

Connection Technologies Enable Modular Single-use Systems for Bioprocessing

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Key Takeaways

- Single-use aseptic connectors make modular systems possible by connecting components within the systems such as tubing, bags, filters and manifolds.
- Both modular and single-use systems present the means to reduce costs, increase productivity, improve quality, reduce risk, and increase flexibility¹ in biopharmaceutical applications.
- The presence of single-use systems continues to grow in biopharmaceuticals. For example, single-use systems in upstream clinical production grew from 45% in 2021 to 64% in 2023.²
- Gene therapies and other biologics rely on closed aseptic processing to minimize the risk of contamination. The integration of closed processing and modular systems further enables efficient, flexible workflows and rapid scaling.³
- The utility of modular design begins with standardization of sterile connectors to all subassemblies within biomanufacturers' networks.⁴



SINGLE-USE SYSTEMS (SUS) AND MODULARITY FOR ADDED FLEXIBILITY, EFFICIENCY

Single-use systems support agile manufacturing and now dominate most new biotechnology processes. Single-use is present in about 85 percent of all pre-commercial biomanufacturing.⁵

The benefits of SUS are clear and the expansion into commercial production continues to grow. They eliminate the downtime between production runs required for cleaning, sterilizing and validating stainless steel equipment. SUS also reduce or eliminate the risk of cross-contamination between processes in the manufacture of drug substances, monoclonal antibodies, vaccines,

biosimilars, cell and gene therapies, and other modalities.

Bioprocessors are now looking to modular designs to further facilitate efficiency and flexibility in their operations. Initial ready-to-use single-use systems have tended to be highly customized and complex, limiting some of the potential flexibility SUS could offer; thus the need for modularity.

WHAT ARE MODULAR SUS?

Subassemblies of larger SUS that can include components such as bags, filters, tubing manifolds and sensors. These prefabricated “building blocks” are then configured and linked together with connectors to create the end-user’s larger biopharma production systems.

WHAT BENEFITS DOES A MODULAR STRATEGY DELIVER?

- Allows companies to adapt to changing needs within an existing production space without negatively impacting current operations.
- Reduces and rationalizes SKUs, which simplifies the purchasing process and increases volumes of commonly used components, driving lead times and costs down.
- Provides protection against supply chain issues.
- Encourages qualifying replacements in advance so they can slot in as needed if one component (e.g., bag or filter) is unavailable.
- Supports plug-and-play readiness and associated efficiencies.
- Helps simplify manufacturing integration and technology transfer between facilities.

To help fulfill the intent of modular systems, bioprocessors and suppliers can start with connector technologies, which are essential to all modular systems.

CONNECTOR IMPACT ON MODULARITY

Take one look at a modular system and you will see multiple connectors throughout (See Fig. 1). These small components have a big impact on modular processing.

Regardless of size or configuration, all modular bioprocessing systems require reliable, easy-to-use connectors to facilitate, protect, and manage fluid flow.

In aseptic processing, for example, sterile connectors link one sterile fluid stream to another – from a container to a sampling line, media to a product vessel, or a filtration assembly to a filling line.

PREFABRICATED BUILDING BLOCKS FOR A MODULAR SYSTEM

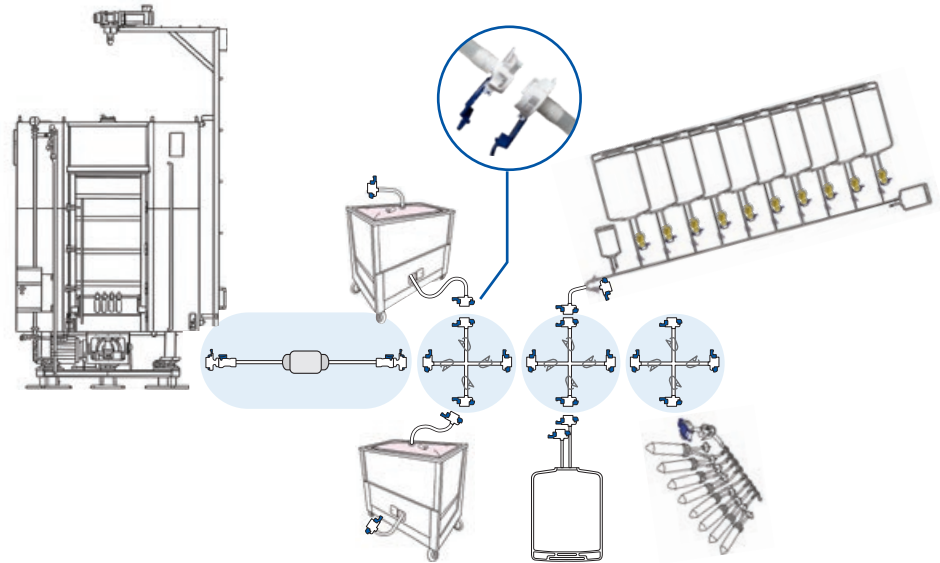


Figure 1: Modular System Subassembly Examples

Single-use, sterile, genderless (no male or female halves) connectors allow biomanufacturers to connect these modular units quickly and efficiently in any environment. The same connectors also facilitate rapid equipment changeovers between production runs without compromising sterility.

