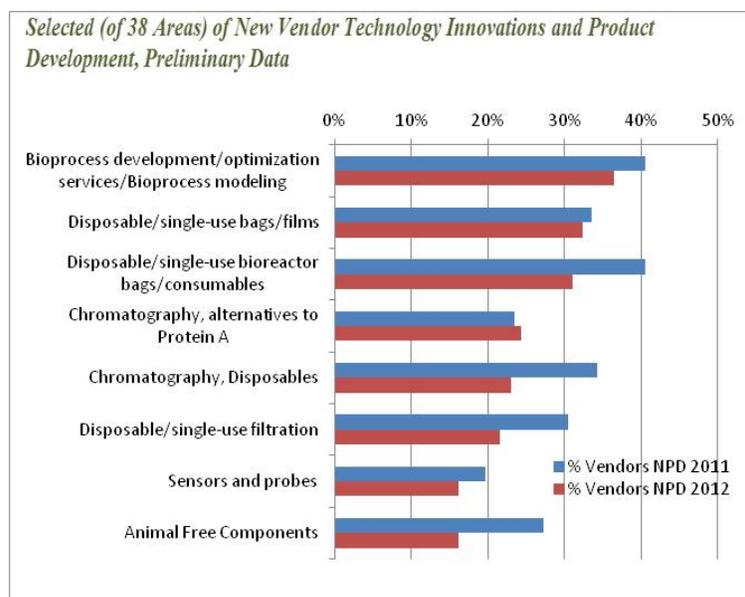
	BioManufacturer Only	CMO's Only
Disposable product: purification	37.4%	39.3%
Disposable products, bags connectors, etc	37.4%	32.1%
Disposable product: probes, sensors, etc	34.2%	57.1%
Analytical assays	32.6%	21.4%

Looking at trends in demands for new products from vendors, we found some significant shifts from last year. Interest in better innovation in disposable, single-use devices for measuring and monitoring (probes, sensors, etc) grew from 29.3% of respondents to 37% over the past year. Further, interest in assays increased from 24.5% of respondents to 31.1%.

Areas that declined in interest included: chromatography products (36.7% down to 29.7%); and process development services, both downstream and upstream (down by as much as 10 percentage points). Cell culture media also dropped roughly 5% points.

Biopharma Vendors Doing their Part

The annual survey also separately evaluates spending and new technology development among 100s of biopharma suppliers. When we match up where vendors are investing their R&D efforts in 2012, we find, from preliminary survey data, that most vendors' budgets are growing significantly, and are aimed at the very areas that biomanufacturers demand. This year, of the 38 new product areas that vendors are developing, the top areas are included in Fig 2.



Selected (of 38 Areas) of New Vendor Technology Innovations and NPD	%-point Change, 2011 vs 2012
Bioprocess development/optimization services/Bioprocess modeling	-4.0%
Disposable/single-use bags/films	-1.1%
Disposable/single-use bioreactor bags/consumables	-9.4%
Chromatography, alternatives to Protein A	0.9%
Chromatography, Disposables	-11.2%
Disposable/single-use filtration	-8.8%
Sensors and probes	-3.4%
Animal Free Components	-11.0%

Source; 9th Annual Report and Survey of Biopharmaceutical Manufacturing, Preliminary Data, Release Date April, 2012, BioPlan Associates, Inc. www.bioplanassociates.com

We note that the 2012 data are preliminary, and may change with additional data collection. It is clear that, although the overall percentage of vendors working on specific new product areas have declined slightly, the overall efforts remain substantial. The top groupings continue to align with the industry’s explicit demands, including areas associated with downstream processing, chromatography, and single use downstream devices.

Biopharmas’ Budget Trends

Budgets are a good indicator of industry strength. And budget estimates for 2012 are, once again, up strongly for acquisition of new technologies, capital equipment, and training. In fact, early returns from respondents to BioPlan’s 9th Annual Report and Survey of Biopharmaceutical Manufacturing Capacity and Production [1] are projecting increases in all 12 areas measured in 2012, except for outsourcing. This budget bump

clearly indicates a healthy continuation of investment and spending trends seen over the previous 3-4 years. Spending this year, in particular, is occurring in:

- New technology
- Capital equipment
- Process development and optimization.
- Personnel training and development

Summary

Across all departments, both budget trends and R&D/NPD efforts are leading indicators of economic constraints being loosening. This is especially evident in areas of expenditures that improve process performance. Our annual survey documents and analyzes how the rebounding and maturing biopharmaceutical industry is moving forward despite recent global economic challenges.

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.



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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.