AVID BIOSERVICES

Where collaboration, quality, and reliability meet.

We take your projects to the next level with our personal commitment for your commercial success.

Avid Bioservices is a dedicated commercial biologics CDMO focused on the development and CGMP manufacture of biopharmaceutical.

With over 28 years of development and manufacturing experience, our team at Avid Bioservices is personally committed to your project success, from beginning to end. In partnering with us, we offer your team world-class customer service and the highest level of quality from process development through commercialization.

Avid Bioservices is located in Orange County, CA. We currently employ over 280 team members across two campuses. Located in Tustin, CA with approximately 158,000 ft^2 of space, the corporate headquarters campus is comprised of four building, with two as our operational commercial manufacturing facilities for the mammalian cell culture services. Additionally, located approximately 5 miles from our corporate headquarters is our 53,000ft^2 Viral Vectors facility.

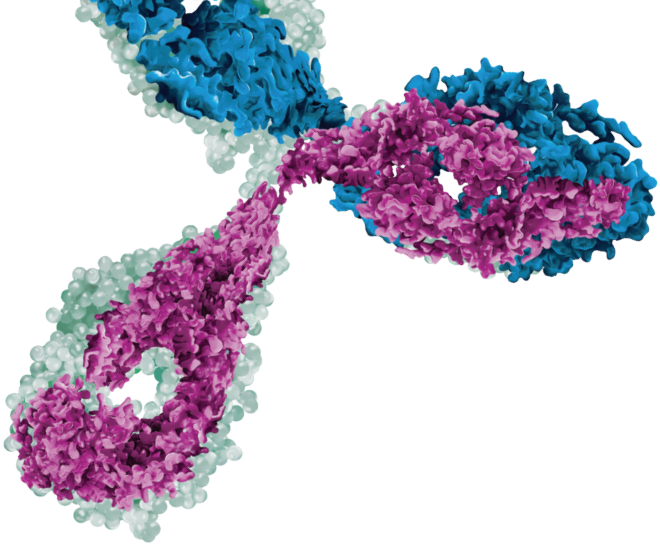
Cell Line & Process Development → Pilot Scale Production → Early & Late Phase Clinical Supply → Process Characterization & Validation → Commercial Supply

Development, Analytical & Manufacturing Services

Exceptional Regulatory Track Record

Avid Bioservices provides preclinical, clinical, and commercial solutions for your molecule.

Our team of experts has years of product development and manufacturing experience enabling us to smoothly transition your molecule onto the next phase, on time, and within budget. We offer state-of-the-art facilities, utilizing the latest systems and technologies, quality processes, and platforms to ensure your project success.



Process Development & Optimization

Our process development team has over 28 years of experience with development, transfer-in, optimization, and scale-up of processes suitable for CGMP manufacturing.

Our services include:

- Cell line development & optimization
- Upstream process development
- Downstream process development
- Analytical development

Analytical Development, Qualification & Validation

Avid Bioservices' analytical & quality control teams offer multiple years of experience in transferring, developing, qualifying, and validating client assays.

We work diligently with you to design and customize your program to adequately characterize your product to meet phase-appropriate regulatory guidelines.

Our services include:

- Purity assays
- Impurities assay
- Identity assays
- Potency & binding assays
- Protein characterization

Quality Assurance

Avid Bioservices' quality team has over 19 years of successful inspection history and have been an approved manufacturer of products marketed in over 90 countries. We aim to provide high-quality clinical and commercial product supply for our clients and in turn, to the patients.

We maintain the highest level of compliance and have the experience with global regulatory agencies by continuously improving our manufacturing and quality systems and processes.

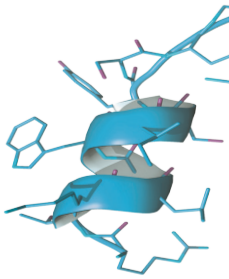
Credentials & Compliances:

- Eight successful PAIs in 2005, 2012, 2014, 2015, 2017 (2), and 2021 (2)
- 2013, 2015, 2017, 2018, and 2021 inspections resulted in zero 483s
- Compliance with U.S. FDA, EMA, ANVISA, Canadian Health Authority, Turkey MoH, Japan's Pharmaceuticals and Medical Devices Agency, and Australian Department of Health
- Compliance with large pharma audits, including Roche, Shire, and others

We offer:

- Full lot release capabilities
- Process support
- Process validation support
- Stability testing
- Drug product testing

Our quality team has extensive experience in ensuring a successful pre-approval inspection for your product and can offer support for your regulatory submission.



Commercial Manufacturing

Our team has over 16 years of commercial manufacturing experienec with over 180 commercial batches produced. We have established an exemplary global regulatory track record for biotherapeutics, with approved products marketed around the world. We partner with our clients and take pride in each step, ensuring success for the products that we manage, as if they were our own.

We use the latest technology and have experience operating multiple single-use systems as well as transitioning from traditional stainless steel to stirred tank single-use bioreactors.