Given the growing importance of modular systems, it is useful to understand the role of connectors in creating them.

A key component in modularity's growth is the AseptiQuik® G connector, which is integrated into most modular systems today. This widely used connector series

	MODULAR SYSTEM BENEFITS	IMPORTANT CONNECTOR CONSIDERATIONS
PRE-DESIGNED SYSTEMS	<ul style="list-style-type: none"> • Able to assemble and configure at the point of use • Drop into facilities for rapid implementation • Construct sections in parallel, which shorten timelines 	Specify connectors that are: <ul style="list-style-type: none"> • Readily available (supply chain) • Work seamlessly with components from multiple suppliers • Undergo rigorous testing and are accompanied by robust validation reporting, which lowers validation and compliance burdens at the manufacturer level.
STANDARDIZATION	<ul style="list-style-type: none"> • Deliver efficiency through the same equipment, SOPs, training and supply chains • Help reduce manufacturing errors due to familiarity with components 	<ul style="list-style-type: none"> • Genderless connectors eliminate complexities with product specification and inventory management associated with gendered connectors (male/female halves) • Connectors that work with any suppliers' components support flexibility and supply chain assurance Example: Industry standard AseptiQuik® sterile connectors can be incorporated into any modular building block
RAPID REDEPLOYMENT	Rearrange modular systems to: <ul style="list-style-type: none"> • Manufacture multiple products with a single set of equipment • Reallocate processing capacity quickly for individual products as needed 	Easy-to-use genderless connectors help: <ul style="list-style-type: none"> • Reduce system complexity • Simplify training requirements • Support rapid process conversion and accelerated timelines
SCALING FLEXIBILITY	Scale up, down or out as product approval status, demand, and bioprocessor priorities change	To simplify scalability, partner with sterile connector suppliers that can support the full product development pathway, from small-volume (<10L) to large-volume processing (e.g., 5,000L)

SCALING FLEXIBILITY

Sterile connectors in a range of sizes simplify scalability

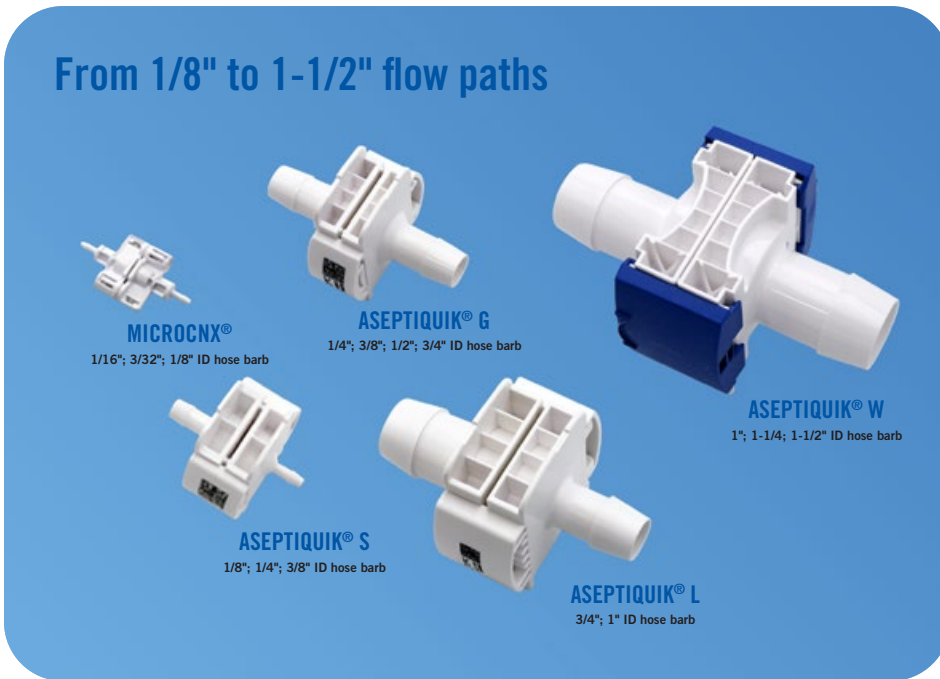


Figure 2: CPC Sterile C connectors

is also readily available in single-use OEM component libraries, contributing to standardization.

Building on the reliability and performance of the industry standard AseptiQuik G connectors, CPC has extended its portfolio to include both the smallest (MicroCNX® Series) and largest (AseptiQuik® W Series) sterile connectors currently available on the market. This range provides flexibility and continuity as drug developers scale their operations.

MicroCNX® connectors help operators create sterile connections about four times faster than tube welding, which eases integration into modular assemblies as processing scales up. They also represent the first alternative to labor-intensive tube welding for small-volume closed aseptic processes.

