The Changing Single-Use Landscape, Part 2

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This is part two of a two-part piece. Part one can be found here *[1].*

In terms of regulatory requirements, the agencies need to be confident that what a manufacturer is doing is both logical and safe. The FDA, EMA and other regulatory authorities are looking for compelling data that make it clear that the process is safe and reproducible – and that means condensed, reliable data rather than reams of data that needs to be interpreted. They need to be assured that the drug product will be the same from one lot to the next, and thus they need to be confident that the leachables and extractables profile for the plastic used to construct the vessels is not only within the prescribed limits, but also remains the same from one vessel to the next, so there will be no impact on the product itself.

For biopharmaceutical manufacturers wishing to move into single-use technology, it is important to partner closely with the vessel supplier. The overwhelming issue becomes one of absolute trust, based on the fact that they will be dependent on that vendor to supply what they need, when they need it. The customer must be certain that the quality and quantity of products they require to meet their own strategic plan will be available. When selecting a vendor, find out if the supplier has the necessary capacity, is there a back-up supply, and will the film used to make the bags remain identical throughout the biopharmaceutical's entire product lifecycle.

The Case for Standardization

There is, however, one area where great improvements still need to be made, and that is standardization. There are many different suppliers of single-use technology, all with their own take on how things should be. But the customer benefits of standardization across suppliers are clear, as evidenced by the success of other industries where common standards have been adopted, such as microelectronics, the automobile industry, and even the food sector. Customers want, for example, to be able to buy the best bioreactor for their particular process, combine it with their own preferred technologies for mixing and downstream clarification, and not worry if it is possible to connect them together.

Standards evolve over time, but suppliers need to reach a consensus, and that is not going to be easy. The best way to move ahead will almost certainly be via industry user groups, where technology providers and end-users can discuss and agree what they need, what is practical, and what has to be done to achieve a set of usable standards.

The standardization of leachables and extractables is well under way. Safety standards like these are already on the horizons of the suppliers, but what the industry - including consumers, customers and manufacturers - is really looking for is engineering compatibility, something that will be much more difficult to achieve without consultation and cooperation. But this type of open architecture will enable them to integrate equipment from different suppliers into their manufacturing train, and greatly facilitate the expansion of the overall market for single-use technologies.

Looking Ahead

The single-use industry is still in its early stages, but gaining traction. Further improvements are still required and are happening all the time. There has been a lot of discussion and activity in the area of single-use probes, for example, but there is still room for a good deal of innovation in that space. In the meantime, the advantages of single-use technologies have been proven and it is projected that market penetration will continue to rise. Add to that the continued development of newer, better, more efficient single-use vessels, components and bioreactors, and it is clear that single-use systems and components have a bright future ahead.

For more information, please visit www.atmi-lifesciences.com *[2].*

Links:
[1] http://chem.info/Articles/2012/10/Processing-Equipment-The-Changing-Single-Use-Landscape-Part-1/
[2] http://www.atmi-lifesciences.com