



CUSTOM-TAILORED SINGLE-USE ASSEMBLIES

Single-Use Assemblies Built Around Your Process.
Configurable Solutions Engineered for Speed, Reliability, and Flexibility.



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WHERE SPEED MEETS PRECISION IN BIOPROCESS MANUFACTURING

Carolina Components Group (CCG) designs and manufactures custom single-use assemblies that simplify complex bioprocessing operations from R&D to commercial scale. With ISO-7 and ISO-8 cleanrooms, injection molding, extrusion, over molding, and one of the industry's largest open-architecture component libraries, we deliver faster, compliant, and customizable assemblies that align with your exact process requirements.

THE F-10 PROCESS

Our F-10 Process ensures speed with precision:

1

CONSULTATION

Define design intent and regulatory needs.

2

DESIGN

CAD modeling and 72-hour drawing turnaround.

3

REVIEW

Specification and validation alignment.

4

BUILD

ISO cleanroom assembly and packaging.

5

DELIVER

Sterilized, traceable, and documented.

✓ ISO 9001:2015 Certified

✓ Lot Release Testing
Available to USP <788>
and <85>

✓ Gamma Sterilized to
ISO 11137

✓ Autoclave-Sterilized
Assemblies Available

✓ Full Documentation
Package Available





ASSEMBLIES ENGINEERED FOR BIOMANUFACTURING

Whether producing monoclonal antibodies, vaccines, or cell and gene therapies, CCG single-use assemblies integrate seamlessly from upstream media preparation to final drug product fill. Our modular systems and validation-ready documentation ensure process consistency, sterility, and scalability.

SOLUTIONS THAT POWER EVERY STEP OF THE FLOW

Upstream Operations: From Media Preparation to Cell Harvest.

MEDIA & BUFFER PREPARATION

Scalable, Smarter Mixing.

Precision-controlled magnetic mixing delivers reproducible media and buffer prep every time. Integrated pH and temperature sensors, sterile powder ports, and automation-ready design eliminate risk and reduce turnaround.

CELL CULTURE & FERMENTATION

Sterile Culture, Flexible Scale.

From rocker bags to closed bottle assemblies, CCG designs weldable, aseptic transfer systems that grow with your process. Sampling manifolds and sterile connectors ensure data integrity without contamination.

HARVEST AND CLARIFICATION

Clarity and Control, Built In.

Integrated FlowPress™ sensors monitor differential pressure in real time, ensuring predictable throughput and efficient harvest. Low hold-up volumes maximize recovery and process yield.



CLEAN, CONFIGURABLE, COMPLIANT

Our configurable single-use solutions meet stringent requirements so you can ensure your contamination control strategy yields operational safety and efficiency in formulation, final filtration, and final filling. Utilizing state-of-the-art manufacturing, our team can work with you to build reliable and clean solutions that provide the highest level of purity in your drug product processing.

SOLUTIONS THAT POWER EVERY STEP OF THE FLOW

Downstream & Fill-Finish: From Purification to Final Fill

CHROMATOGRAPHY & TFF

Precision Flow for Critical Purification.

Overmolded FlowLinX® connections and pre-qualified tubing assemblies deliver consistent, leak-free chromatography and TFF performance. Built to handle high-pressure applications while maintaining single-use simplicity.

SAMPLING AND STORAGE

Closed Sampling. Secure Storage.

Sampling and storage assemblies maintain aseptic integrity and traceability across every batch.

STERILE FILTRATION & FILLING

Sterility Assured, Every Time.

From PUPSIT-ready filter assemblies to overmolded transfer sets, CCG delivers confidence at final fill. Leak-free overmolds and beta bag transfer compatibility maintain integrity from bulk to vial.

**ASSEMBLIES THAT DEFINE PERFORMANCE**

From Standard Configurations to Custom Innovation

**FLOWMIXER™ MAGNETIC MIXING BAG:**

Closed magnetic mixing for rapid repeatable preparation and formulation

**PUPSIT ASSEMBLY:**

Validated sterile filtration assembly with designed PUPSIT capability

**OVERMOLDED ASSEMBLY WITH FLOWPRESS™ SENSOR:**

Leak free overmolded connection with inline FlowPress™ monitoring for real time process control

**2D BIO BAG ASSEMBLY:**

Custom 2D bags with configurable ports and sterile connectors for storage and transfer

**FLOWTAINER® CLOSURE SYSTEM:**

Closed cell culture, sterile transfer and storage systems designed for reliability

**ASEPTIC SAMPLING ASSEMBLIES:**

Precision sampling manifolds from bioreactors and closed systems



FREEDOM TO DESIGN WITHOUT LIMITS

CCG's assemblies integrate trusted component brands for performance, flexibility, and security of supply. Each system can be configured to your exact process requirements — with all connections pre-qualified and validated for bioprocess use.



