



The Perfusion CDMO

Making Large Molecules Less Challenging

Small- to Mid- Scale Mammalian GMP Manufacturing

This is our focus. C3 has served over 1,700 organizations in 30+ years and performed over 25 GMP projects. What sets us apart is our ability to cost-effectively perform GMP manufacturing for preclinical to commercial stage, small- to mid-scale monoclonal antibodies and recombinant proteins.

CDMO Services: Protect Quality. Improve Timelines. Reduce Costs.

C3 is committed to quality, expertise and service. From upstream cell culture to downstream processing and analytical testing, we can use our decades of experience to help you with your custom needs. C3's right-sized R&D and GMP suites enable the production of multiple concurrent projects.

Technology

Our team understands the need for robust, predictable processes that support monoclonal antibody and recombinant protein manufacturing. This requires flexibility in how we apply technology. We utilize our proprietary perfusion bioreactors along with traditional cell culture methods for both adherent and suspension cells.

C3 Advantage

Cell Culture Company (C3) is unique among CDMOs. What sets us apart is our ability to cost-effectively manufacture GMP-quality, small- to mid-scale batches of recombinant proteins and mAbs for pre-clinical to clinical and small batch commercial needs. We accomplish this by using our flexible manufacturing platform and right-sized GMP suites, which enable multi-product custom manufacturing. For the last 30 years, we have served over 1,700 organizations and manufactured over 25 GMP projects.

With C3 You Get:

- GMP-compliant upstream, downstream and analytical services
- Cost-effective R&D- to commercial-scale protein production
- Single-use, continuous processing utilizing perfusion bioreactors
- Cell line expansion services for the production of whole cells and cellular extracts
- Full process development gram vial to vial
- Dedicated project manager for your protein (Life sciences PhD-, Masters-level)



CDMO Services

Our staff understands the challenges associated with developing and running a robust biomanufacturing process. Our 30,000 ft² facility features individual suites for R&D, Process Development, and GMP grade clean rooms. Our perfusion bioreactor technology allows us to produce small-to mid-scale proteins at a reduce cost and risk.

Upstream

We bring the knowledge and skill that comes with expanding more than 2,650 different cell lines to produce monoclonal antibodies, recombinant proteins, viruses, whole cells and cellular extracts from mammalian and insect cell production platforms. We use perfusion bioreactors as well as traditional cell culture techniques for both adherent and suspension cells.

C3's perfusion bioreactors support cell densities at 1×10^9 cells/mL, achieving in vivo-like conditions, which enhance cell-to-cell communication. Results include improved cell health and greater yields, especially for low-expressing cells that struggle in tanks.

Upstream Services include:

- Process Development
- MCB/MWCB Generation and Characterization
- Custom Large-Scale Production of Whole Cells and Conditioned Media
- cGMP and R&D Production of Monoclonal Antibodies and Recombinant Proteins

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Downstream

Nothing compares to experience. We have the expertise to assist you in creating the ideal downstream process and provide a wide range of technical services.

Technical Services and Support

- Process development
- Process evaluation, and validation
- Clinical and Commercial Manufacturing
- Technology Transfer
- Comparability
- Quality by design
- Regulatory Support

Antibody and Non-Antibody Protein-based Purification

- IgG & IgM
- Fc-fusion proteins
- His tagged proteins

Capture Chromatography

- Protein A, G Affinity
- Ceramic Hydroxyapatite (CHT)
- Metal Affinity

Finish Processing

- Formulation
- Conjugation
- Final Fill

Polishing

- Cation/Anion exchange chromatography
- Size Exclusion Chromatography (SEC)
- Viral inactivation, filtration, and clearance
- TFF/Diafiltration

Analytical

Our highly experienced team understands that decisions made during the development of your analytical process can impact the reproducibility, scalability, and cost-effectiveness of your process. Our team understands the requirements for a robust and predictable process that supports scale-up, GMP manufacturing, and regulatory requirements.

Custom Methods:

- Development
- Qualification
- Validation
- Impurity characterization
- Recombinant Protein/ mAb characterization

Standard Methods:

- A280
- ELISA
- Host Cell Protein (HCP) Testing
- HPLC/UPLC
- SDS/IEF/Western Gels
- pH

Technology

Cell Culture Company (C3) is an expert in [Automated Single-use Hollow Fiber Perfusion Bioreactors](#).

Pioneered to improve the quality of cell culture by creating in vivo-like conditions, our ACUSYST® (Automated Culture Systems) technology is used to expand mammalian and insect cell lines for the production of expressed proteins. Designed to provide the optimal environment for cell growth and production, our ACUSYST® technology offers significant advantages over traditional cell culture platforms for many applications.

Our platform of Hollow Fiber Bioreactors is designed to meet research-, pilot-, and production-scale needs of cell-derived product from pre-clinical through commercial.

Key benefits of our technology include:

- **Reduced Costs:** Reduced capital, labor, facilities, and materials expenditures.
- **Perfusion:** Improve cell health with in vivo-like conditions that support a high density of cells and allow for long culture times, consistent metabolic parameters, and stable protein expression.
- **Continuous Manufacturing:** Easily harvest cell-free product throughout a manufacturing run and eliminate downstream processing steps, including concentration and filtration.
- **Single-Use:** Decreased production risk as a result of using our closed, single-use system.
- **Improved Efficiency:** Increased protein production per square foot of production space.
- **Scalable:** Increased speed to market due to reduced upstream validation requirements. Achieve larger production scales by adding cartridges in parallel, and reduce re-validation

Deployed worldwide since 1981, our bioreactors support research, clinical trials and manufacture of regulated therapeutics, diagnostics, and veterinary products for:

- Contract Research Organizations (CRO)
- Contract Development and Manufacturing Organizations (CDMO)
- Academic and Not-for-Profit Research Communities
- Diagnostic Healthcare
- Therapeutic Healthcare
- Animal Health

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Cell Culture Company is very interested in hearing from you, and upon request, it would be our pleasure to email you with news and updates.

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