



Streamline Therapeutic Development by Overcoming Single-Use Customization Misconceptions

Single-use strategies and tools are constantly evolving to better serve industry needs, and adept solutions providers can help streamline development with simple, custom adaptations.

By Gregg Johnson and Evan Hagen, Charter Medical

Contrary to popular belief, custom single-use solutions aren't always complex, costly, and disruptive. While standard solutions may seem easy and guaranteed to work in any situation, they often create challenges in manufacturing workflows. For example, standard connectors, tubing, or other components can cause compromised sterility and labor-intensive operator procedures.

Still, therapeutic developers often default to using standard single-use solutions based on industry-wide misconceptions about the complexity, costs, supply risks, and lead times of custom solutions. In some cases, developers adopt standard products simply because they are unaware of customization options. Not only do custom single-use options exist for many applications, but they can be both straightforward and cost-effective.

Misconception #1: Custom Single-Use Designs are Always Complex

A common phrase states that there is elegance in simplicity. Custom products aren't always complicated. In fact, the best custom solutions employ as much simplicity as process requirements allow. Many types of customizations can be designed with standard materials of construction and componentry, which mitigates component supply risk and can reduce implementation efforts.

Instead of making connections in the manufacturing suite, for example, two single-use products can be combined prior to the sterilization process, avoiding unnecessary handling steps and mitigating process risk. Further, multi-container assemblies can be optimized based on the size and number of containers, which empowers users to reduce product waste. As another example, simply lengthening tubing may remove the need for lifting and improve personnel ergonomics. Conversely, shortening tubing could permit other processing tools to be readily available in the workspace and promote workspace tidiness. Small changes can have big impacts.

That said, not every situation can be broken down so succinctly. In some cases, new tooling may be created if a new bag size, port configuration, or new injection molded component is required. Knowledgeable custom solutions providers can span the range of complexity to create a design that can suit almost any need.

Misconception #2: Custom Single-Use Products are Only Worth Implementing in Large Buys

Single-use custom products don't always require a high minimum order quantity to be sustainable. Custom product volumes will vary depending on needs throughout each development stage. While volume is an essential part of initial discussions with any vendor, single-use partners can maintain fiscal viability at lower product volumes when recognizing that clinical successes sustain a healthy custom single-use service program. Regardless of project size or order quantity, users benefit most from collaborative partners who help navigate feasible standard or less-complex custom solutions when low-volume buys are necessary.

Misconception #3: Single-Use Product Lead Times are Longer for Custom Solutions than Standard Solutions

Lead times for custom solutions don't necessarily impact project timelines. In some instances, there is no difference in lead times between standard and custom products from design through delivery. Single-use partners with in-house equipment and operational processes developed specifically for customized products have shortened lead times to be comparable to, or the same as, standard solutions.

A single-use design team with substantial experience and expertise can remove significant trial-and-error time from the prototyping process. They can also map out how the single-use product interfaces with the overar-

ching processes and identify specific requirements in advance to minimize risks. These elements are valuable in early conversations with any single-use partner to keep process quality and project timelines in check.

Misconception #4: Custom Single-Use Products are Expensive

Custom products don't have to break the bank. In fact, adding some costs up front for simple customized single-use product integration can provide cost savings later. In addition to direct savings resulting from immediate process improvements, custom single-use solutions can optimize cleanroom and equipment usage. For example, if a custom solution enables a task to be moved outside a cleanroom or to a lower facility classification, the cost of production could decrease while also potentially diverting new or other processes into those controlled environments.

Other custom-designed solutions like [manifolds](#) enable users to fill multiple single-use bags simultaneously, saving time and mitigating risk by reducing hands-on operator touchpoints required to fill those containers.

These are only two examples of the numerous instances in which an organization could save time, space, and skilled personnel by using custom solutions — realizing cost savings that can surpass their initial investment in custom products.

Final Thoughts

Whether simple or complex, customized single-use solutions are an enabling option to achieve greater long-term value when compared to standard solutions cobbled together. The pros and cons associated with single-use solutions are highly dependent on the therapeutic developer's product, process, and situational need. Fortunately, strategies and tools are constantly evolving to better serve diverse industry single-use demands. Developers of all sizes and clinical stages should engage with a knowledgeable partner that can clarify how to overcome perceived challenges when adopting single-use solutions and how to fully take advantage of the benefits they provide.

Don't let single-use misconceptions get in the way of building a more efficient process. To learn more, visit <https://chartermedical.com/customization-services/>

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About Charter Medical, LLC

Charter Medical, LLC has more than 30 years of experience developing and providing specialty single-use products to the cell therapy, blood transfusion, and pharmaceutical markets.

Our 16,000 square feet of cleanroom space located in Winston-Salem, North Carolina, USA, is ISO 13485 certified and FDA registered, with a focus on designing and supplying single-use solutions for cell growth, frozen storage, and biological fluid handling. Custom product design services are available for clients who need specialized single-use products for biomanufacturing. Our team of engineers will work with you to develop the best solution for your specific requirements.

Charter Medical is committed to providing quality products and services with an experienced staff dedicated to exceeding customer expectations from product development, delivery, and implementation.

