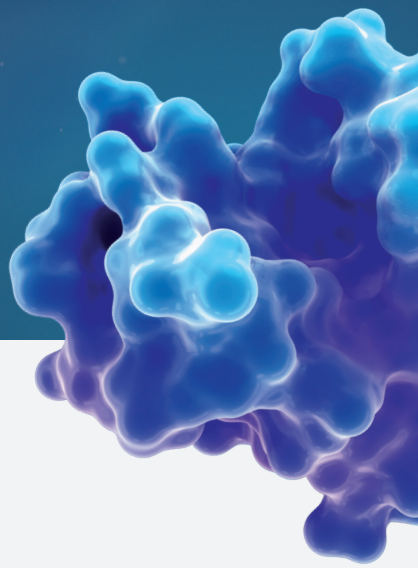
CMC biologics

Process Development and cGMP Manufacturing



CMC Biologics Will Help You Achieve Your Manufacturing Goals

When you choose CMC Biologics as your partner for contract manufacturing, you will benefit from our many years of biologics process development, technology transfer, and cGMP manufacturing expertise. Our experienced team is dedicated to the successful completion of your project and committed to helping you meet your goals.

CMC Biologics' technical professionals, many with more than 20 years' industry experience, will provide energy, enthusiasm, expertise, and drive to ensure you achieve your project goals from start to finish, including:

1. DEVELOPMENT & MANUFACTURING
2. DOWNSTREAM DEVELOPMENT
3. FORMULATION DEVELOPMENT
4. QUALITY CONTROL
5. QUALITY ASSURANCE AND REGULATORY COMPLIANCE

The Strategic Advantage

Whether you need assistance developing a new manufacturing process, improving existing processes, or getting ready to manufacture your product, you will benefit from CMC Biologics' expertise. Our technical specialists will develop the most effective processes for the production of your clinical and commercial materials. Our extensive experience enables us to replicate existing processes and to develop customized processes. We can also develop late-stage processes that utilize common production techniques, resulting in maximum scalability and efficient process transferability.

1. Development and Manufacturing

- Pilot-scale facilities for production of research and non-clinical lots
- Stainless steel and single-use technologies
- Versatile range of bioreactors for cGMP production from 100L–12000L
- Batch, concentrated fed-batch, and perfusion processes available
- High-level product expression in mammalian and microbial host cells
- Rapid host cell line development, upstream process development (animal component-free media), and downstream process development (purification)
- Statistical design of experiment (DoE) and analysis
- Extensive experience developing regulatory submissions for clinical and commercial products in US, Canada, Europe, and developing markets including protein characterization for comparability studies

2. Downstream Development

CELL SEPARATION TECHNIQUES

- Centrifugation
- Depth filtration
- Tangential flow filtration

SEPARATION CHROMATOGRAPHY TECHNIQUES

- Affinity
- Ion exchange
- Hydrophobic interaction
- Gel filtration
- Single-use
- Various viral clearance technologies

DOWNSTREAM TECHNIQUES

- Recovery and refolding
- Single-use
- Various viral clearance technologies

ANALYTICAL DEVELOPMENT AND CHARACTERIZATION

- In vitro bioassays (CDC, ADCC)
- Electrophoresis (SDS-PAGE, IEF, CE, icIEF)
- HPLC (SEC, RP, IEX, HIC, peptide mapping)
- Aggregate analysis (On-line static light scattering with SEC)
- Analytical methods for analysis of complex carbohydrates (glycan analysis, monosaccharides, and sialic acids)
- Binding methods (ELISA, SPR, isothermal titration calorimetry)
- Biophysical (CD, FTIR, fl uorescence)
- Mass spectrometry (intact Mass, LC-MS/MS peptide mapping)

3. Formulation Development

- Extensive track record of developing formulations (liquid and lyophilized) for clinical products
- High-throughput DoE scanning fluorimetry for excipient screening
- High-dose formulation development (viscometry, DLS)
- Lyophilization cycle development
- Broad range of studies offered, including stress-degradation, non-GMP stability, delivery system compatibility

4. Quality Control

- Lot release and stability testing
- Broad range of analytical methods including:
  - In vitro bioassays
  - Immunological assays
  - Electrophoresis (SDS-PAGE, icIEF, IEF, CE)
  - HPLC (SEC, RP, IEX, HIC, peptide mapping)
  - Microbiological methods (endotoxin, bioburden, microbial identification)
  - General chemistry (pH, osmolality, visual appearance)
- Analytical method validation and method transfer program
- Stability testing programs utilizing ICH compliant storage conditions

5. Quality Assurance And Regulatory Compliance

- Support to regulatory submissions (IND, IMPD, BLA, MAA)
- Integrated quality system incorporating US, European, and ICH cGMP requirements
- Comprehensive Quality Agreements
- Regulatory compliance and validation expertise
- History of successful client audits and regulatory inspections
- EU GMP Certification