

Capacity to Accelerate Your Success

Integrated, Comprehensive, Flexible Services to Accelerate the Path to Market

As a CMO partner, Avid Bioservices provides fully integrated services across the process chain to develop and commercialize a biologic, including cell line and process development, analytical methods development, clinical and commercial cGMP manufacturing, and regulatory submissions. Being the wholly owned subsidiary of Peregrine Pharmaceuticals — a clinical-stage, publicly traded biotechnology company with a portfolio of monoclonal antibodies in clinical trials — gives us first-hand expertise and knowledge to navigate a biologic from concept to commercialization. Our experience developing and manufacturing Peregrine’s clinical products, combined with an accomplished management team in the field of development and commercialization of therapeutic proteins, allows us to provide our clients with unique insights into managing the process, scale-up, and validation challenges of drug development and commercialization — all while mitigating risk, reducing costs, and accelerating our clients’ time to market. Avid has produced more than 185 cGMP runs in more than 15 different indications (Table 1).

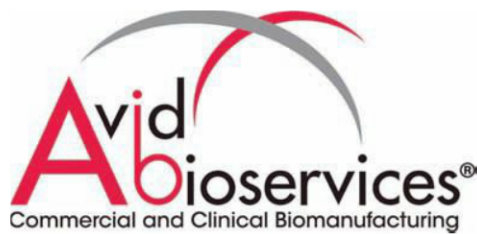


Figure 1: Bioreactor capacity

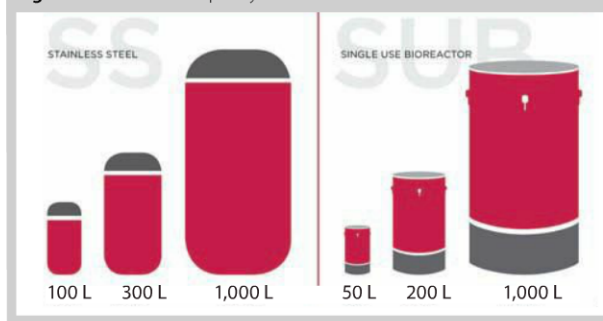


Table 1: Project history

Therapeutic Area	Clinical Phase				Bioreactor Size (L)			cGMP Runs
	Pre	1	2	3	100	300	1,000	
Oncology	✓	✓	✓	✓	✓	✓	✓	145
Inf. Disease	✓	✓	✓				✓	13
Other	✓	✓	✓	✓	✓	✓	✓	30

DEDICATED FACILITY

Avid’s facility currently has 2,650 L total capacity (Figure 1), with both single-use bioreactors (SUBs and STRs) and stirred-tank, stainless steel (SS) bioreactors. We provide clients with flexible manufacturing-scale solutions to meet any phase of production. Our established partnerships further advance our expertise and scale-up capacity.

Our fully integrated service offerings allow us to streamline development and manufacturing by executing multiple parts simultaneously and effectively utilizing the results in subsequent and ongoing processes. Through all stages of a project, we ensure seamless transitioning and provide the client with a single point of contact to simplify information dissemination. We pride ourselves on being able to efficiently and effectively apply our broad knowledge and experience to our clients’ projects at every step. Our manufacturing expertise encompasses clinical to commercial production, including commercial API production since 2005.

COMPREHENSIVE DEVELOPMENT, ANALYTICAL, AND MANUFACTURING EXPERTISE

Our development teams can assist with any challenges you face: from scale-up to process optimization to analyzing and characterizing your antibody or protein. A broad understanding of bioprocesses and bioreactor cell culture enables significant improvements in recovery rates, stability, and actual protein expression through upstream and downstream process development and optimization — all aimed at accelerating the time to market. Protein characterization assures safe, stable, and efficacious products, providing our clients with well-characterized biopharmaceutical products.

SUPERIOR QUALITY AND CUSTOMER SERVICE

Avid’s proven track record of quality and customer service speaks for itself. Since our inception in 2002, our successful inspection track record continues to grow, ranging from audits by the US FDA, European agencies, and the State of California, as well as other regulatory agencies and clients. This is further supported by the robust quality systems we have in place and our dedication to produce high quality products each and every time. At Avid, our dedication to setting the standard in customer service is clear. Our project management team’s extensive experience collaborating with clients, combined with our flexible approach to project execution by tailoring each project plan to the client’s specific requirements, we believe contributes to our clients’ success. 🌐

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CAPACITY TO ACCELERATE SUCCESS

YOUR CMO
PARTNER ON
THE PATH TO
MARKET

1

CELL LINE DEVELOPMENT

- Cell line development & selection
- Cell line characterization & optimization
- Subcloning
- Suspension adaptation

2

PROCESS DEVELOPMENT

- Upstream & downstream process development
- Technology transfer & verification
- Scale-up/down & optimization
- Process validation & viral inactivation/removal

3

ANALYTICAL METHODS DEVELOPMENT

- Development, feasibility, optimization, transfer, qualification & validation of methods
- Identity, purity, potency, safety & characterization

4

cGMP BIOMANUFACTURING

- Multi-product cGMP manufacturing
- ICH Q7 compliant facility
- Flexible manufacturing-scale solutions
- Stainless steel and single-use systems
- FDA & EU inspected

5

VALUE-ADDED SERVICES

- Regulatory strategy & submissions
- cGMP CMC Section 7 support
- In-process & release testing
- Process & equipment validation
- Stability testing
- Reference standard generation