



# Innovative Science. Consistent Biologics. Experienced Partner.

## Aldevron makes high quality proteins supporting:

Gene Editing

Recombinant Antibodies

Therapeutics

Diagnostics

Cell Editing

Custom Enzymes

Reagents



### Aldevron makes the highest quality biologics.

Our protein production capabilities range from parallel screening of several constructs, through process development optimization, to scale-up manufacturing in *E. coli*, insect and mammalian cell lines. We have experience producing thousands of different proteins.

We start each project by defining goals, identifying potential risks, determining if we transfer existing protocols or if we are developing a new method. Next we identify risks and engineer a solution to meet any required specifications. Your dedicated Aldevron team is responsive, has extensive technical experience and expertise, and provides a strong project management approach insuring a successful outcome. We are ready to be your trusted, long-term partner.

#### E. coli Fermentation

Aldevron offers on-site fermentation services to support development, manufacturing and transition to cGMP production.

We can adjust fermentation to meet your requirements from small-scale for optimization experiments, through high-volume batch and fedbatch fermentation. Aldevron clients can transfer their protocols or utilize our fermentation scientists to guide development and optimization.

Our equipment includes:

- C4 X 1L bioreactor systems
- 2 x 20L fermenters
- 2 x 200L fermenters
- 1 x 1000L fermenter

#### **Recombinant Antibody**

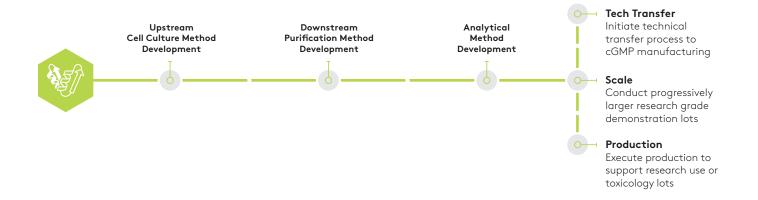
Antibody production is available for full-length IgG, antibody fusions and bi-specific, among other unique formats.

Services include:

- Antibody sequencing, construct options and gene synthesis
- Expression verification and screening
- Transient mammalian expression
- Affinity, SEC and IEX
- Delivery of low-endotoxin (LAL) and highly monomeric product (aSEC)
- Parallel processing
- Scaling and processing hybridoma and stable cell lines

#### **Development Process**

We have a dedicated, experienced team of project managers and senior scientists to create a plan and guide research grade development work, ensuring that methods are suitable for final manufacturing, quality grade and application. Once development is complete, clients may elect to scale lots, initiate technical transfer or execute production.





#### **Clinical and Commercial Manufacturing**

Aldevron provides timely and cost-effective solutions to customize cGMP and GMP-Source® (GMP-S) protein manufacturing in *E. coli.* GMP-S is a cost effective alternative to GMP. Our GMP service provides the highest quality oversight, process control and can support any application.

Stages of manufacturing:

- Master/working cell bank production
- Engineering run
- Column chromatography purification
- Aseptic fill/finish

Gene synthesis & cloning    Expression method development  Chromatography method development  Standard QC tests
Chromatography method development ✓ ✓ ✓ ✓
Standard QC tests ✓ ✓ ✓ ✓
Certificate of Analysis (CoA) ✓ ✓ ✓
TSE/BSE statement ✓ ✓ ✓
Custom QC development ✓ ✓ ✓
Manufacturing Summary Report (MSR) ✓ ✓
Validated QA oversight   ✓
Process control ✓
Change control ✓
Project-specific master batch records   ✓
ISO classified suites   ✓
Environmental monitoring   ✓

#### Contact us about Aldevron Protein

4055 41<sup>st</sup> Avenue South, Fargo, ND 58104 USA +1 (701) 297-9256 Toll-free (U.S. and Canada): +1 (877) 787-3362

Additional facility in Madison, v

Visit: aldevron com/contact



Since 1998, Aldevron has been a proud partner of research laboratories through the production of:

- Plasmid DNA at any scale, with fast turnaround times
- Proteins in bacterial, insect and mammalian expression systems
- mRNA to your specifications using a robust and scalable process

Aldevron supports research-use production through commercialization.