CONNECTORS IN A MODULAR SYSTEM

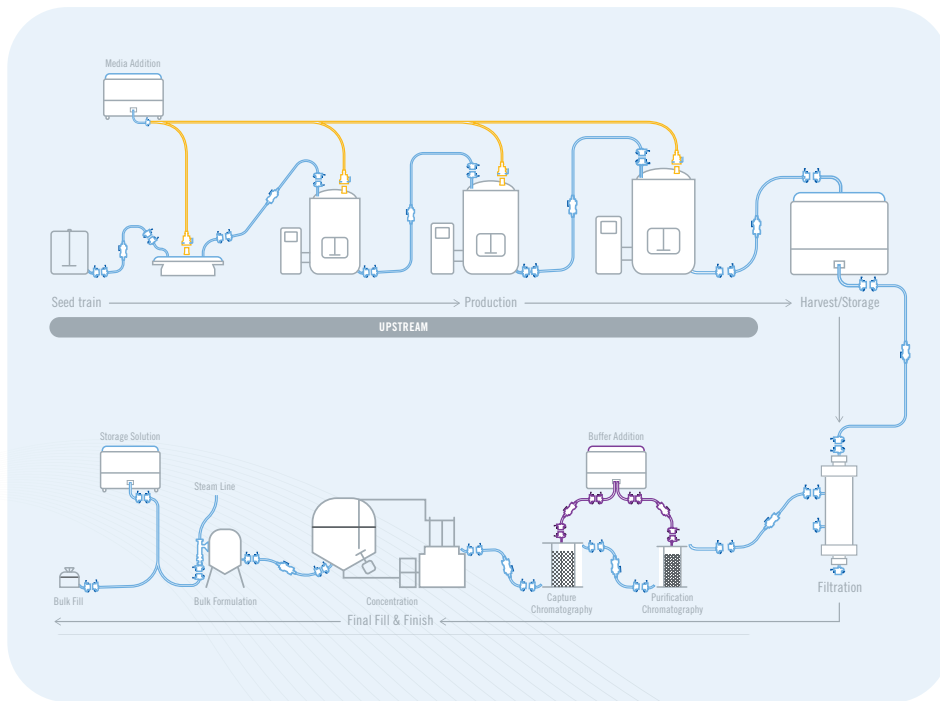


Figure 3: Modular System with CPC Connectors - The use of robust single-use connectors in both upstream and downstream operations enables operators to swap out products as needed and quickly link components and systems with confidence.

“Standard connections, layouts and equipment simplify training and reduce the time to develop, deliver and receive training and operating procedures.”

Source: “Accelerating Multi-product Biopharmaceutical Manufacturing Facility Project Lifecycle Through Modular Design.” BioPhorum Report, June 2022.

CHALLENGES TO MODULARITY

The “one size fits most” approach of modular assemblies helps address concerns around custom assemblies that vary greatly by user and supplier, affecting production operations.

However, it is estimated that more than 70% of single-use designs are customized for end users’ particular applications,⁶ which can present challenges:

- When each supplier applies their own customization method and proprietary components, it is difficult to consistently and reliably replicate systems, defeating some of the efficiencies modular systems are designed to deliver.
- Hard-to-procure components, the inefficiencies of handling complicated systems on the floor, and long lead times for complex systems all impact streamlined production.

These factors increase costs, slow production timelines, and threaten both product viability and time-to-market. For these reasons and more, the bioprocessing experts emphasize that driving “toward a higher level of standard, modular designs is required for continued industry success.”⁴

CONNECTORS MAKE MODULARITY POSSIBLE

Sterile connectors literally bring components together into a well-functioning, modular bioprocessing system.

Connectors allow the flow of product from the beginning of the process all the way to final fill-and-finish. Early adoption of aseptic connectors also can streamline scalability from the benchtop to commercialization.

In a typical process, there may be dozens—or even hundreds—of connections. These critical connection points are where you’ll find CPC. CPC focuses exclusively on designing, manufacturing and implementing connection technologies.

When CPC connectors are specified into a modular system design, they help deliver the flexibility, efficiency and supply chain assurance modularity is intended to achieve.

About CPC Biopharma

CPC (Colder Products Company) is a global leader in single-use connection technology, offering a wide variety of connectors for biopharmaceutical manufacturing, cell therapy and gene therapy. Innovative, flexible designs easily combine multiple components and systems including process containers, tubing manifolds, transfer lines, bioreactors and other bioprocess equipment. Robust single-use connectors maintain media sterility and integrity while improving production yields, decreasing time to market and reducing costs. The company’s well-known AseptiQuik® connectors provide quick and easy sterile connections even in non-sterile environments. Learn more about our entire portfolio at cpcworldwide.com/bio. Connect with confidence with CPC, an operating company within Dover Corporation.

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We Inspire Confidence at Every Point of Connection.

