

Contract Pharma

Topic: Disposables

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CMOs Spending Twice as Much as Drug Innovators on Single Use Devices; *Industry Adopting more Complex Devices*

With CMOs dependent on quick campaign turnaround, efficient process development, and high productivity, it is not surprising that they are spending proportionately more on disposables than developers. But by just how much is a revelation. For example, according to data released in our *8th Annual Report and Survey of Biopharmaceutical Manufacturing Capacity and Production* [1], CMOs budgeted an average of over \$308,000 for single-use buffer containers in 2011, compared to under \$82,000 on average allocated by drug developers. To be sure, that level of disparity does not hold across the board, but we found CMOs to be spending at least double the amount as drug innovators in eight of the 16 components we identified, including seven of the top eight by budget size.

Drug developers are allocating their largest average single-use budgets to bioreactors, at just under \$147,000/facility, but even that figure is eclipsed by CMOs' average bioreactor budget of \$260,000 (76% more for CMOs than drug developers). Of course, bioreactors are high-ticked items, so overall spending on these devices are expected to be higher. While both CMOs and developers' spending is on par for media bags, CMOs opened their wallets at a far greater rate on other non-filtration components, such as: mixing systems, where CMOs outspent developers nearly triple; media bags, filled, wet, saw CMOs outspending developers by more than double; and tubing for disposables applications, where they outspent developers by more than 4 to 1.

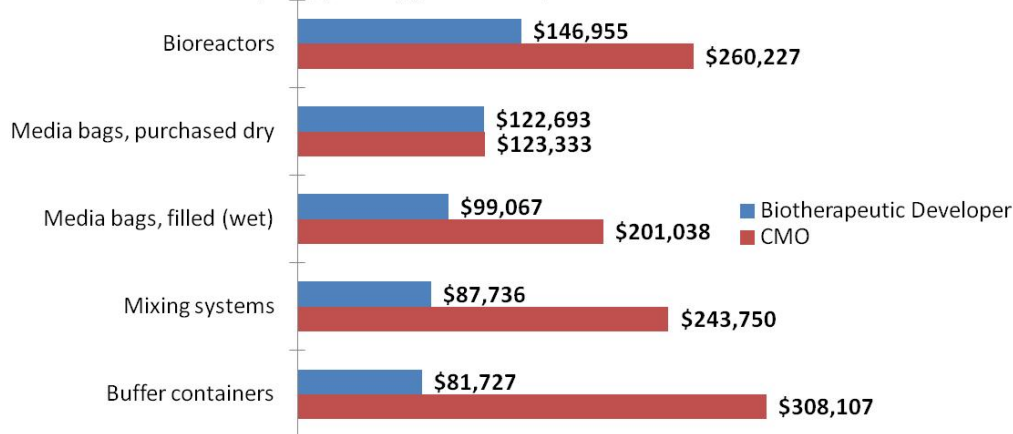
Factoring in depth filters, and connectors, clamps and we can see the substantial increase in overall CMO spending for disposables for all items. Indeed, of all the components we identified, developers only outspent CMOs in one area: waste containers (\$63,000 vs. \$32,000).

This spending trend is further evidence that the biotech industry is becoming more comfortable in the use of these items in terms of regulatory burden, cost and benefit to manufacturing. CMOs tend to pass the material and labor costs on to the client; in many cases, disposables can make economic sense for both client and CMOs. They reduce capital expenditures on equipment that may not be used frequently enough to cover their cost. They can also save time, which is usually critical to clients. CMOs are also more concerned with cross-contamination between different campaigns, and the need to validate cleaning, so overall, these findings are not unexpected.

Fig. 1: Selected Average Facility Budget for Single Use Devices; Biotherapeutic Developers vs. CMOs

Average Budget for Single-use / Disposable Components 2011

(US\$/facility), Biotherapeutic Dev. vs CMO



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

| | Biotherapeutic Developer ONLY | CMO ONLY |
|---------------------------|-------------------------------|-----------|
| Bioreactors | \$146,955 | \$260,227 |
| Media bags, purchased dry | \$122,693 | \$123,333 |
| Media bags, filled (wet) | \$99,067 | \$201,038 |
| Mixing systems | \$87,736 | \$243,750 |
| Buffer containers | \$81,727 | \$308,107 |

Overall SUS Budget Trends Remain Positive

Projected budgets among our 352 qualified developer and CMO respondents were clearly affected by the economic situation. Although most organizations indicated an increase in overall budgets, recent economic constraints, and potentially even the expectation of these constraints, were reducing respondents' assessment of their budget expenditures for single use devices. However, when we evaluated the trend in budgets since 2007, we found a relatively consistent *budget* growth rate among most devices. This ranges between around 5% and 8%.

Note that this represents the projected individual *budget* growth, not the growth in device sales. A few very large purchasers could substantially increase the total annual *sales revenue* for a device, but not significantly change the average facility budget data.

