Productivity Bottlenecks Drive the Demand for Innovation

by Eric S. Langer

Spending is up, the global economy is slowly getting back on track, and the biopharmaceutical industry continues to roll along at double-digit growth. Productivity has been the primary industry focus over the past few years, and it remains a hot topic. Companies are aggressively going after the bottlenecks to their efficiency, and now they're opening their wallets to fix what's broken.

One of the biggest productivity fixes today centers on improved single-use devices and systems. They top a long list of product innovations that biomanufacturers demand today. According to our just-completed Eighth Annual Report and Survey of Biopharmaceutical Manufacturing Capacity and Production, innovative products are needed especially in downstream purification. Biomanufacturers are willing to pay for a wide range of product improvements. Their wish list includes single-use purification systems, for which 37.9% of the biopharmaceutical industry has indicated it needs more innovative devices. The demand for disposable probes and sensors is nearly as big, with 37% of survey respondents looking for something better. Even bags and connectors 36.5% need improvements to counter critical production problems. Innovative single-use bioreactors are another major need, with 29.2% of respondents asking for more.

Successful innovation will require much closer supplier–end-user–regulator interactions. To define the future, we interviewed industry vendors and end users in March 2011 on these challenges, product plans, and their understandings of client needs. In terms of challenges, FDA and other regulatory requirements present continuing hurdles for supplier innovation and adopter integration. Streamlined, more efficient regulatory procedures would expedite both client and supply side production cycles. Doug Neugold (ATMI's chief executive officer) said, "It is worth the regulators thinking about what processes or data packages can be streamlined or safely reduced since the incrementalism of always asking for more can lead to inefficiencies."

Vendors acknowledge that regulations can create a pathway in advancing single-use innovation. Regulatory challenges to cleaning and quality assurance have fueled interest in disposables. Before that, "most customers just 'needed' a solution to cleaning validation or toxic metal ions," noted Jerold Martin (senior vice president of global scientific affairs for biopharmaceuticals at Pall Life Sciences). "It took the suppliers to come up with these solutions."

Suppliers respond resoundingly that they don't lack innovation; instead, industry adoption of single use technologies is the issue. In this market, suppliers have to innovate and take the risk in product development. Mani Krishnan (director of single-use processing systems for

EMD Millipore) agrees: "When we present to our customers technologies that they see real value in, adoption of these technologies has not been an issue."

Deeper collaborations between regulators, end-users, and vendors will be needed to create an innovative environment. Suraj B. Baloda (director of quality assurance at Ben Venue Laboratories/Boehringer Ingelheim) concurs: "Although some suppliers have developed products that reflect incremental design, others (through collaboration with end-users) have successfully developed new and innovative products." And Ken Bibbo (vice president of operations at HyNetics Corp.) chimed in: "Most single-use device manufacturers have the ability to innovate beyond their current product offering. However, we as an industry sector are not being challenged by the end users for innovation."

Disposables integration into bioprocessing is on-going. Many companies are introducing single-use devices into their facilities as part of hybrid systems, adding new flexibility into their manufacturing. Accordingly, as biomanufacturers have integrated disposables, both customers and suppliers have gathered data on their usefulness. We've learned how to transition from small-scale into commercial production and even into less complex, modular units and unit operations that are easier to change out, modify, and monitor.

As integration continues, suppliers are looking to bridge the gaps into a full "start-to-finish," streamlined single-use technology product line with scale-up possibilities, says Baloda. However, to make this work, there will be a need for improved (and potentially brand new) materials, which can insert regulatory hurdles back into the timeline. Introduction of novel materials can control the entire innovation process. That can slow research, development, evaluation, integration, and design.

"It is highly likely that we will see the need for different materials or processing/handling methods," says Krishnan. Beyond basic process and products innovation, vendors to this industry will need to place sustained investment in regulatory- and end-user relationships as well as development of a culture of innovation with the people skills and mindsets to apply requisite resources — not only to meet existing needs, but also to imagine how future technologies will integrate into global biomanufacturing.

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