AVID BIOSERVICES

Where collaboration, quality, and reliability meet.

Committed to Your Success.

We have state-of-the art upstream, downstream and pilot-scale development space conveniently located in Orange County, California. Our process development (PD) laboratories are collocated with our manufacturing facilities on one corporate campus--less than 10 minutes from John Wayne Airport (SNA) and 40 miles from Los Angeles airport. Our PD team has over 30 years of experience developing, optimizing, and scaling-up bioprocesses scalable for large-scale clinical and commercial CGMP manufacturing. We partner with the biopharmaceutical, diagnostic and veterinary industries.

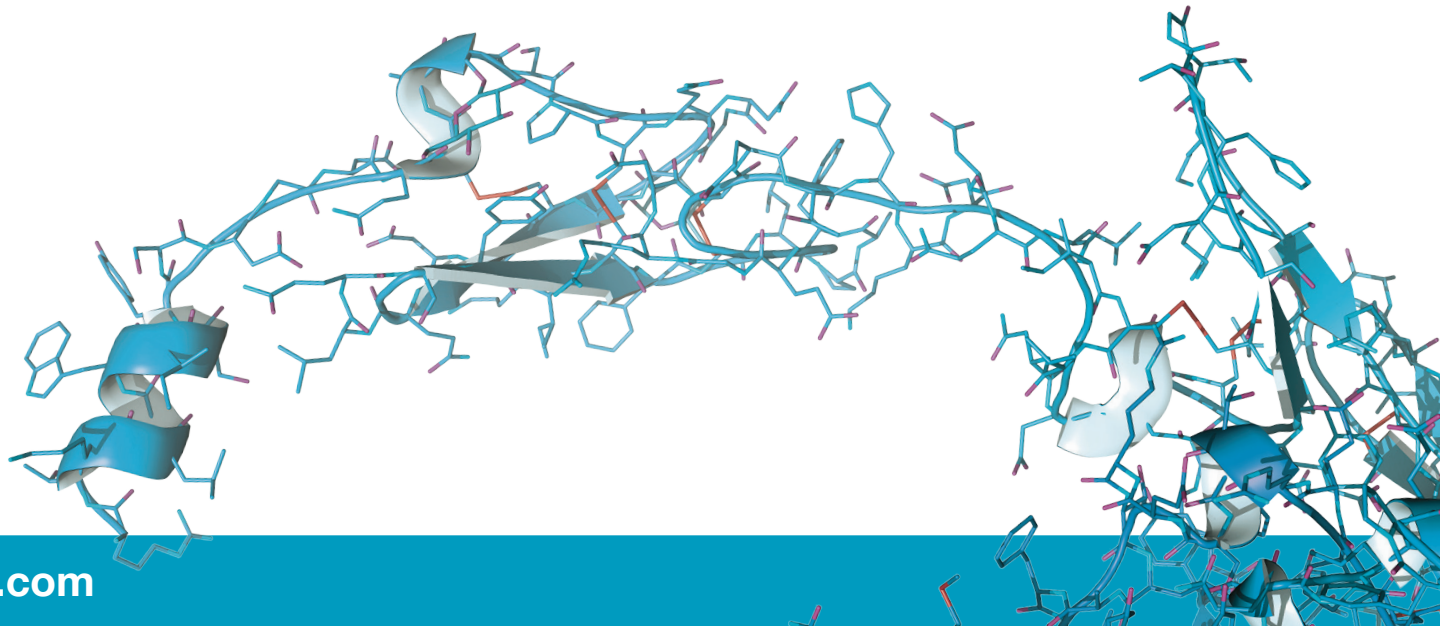
In our development laboratory spaces, we will support your research and development needs, process and analytical development, technical transfer and process scale up and optimization as well as process characterization projects with 30 modern, identical bench-top bioreactor systems enabling automated process control and QbD-based statistical Design of Experiments (DOE) programs. Our PD laboratories were designed to complement our manufacturing capabilities, providing downstream development which incorporates our Akta chromatography systems and fully automated filtration systems. We have several pilot scale single-use bioreactor systems ranging from 50 to 200 L scale to support scale-up and pre-clinical supply, fully aligned to support our manufacturing facilities. Our goal is to ensure our clients receive a scalable, robust process that meets both product quality and process yield expectations for every biologic in our hands. The Avid Bioservices' PD team can also provide material from our bench top and pilot scale equipment for R&D material supply, reference material generation and pre-clinical pharmacology/ toxicology studies.

