The Changing Single-Use Landscape, Part 1

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The landscape for equipment in the bioprocessing industry has changed dramatically in recent years. Once considered inferior to fixed, reusable equipment made of stainless steel and glass, single-use technology has since made great inroads into the market. While it may seem counterintuitive, moving from fixed reactors to those that are used once is actually more cost effective. This is especially the case for a new facility where the investment in processing equipment has not already been made.

Single-use technology first penetrated the market in the form of storage containers where they were used for buffers, reagents, media and even final products. Over the last decade, there has been a gradual shift toward the design of increasingly complex vessels in disposable form. Innovations from vessel manufacturers have moved the market from bags to mixers, from simple mixers to mixers with sensors, from mixers with sensors to bioreactors, and now there is a real desire among biopharmaceutical manufacturers to integrate one unit with another. Single use technology is no longer restricted to stop-gap solutions for fluids handling. It has graduated into a full-scale turnkey manufacturing option.

Alongside these increases in the complexity of the technology, there have been advances in both production efficiency and quality standards. End-users tend to report that regardless of which company is supplying their single-use bags, they are

generally happy with the quality and not concerned about potential risks. Only a few years ago, the number of improperly constructed bags was significantly higher than it is now. Indeed, at ATMI we get almost zero reports of bag failure, and the majority of the rare cases we do see are a result of customer mishandling.

Advantages Drive Adoption

The initial driver for moving away from fixed vessels towards single use was the dramatic reduction in validation requirements. The bags arrive from the supplier in guaranteed sterile condition, and can simply be plugged into the customer's production process without the need for any further testing. The time it takes to validate a facility is greatly reduced, as is the time to turn it around between production runs. In addition, the risks of inadvertent microbial contamination of the batch, or cross-contamination from one run to the next, are negligible, thanks to the unused vessel's sterility, and the fact that it has not been used before.

Over time, further advantages of single use have become evident. Time-savings are made in facility planning and process engineering. The speed at which a staff of experienced single-use operators can configure an entire new production scheme and scale the manufacturing process up is reduced – to the extent that, for a new product, it can be cut to just a few weeks or months. This continues to be a driver today, and there are few large-scale biologic manufacturers who do not have dedicated internal teams using single-use technologies on their products.

Considerations and Uses

In terms of market demand, there is an inflection point happening right now – the adoption of single-use technologies in the development and early clinical trials stages. At the much smaller volumes required for early lab development, there is a growing emphasis on developing bench-top reactors with scalability planned in as a primary requirement from the outset. Even in big facilities that rely on 20,000-liter cell culture reactors, down the hallway there will often be process improvement trials under way, which tend to be using single-use reactors.

There will always be a need for fixed reactors on the very large scale; single use is unlikely to be a viable option for volumes higher than about 3,000 liters. Up to that cut-off point, however, single-use is becoming the preferred choice. But even with a process that starts with a cell culture in a 20,000-liter vessel, once the culturing process is completed, the product is very quickly concentrated and clarified down to smaller volumes. Single-use vessels soon become appropriate for downstream steps in the manufacturing process.

Single use is particularly appropriate for emerging cell therapy treatments, if not essential in the case of personalized, autologous cell therapies where every batch is different. Suppliers like ATMI are working hard on improving the process efficiency of single-use bioreactors, whether this is by optimizing the microenvironment of the cells through altering shear force or improving the mass transfer of oxygen, or by shrinking the footprint of the bioreactor thanks to increases in efficiency and clever engineering design.

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