VertMarkets, Inc. Trends in Single-Use Technology
Topic: Single-Use Adoption Rates Increasing
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BioPharma Industry Getting Comfortable with Complex Single Use Devices:
Penetration Crosses 75% for Bioreactors

The rate of usage of disposables in biopharmaceutical manufacturing has increased substantially over the past six years in a variety of areas, but most notably for complex devices, that are also among the most expensive. Results from our *9th Annual Report and Survey of Biopharmaceutical Manufacturers* suggest that market penetration is beginning to grow for complex technologies. Because adoption of new technologies, such as single use devices, in currently approved bioproduction processes is difficult, switching to plastic single use production typically is considered for new products, not existing production.

In our study, we asked respondents which types of disposable and single-use systems they used at any stage in bioproduction (R&D through commercial production). We found that the adoption of bioreactors, which had grown only marginally from 65.2% in 2010 to 68.1% in 2011, jumped to 77.3% this year, representing ~9% year-over-year growth in adoption. Overall, bioreactor usage has now grown from 21% in 2006 to 77.3% in 2012.

Other complex systems also demonstrate rapidly growing penetration rates. This year, 72.7% of the hundreds of qualified biotherapeutic developers and CMOs we surveyed reported using mixing systems, a 33% leap from 54.8% the previous year. This is notable, given that adoption of mixing systems had remained basically unchanged from 2009, when penetration stood at 55.6%. Looking as far back as 2006, we now find that adoption of mixing systems has almost quadrupled, from 19.4% then to 72.7% now.

Relative to the above, growth of membrane adsorbers, which increased from 50.6% of respondents to 53% this year was minimal. But when compared with the 12.9% penetration registered in 2006, we can still observe a significant trend towards greater adoption of these systems.

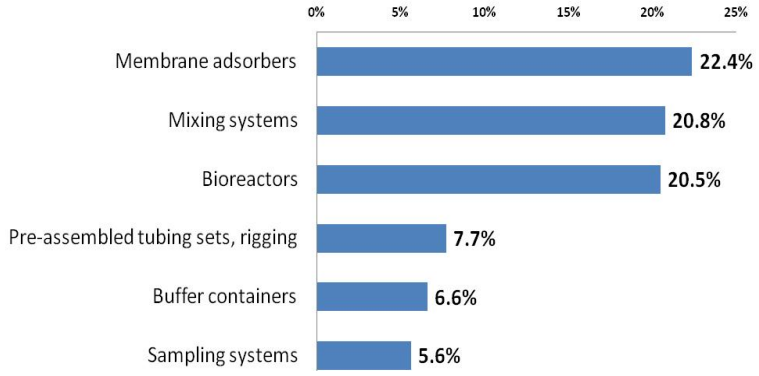
CAGR Down, But Still Impressive
Growth rates for these devices are cooling down, for the most part. To an extent, this is a function of market saturation, and the way compound annual growth rate (CAGR) is

calculated. For example, the 30% point jump in adoption experienced by membrane adsorbers from 2006 to 2007 is simply not sustainable over a six-year period. CAGR will necessarily dampen over the years even as penetration increases, until an equilibrium is reached.

Based on the growth rate trend lines for 'first use' of these devices over the past 6 years, for common disposable devices (bags, tubing, connectors, clamps, and other containers), we estimate the market is growing for these devices at between 1% and 8% annually. Complex devices continue to top the list, though. For example, membrane adsorbers lead again with a CAGR of 22.4%, down from a leading 25.6% in 2011, and from 28.8% in 2010 and 40% in 2009. Mixing systems takes the second spot this year with a CAGR of 20.8%, compared to 18.9% in 2011 and 23.1% in 2010. And bioreactor usage exhibits a CAGR of 20.5%, slightly less than 21.7% last year, and down from 25.4% in 2010, and 30% in 2009.

Other products with significant adoption CAGR include pre-assembled tubing sets, rigging (7.7%), buffer containers (6.6%), and sampling systems (5.6%). Each of those saw notable increases in penetration (use at any scale within their facility) from 2011 to this year: sampling systems jumped from 71.1% to 80.3% of respondents; pre-assembled tubing sets, rigging rose from 69.9% to 77.3% of respondents; and buffer containers increased from 76.5% to 83.3% of respondents.

Fig 1: Selected Results, Annual Growth Rate for First Adoption of Single-use Devices



Source: Preliminary data, 9th Annual Report and Survey of Biopharmaceutical Manufacturing, BioPlan Associates, Inc.
www.bioplanassociates.com

The Outlook is Positive

Disposable products offer distinct advantages compared to fixed stainless steel systems in cleaning and validation, and can significantly reduce the time and capital required to get a facility up and running, compared to the installation of a fixed, stainless steel facility.

Based on the adoption and growth rate trends we have identified over the years surveying biomanufacturers, we can expect the adoption of single-use devices to continue to expand, but at a slower rate until these products reach market saturation. Disposable devices continue to make advances in manufacturing, and have already become increasingly common in most areas. Although there are few non-rigid single-use devices used in GMP applications, this is beginning to change as new products move through the development pipeline, into clinical scale manufacturing, and on to regulatory approval for commercial GMP production. Further, as regulators gain familiarity with the safety profiles and materials used in these devices, necessary approvals for product manufacture will be facilitated, leading to a significant increase in the market volume for single use devices.

References:

1. 9th Annual *Report and Survey of Biopharmaceutical Manufacturing Capacity and Production*, BioPlan Associates, Preliminary Data, Release April 2012.

About the Author

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Survey Methodology: The 2012 Ninth Annual Report and Survey of Biopharmaceutical Manufacturing Capacity and Production (preliminary results) yields a composite view and trend analysis from 340 responsible individuals at biopharmaceutical manufacturers and contract manufacturing organizations (CMOs) in 30 countries. The methodology also encompassed an additional 130 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.