We have extensive experience supporting discovery phase R&D programs and can add value to the emerging fields of cell & gene therapy as well as new modalities, including but not limited to, nucleic-acid based products and cell-based meat production and are open to discuss your program needs. Based on our experience, some industry clients benefit from partnering with

a contract development and manufacturing organization which offers flexibility by uncoupling process development and manufacturing services. For this reason, with the implementation of our modernized PD laboratories, we are now offering process development activities as a standalone capability. That said, we continue to develop processes, which are scalable for manufacturing and take these processes to manufacture on behalf of our clients.

Our PD team has successfully developed processes for numerous product classes and mammalian expression systems across the entire lifecycle of biologics development from R&D discovery to preclinical, all phases of clinical trials through late phase clinical, validation and commercial supply. We have experience with innovator and biosimilar molecules. We also support orphan (rare disease), fast track and breakthrough designations.

Modes of Production: Batch | Fed-batch | Perfusion		
CELL LINES	MOLECULE TYPES	
▸ CHO-K1, ▸ CHO-DG44 ▸ CHO-GS ▸ CHO-S ▸ and others	▸ Monoclonal antibodies ▸ Bispecific antibodies	▸ Vaccine subunits ▸ Enzymes
▸ Murine (NS0, SP2/0)	▸ Fc fusions	▸ Biosimilars
▸ HEK293	▸ Complex rec. proteins	▸ Fusion proteins



Process Development Services

Our team is highly experienced in rapid technology transfer, process development and process characterization. Our discovery, upstream, and downstream development processes are harmonized to ensure you receive a well-developed process & characterized biologic with consistent product quality.

Discovery Support

- Transient transfections
- Clone selection / cell line stability
- Manufacturability assessments
- R&D material supply.

Upstream Process Development

- Platform upstream process for MAbs
- Rapid process development (seed train, basal media, feeds, aeration, pH)
- Perfusion-based processes
- Pre-clinical tox material production in pilot scale bioreactors (50 – 200 L)
- Process characterization studies based on statistical Design of Experiments (DOE) and analysis
- Harvest clarification filter sizing studies

Downstream Process Development

- Platform purification process for MAbs
- Custom purification processes for unique, complex biologics
- Experienced in developing chromatography steps with all modalities (affinity, ion exchange, mixed-mode, HIC, hydroxyapatite, size exclusion)
- Membrane and depth filtration (all filter suppliers)
- Viral inactivation (pH & Solvent/Detergent)
- Concentration by UF/DF (all membrane suppliers)
- Pre-clinical tox material production with pilot scale Akta system

Analytical Methods Development

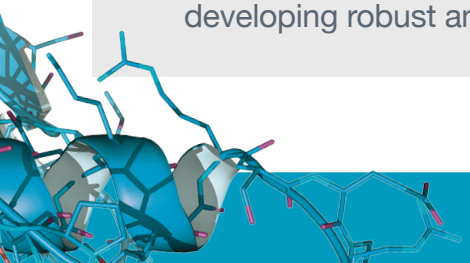
- Purity assays
- Identity assays
- Impurity assays
- Potency & binding assays
- Protein characterization

Technology

Our team utilizes 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, guide glycosylation and other product quality attributes
- World-class purification experience, with the know-how to provide the downstream process steps 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 cell-based bioassays
- Extensive experience in robust scale-up and rapid tech transfer into cGMP manufacturing
- Flexibility in offering standalone process development services while also focusing on developing robust and scalable processes which are manufacture ready



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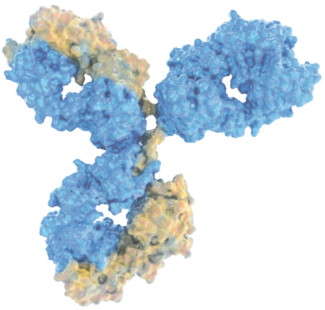

