



CSR[®]
Custom Single Run

Scalable Single Use Solutions



SCALABLE SINGLE USE SOLUTIONS

ABEC's Custom Single Run (CSR) product line is a new paradigm for single use implementation. Leveraging ABEC's long experience in equipment design, our custom approach, and our exclusive focus on production scale bioprocessing, CSR sets new benchmarks in single use performance, including:

- Largest Production Volumes
- Lowest Cost of Goods
- Maximum Process Flexibility
- Faster Container Loading
- Robust, Non-Proprietary Supply Chain

LARGEST PRODUCTION VOLUMES

The CSR product line leads the industry with bioreactor volumes up to 4,000L working volume, and liquid mixing systems up to 5,000L working volume; delivering significantly more product per unit area of floor space; a key metric in high-value multiproduct biopharmaceutical facilities.

LOWEST COST OF GOODS

The CSR brings true economy of scale to single use processing. Capacity is almost doubled within a similar footprint when comparing to the 2,000L systems currently on the market. Because equipment performance is comparable to stainless steel systems, high yield is achievable at large scale. Additionally, facility depreciation and labor costs are reduced.

MAXIMUM PROCESS FLEXIBILITY

ABEC is unique in the industry with the capability to provide fully customizable single-use and stainless steel process solutions with comparable performance. Similar to our approach for over 40 years with stainless steel systems, CSR designs can be developed for customers' particular process, facility, and operational needs. For example, mixing and mass transfer can be optimized for particular cell lines, equipment can be arranged to accommodate space constraints and utility access, and control systems can be tailored to maximize productivity. Additionally, the higher volume capability of the CSR better enables multi-product production, since production needs can be achieved with fewer batches.

A clear process advantage of the CSR platform is the ability to tailor designs to provide solutions that seamlessly scale or transfer to/from existing processes. From a design perspective, the only difference between the CSR and stainless steel equipment is the material of construction.

FASTER CONTAINER LOADING

Reducing risk of container failure and minimizing system turnaround time are critical for a single use manufacturing operation. The CSR product line features innovative, safe and ergonomic solutions for packaging and handling of the CSR Disposable Container (DC). The CSR-DC's are packaged to prevent mishandling that might adversely impact film integrity. Once the CSR-DC reaches the equipment, simple tools are used to assist installation; even the largest Disposable Container can be installed by one operator in less than an hour.





ROBUST, NON-PROPRIETARY SUPPLY CHAIN

Implementing new product contact materials in a cGMP operation can create significant challenges related to sourcing, change management, quality assurance, and validation. The CSR product line addresses those challenges by utilizing only non-proprietary, commercially available raw materials, instruments, and components. Clients can develop and manage their supply chain to standards that align with their requirements, rather than being forced into a single source of supply. The design and selection of materials used in the fabrication of the CSR-DC is collaborative in order to leverage clients' existing material qualification and validation efforts. This strategy enables flexibility in component selection across different unit operations to minimize process, quality and supply chain risk. Clients are also able to significantly consolidate product contact materials used throughout the entire bioprocess to minimize inherent risks associated with raw material supply.

To further insure a robust supply chain, ABEC has implemented in-house, multi-site global manufacturing to provide short DC lead times and redundancy of supply. All CSR-DC's are built with industry-proven product contact materials offering clients unprecedented transparency and control of the container and component supply chain, resulting in improved material management, quality assurance and change management.

UPSTREAM & DOWNSTREAM APPLICATIONS

CSR-Bioreactors

- Batch, Fed-Batch, and Perfusion Cell Culture
- Customizable working volumes from 50L to 4,000L
- Mixing, mass transfer, and control systems tailored to process requirements

CSR-Solutions Processing

- Harvest, Purification Pooling, Viral Inactivation
- Customizable working volumes up to 5,000L
- CSR-General Mixer with best in class blend times

CSR-Buffer Hold

- Multiple buffers >3,500L
- Stable buffer delivery at high flow rates
- Reduced floor space and consolidated tubing runs



How a CSR Bioreactor provided an ABEC customer with seamless process transfer to commercial production

The Challenge: Substantial differences in design between standardized single-use bioreactors and existing large scale stainless steel production systems required significant time and resources for process development and transfer.

The Solution: ABEC provided a 200L CSR bioreactor custom-designed for performance equivalent to the large scale production bioreactors. ABEC determined baseline mass transfer and blend time of the large scale equipment, and engineered the CSR to ensure equivalent performance.

The Results: Measured oxygen transfer rates (OTR) and blend times were equal to or better than the targets determined as part of a scale up/scale down study. Most importantly, Viable Cell Density and Titer results were equivalent between the 200L CSR and the production bioreactors. The CSR provided a clear path for the rapid >10x scale-up and transfer of cell culture processes across different sites and between single use and multi-use stainless steel platforms.

For more CSR scalable single use capability success stories, email: singleuse@abec.com.



Since 1974, ABEC has been a leader in delivering integrated process solutions and services for manufacturing in the biopharmaceutical industry. A majority of the world's pharmaceutical and biotech companies are ABEC customers; with many of today's leading therapies manufactured by processes and equipment engineered, manufactured, installed and serviced by ABEC.

ABEC's unique value is based on long experience, complete in-house capabilities, a custom, flexible approach, and long-term credibility. Whether adding capacity or improving existing facilities, ABEC's turn-key solutions and support reduce overall cost and time to market while delivering maximum productivity.

To learn more about ABEC, visit abec.com or email info@abec.com.

