



Committed to Your Success.

Concept to Commercialization — Our process development (PD) team has over 26 years of experience with development, transfer-in, optimization, and scale-up of processes suitable for CGMP manufacturing. We develop product specific and compendial analytical assays that include feasibility testing, assay development, and pre-qualification activities. Our goal is to ensure our clients receive a scalable, robust process that meets both product quality and process yield expectations for every molecule in our hands. Avid Bioservices’ PD team also supports supply of material for use in toxicology studies, performing both small scale and pilot run studies.

Located in Tustin, CA, we have over 7,000 ft² of upstream, downstream and pilot-scale development space. Additional expansion plans will increase the process development space to over 10,000 ft² and includes the addition of 24 new bioreactors. In the near future, we will also include additional instrumentation and technology systems that will increase efficiencies to our current PD processes, enabling our clients to move their molecule to the next phase even faster.

Our PD team has experience with numerous product classes and mammalian expression systems. We offer the cell lines and modes of production mentioned below for all program phases including: preclinical, all clinical trial phases, PPQ, and commercial supply. We have experience with innovator and biosimilar molecules. We also support Orphan, Fast Track and Breakthrough Designations.

Modes of Production: Fed-Batch, Batch, Perfusion

| CELL LINES | MOLECULE TYPES | |
|------------|-------------------------------|---------------------|
| ▶ CHO | ▶ Monoclonal antibodies | ▶ Vaccine subunits |
| ▶ NS0 | ▶ Antibody fragments/variants | ▶ Enzymes |
| ▶ SP2/0 | ▶ Fc fusions | ▶ Biosimilars |
| ▶ HEK293 | ▶ Complex rec. proteins | ▶ ADC intermediates |

Process Development Services

Our cell-line, upstream, and downstream development processes combine to ensure you receive a well characterized biologic with consistent product quality. Our team is highly experienced in rapid technology transfer and process validation.

Cell Line Development & Optimization

- Transient transfections
- Stable cell line generation
- Manufacturability assessments
- Cell line stability studies

Upstream Process Development

- Cell line optimization
- High throughput media screening and process optimization
- Off-the-shelf or custom feeds
- High density cell culture
- Perfusion
- Design of experiments for process characterization
- Process scale-up & bioreactor mixing characterization
- Transition from traditional stainless steel to stirred tank single-use bioreactors

Downstream Process Development & Optimization

- Monoclonal antibody platform process
- Protein A Affinity chromatography
- Low pH virus inactivation
- Cation exchange chromatography
- Separation of complex proteins
- Experience with multiple vendor resins and filtration/membrane formats
- Anion exchange chromatography
- Virus filtration
- Concentration by UF/DF

Analytical Methods Development

- Purity assays
- Identity assays
- Impurity assays
- Potency & binding assays
- Protein characterization

Technology

Our team utilizes some of the industry-leading systems and platforms from top companies such as GE, ThermoFisher, Waters, Repligen, MilliporeSigma and Sartorius Stedim Biotech. In partnering with these companies and utilizing their latest systems; our team ensures that your projects are efficient and cost-effective.

Why our process development team stands out?

- Demonstrated expertise in cell culture development, with the proven ability to maximize productivity and guide glycosylation
- World-class purification experience, with the know-how to provide the chromatography media and methods to yield the highest productivity and product quality
- A full spectrum of analytical capability, extensive experience and technical knowledge required to develop difficult assays, including live-cell assays
- Extensive experience to scale-up and transfer to CGMP manufacturing

From process to patients, let us personally take you there.