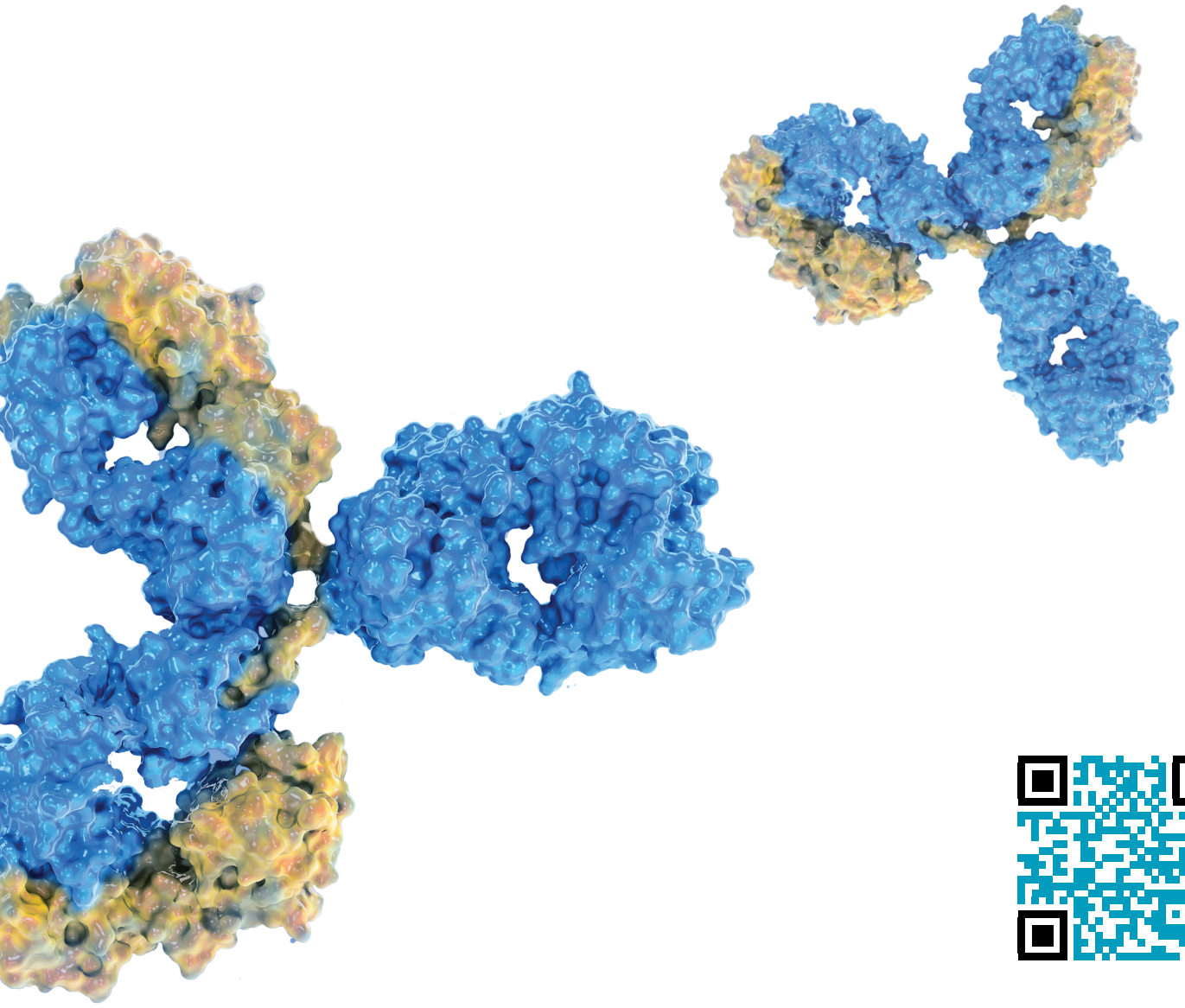

From process to patients, let us personally take you there.

avidbio.com