FLOWLINX™

Clamps, fittings, tubing and more



FLOWTAINER®

Bottles, carboys, and closure systems



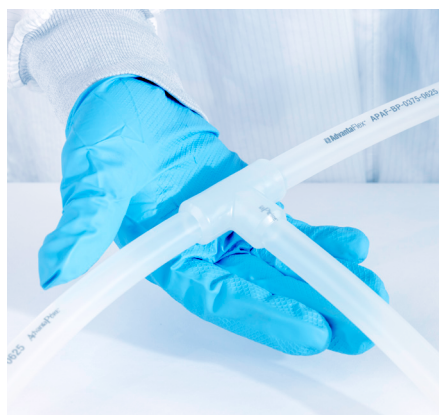
FLOWPRESS™

Single-use inline pressure sensors



FLOWMIX™ / FLOWMIXER™

Benchtop and automation-ready mixing platforms



CCGP / ECOFLEX™

CCGP pump tubing; TPE tubing, bio-based, weldable



FILL-FINISH ASSEMBLIES

Efficiency in final filtration, final filling, and compounding

QUALITY & COMPLIANCE

Quality You Can Trust. Documentation You Can Depend On.

Every CCG assembly is built under ISO 9001:2015 controls, manufactured in ISO-7 and ISO-8 cleanrooms, and backed by full traceability documentation. Our quality management system ensures every assembly is compliant, validated, and ready for audit.

- Certificates of Compliance and Sterility
- USP <85>, <788>, <665> compliance available
- Gamma validation to ISO 11137
- Visual inspection for each lot
- Connection verification program
- Customer specific PEPs (product enrollment packages)



SUSTAINABILITY & IMPACT

Sustainability is built into how we think, design, and operate. We believe that a responsible bioprocess supply chain starts with thoughtful product design, ethical partnerships, and continuous improvement, not just compliance.

From energy use and materials selection to packaging, waste reduction, and supplier engagement, every decision reflects our commitment to minimizing environmental impact while strengthening long-term business resilience.

Our Sustainability Committee, representing Operations, Procurement, HR, and Senior Management, oversees four pillars that guide our journey:

1. **Environmental Stewardship:** Reducing resource use, waste, and emissions through smarter operations and circular design.
2. **Sustainable Procurement:** Partnering with suppliers who share our values for transparency, quality, and ethical responsibility.
3. **Business Ethics & Integrity:** Operating with accountability, fairness, and trust at every level of the organization.
4. **People & Community:** Protecting the health, safety, and growth of our employees and contributing to our local community.



Together with our partners, we're building a more sustainable bioprocessing ecosystem, one assembly at a time.

We are advancing toward broader environmental goals by promoting reusability, recyclability, and lower-carbon materials, while maintaining the high purity and compliance our customers depend on.

- Design with purpose: reduce waste, optimize efficiency
- Operate with transparency: ethical, compliant, auditable
- Source responsibly: choose partners who share our values
- Protect people: safe workplaces, fair labor, equal opportunity
- Innovate for the future: bio-based and circular material solutions





Because we're passionate about making a difference in the lives of our customers, CCG single-use assemblies and FlowLinX® components are trusted in bioprocess applications worldwide.

CUSTOMER EXPERIENCE

Our mission is simple: deliver assemblies that perform flawlessly and service that earns loyalty. From rapid prototyping to large-scale production, CCG partners with you at every stage.

RAVING FANS IN EVERY FLOW

"It is evident they know the biotech and pharma world so well. When you show them the issue, they understand it and can help with solutions and because they've worked with so many other companies in the area, they have potentially seen this issue elsewhere, so their time frame of coming up with a solution is rapid. I've never had any issues with delivery times. They're always delivering on time, within budget."

CHUCK CROSIER

Capital Project Engineer
CCG Customer