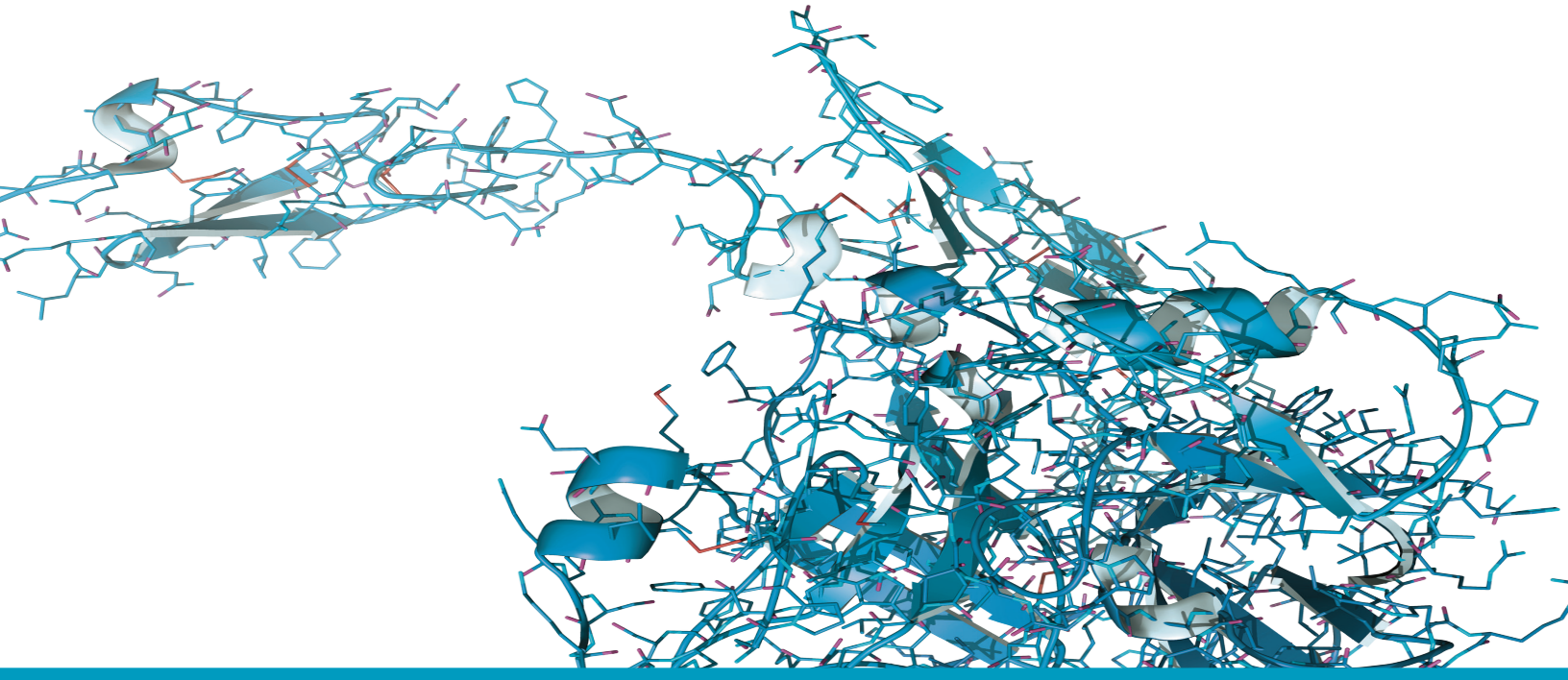
We have completed 10 “PPQ” validation campaigns in support of our clients’ goal to provide new medicines to patients.

Project Management

Avid Bioservices maintains a strong reputation for providing flexible, client-focused project management and timely responses. Our project management team averages over 13 years of drug development, quality, and manufacturing experience in the CDMO industry. With many team members holding high-level scientific degrees, we understand what it will take for your project success. Our PM team has a proven track record of excellence for client satisfaction.

Technology

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



Our Facilities

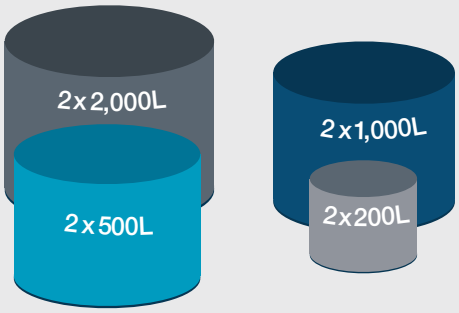
Located in Tustin, California, our CGMP state-of-the-art facilities are dedicated to mammalian cell culture with production for both clinical and commercial biologics. We provide flexibility to our clients by offering stainless steel and single-use options.

Our legacy, Franklin facility houses both stainless steel and single-use bioreactors from 100L to 1,000L scale.

Myford North Facility

- State-of-the-art facility commissioned 2016
- Single-use bioreactors from 200L to 2,000L scale
- Flexible single-use platform options
- Modular cleanroom technology
- ~42,000 ft² fully equipped
  - Includes utilities, QC labs, warehouse

Bioreactor Capacity

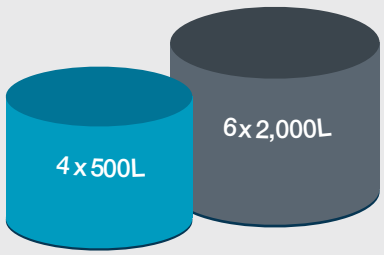


Single-use

Myford South Facility—Coming Soon

- Expansion in progress
- Single-use bioreactors 200L to 2,000L scale
- Adding 14,000L in bioreactor capacity
- Modular cleanroom technology
- ~42,000 ft² of cleanroom and supporting areas

Bioreactor Capacity



Single-use

We pride ourselves on the personal commitment that our team offers, to ensure your project success, at every step of the way. For more information, please visit **avidbio.com**