



Process Development

AGC Biologics will help you achieve your process development goals

When you choose AGC Biologics as your partner, you will benefit from our many years of biologics process development expertise. Our experienced team is dedicated to the successful completion of your project and committed to helping you meet your goals. Our technical professionals, many with **more than 20 years of industry experience**, will provide energy, enthusiasm, expertise, and drive to ensure you achieve your project goals from start to finish, including:

- 1. Upstream Development**
- 2. Downstream Development**
- 3. Formulation Development**

The Strategic Advantage

Whether you need assistance developing new manufacturing processes, improving existing processes, or preparing to manufacture your product, you will benefit from AGC 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 or develop a customized approach, depending on your needs. We can also develop late-stage processes that utilize common production techniques, resulting in maximum scalability and efficient process transferability.

Upstream Development

- 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 100 L to 12,000 L
- Process development, optimization, and qualification of small-scale bioreactor models in Ambr250 and bench-top 15L vessels
- 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
- Small Model Qualification and Process characterization to identify critical process parameters and ranges for process robustness in manufacturing

Downstream Development

- **Cell Separation Techniques**
 - Centrifugation
 - Depth filtration
 - Tangential flow filtration
- **Downstream Separation Chromatography and Product Recovery Techniques**
 - Affinity
 - Ion exchange
 - Hydrophobic interaction
 - Gel filtration
 - Various viral clearance technologies
 - Recovery and refolding
 - Single-use

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, fluorescence)
- Mass spectrometry (intact Mass, LC-MS/MS peptide mapping)

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-cGMP stability, delivery system compatibility

Regulatory Submissions

- Experience developing regulatory submissions for clinical and commercial products in the U.S., Canada, Europe, Asia, and developing markets, including protein characterization for comparability studies