We also evaluated the growth rate for budgets (spending) on disposable components for 2007 through 2011 based on compound annual growth rates (CAGR). Note that because this calculation uses initial 2007 budget figures, for devices with small initial budgets, there can be a deceptively high CAGR. For example, the highest growth items for that time period were mixing systems, which were relatively new to the industry, compared to buffer bags, media

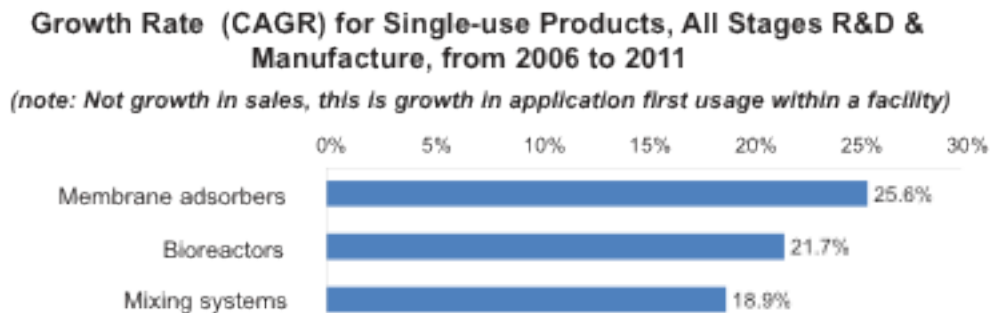
bags and tubing. Based on the growth rate trend lines over the past 5 years, for common disposable devices (bags, tubing, connectors, clamps, and other containers), we estimate the market is growing for these devices at between 5% and 20% annually. Specifically, behind mixing systems, with its high CAGR of 36.9%, the other components with positive CAGR included connectors, clamps (11.6%), depth filters (7.3%), buffer containers (5.2%), bioreactors (3.1%), waste containers (2%), and tangential flow filtration devices.

Complex Devices Show Greatest Adoption Growth

We measured adoption rates of single-use devices (first-use). In 2011, we found a consistent slowing of the *growth rate* in first-adoption. This is to be expected. As more facilities use them, rapid growth in adoption of single use devices necessarily slows until a market equilibrium is reached. What is notable, however, is that the greatest increases have occurred for complex devices that are also among the most expensive of disposable products.

Use of membrane adsorbers tops the list, having jumped 37.7% percentage points in market “first-adoption,” from 12.9% in 2006 to 50.6% in 2011 of respondents reporting using disposables for the first time that year (a CAGR of 25.6% (down from 28.8% last year, and from 40% in 2009). Bioreactor usage grew from 21% in 2006 to 68.1% in 2011, a 47.1% point increase, and a CAGR of 21.7% (down from 25.4% last year, and from 30% in 2009). And mixing systems usage grew from 19.4% in 2006 to 54.8% in 2011, a 35.4% percentage point increase, and a CAGR of 18.9% (down from 23.1% last year).

Fig. 2: Selected Single Use Devices, Average “First Adoption” Rate, 2006-2011



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

These complex devices still lag in overall adoption behind more common ones, though. Not unexpectedly, the most widespread devices in usage among respondents in 2011 were disposable filter cartridges (92.8%), while the great majority are also using tubing for disposable applications (86.1%). Other common disposables include depth filters (83.1%),

buffer containers (76.5%), connectors, clamps (73.5%), tangential flow filtration devices (72.3%), and sampling systems (71.1%).

Growth rates for these devices are also cooling down. As we reach a market equilibrium for new product introductions, it will take a new push, such as greater regulatory acceptance for plastics usage, or approval of more commercial-scale products manufactured in disposables. Among the reasons why the penetration of single-use disposables or the adoption rates are not growing as rapidly as in the past include the poor economy, mergers, and fewer new companies. The decreasing number of new smaller emerging biopharmaceutical companies who typically adopt single-use disposable systems for clinical production has directly impacted penetration rates. Also, mergers and acquisitions have had an effect, as smaller companies with good product opportunities, who may have been using single-use systems, have been taken over. Many of the larger companies after a merger close down several operations or plants to better manage their business portfolio. Another factor is the depressed world economy, which may be forcing companies using these systems for clinical production to cut spending on inventory.

Bioreactors Tops List of Newly Introduced

Overall single-use device adoption may be slowing, but complex devices are showing the greatest growth. We asked our respondents to indicate which disposable systems had been introduced over the past 12 months at their facility. The leading ‘newly introduced’ systems were: bioreactors, seed (being newly introduced by 36.2%); buffer prep systems (34.8%), buffer storage systems (34%); and bioreactors, production (32.6%). In 2010, by contrast, the top ‘newly introduced’ disposable device was for buffer storage.

Meanwhile, recent advances continue in the area of single-use bioreactors, where the size or scale of the vessels are increasing along with the automation. A few years ago the industry could only boast of bioreactor sizes up to 1000L, whereas now companies offer bioreactor sizes up to 2000L. Indeed, disposable bioreactors’ lead this year in terms of newly introduced applications is not necessarily surprising, as small emerging biopharmaceutical companies are employing these bioreactor systems to advance their product pipelines.

In fact, more companies are adopting single-use technologies to reduce their initial capital investment for product development. As the competition grows, our study shows that vendors continue to invest aggressively in R&D to introduce technologies, such as single use sensors and mixers, to differentiate themselves from their competition. This also bodes well for customers, as competition increases technology advances, drives down prices and offers greater options.

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.

NOTE: IMPORTANT TO INCLUDE THIS SO READERS UNDERSTAND HOW THE STUDY WAS CONDUCTED