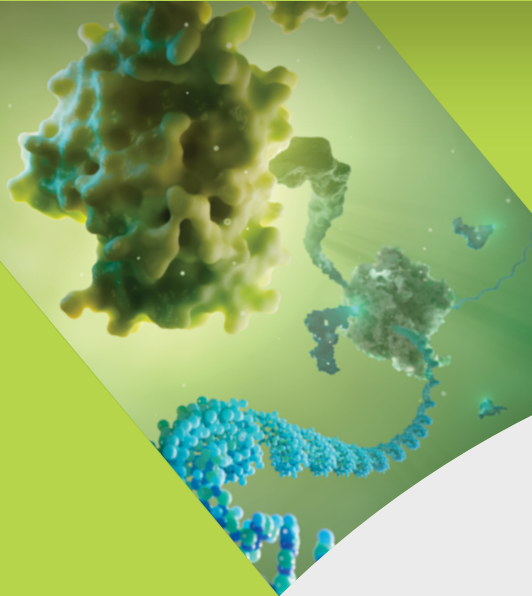




Protein

PROCESS DEVELOPMENT & MANUFACTURING



**Innovative Science.
Consistent Biologics.
Experienced Partner.**

Aldevron makes high quality proteins supporting:

Research and Discovery

Gene and Cell Editing

In vitro Transcription

Therapeutics

Diagnostics



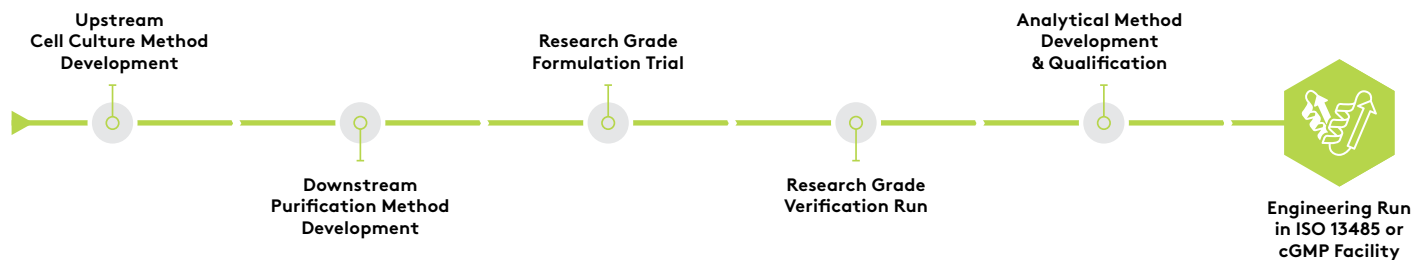
Aldevron makes the highest quality biologics.

Our protein production capabilities range from the parallel screening of growth conditions for numerous constructs, through process development and optimization, to scale-up manufacturing in bacterial expression systems. We have experience producing thousands of different proteins starting from an electronic sequence, through process development or utilizing a client-provided protocol.

Aldevron begins each project by defining goals and identifying potential risks. Next, we engineer a solution to meet required specifications, including technical transfer or new method development. Your dedicated Aldevron team is responsive, has extensive technical expertise, and provides a strong project management approach to ensure a successful program. We are ready to be your trusted, long-term partner.

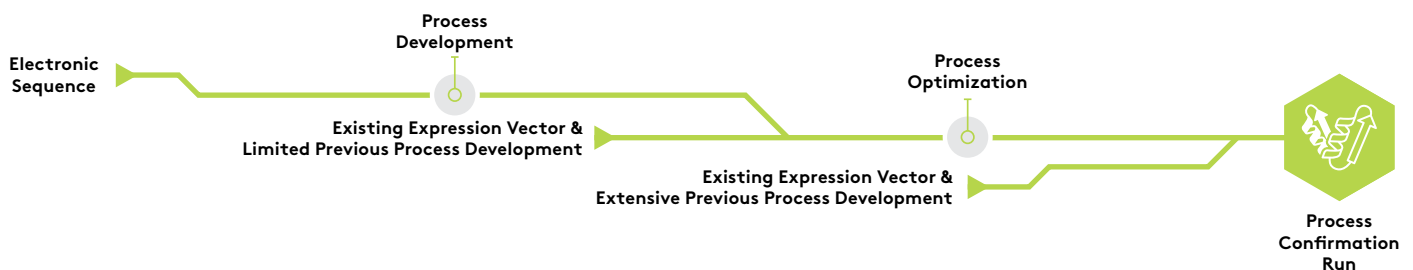
Development Process

We have a dedicated, experienced team of client support specialists, project managers and senior scientists to create a plan and guide product development work, ensuring that the methods are suitable for manufacturing based on a client's application. Process optimization ensures a seamless transition to our manufacturing group. Once development is complete, clients may elect to scale manufacture of research grade product in either our ISO 13485 certified facility or our cGMP facility.



Transfer of Existing Process

Clients interested in protein manufacturing in support of clinical, diagnostic, and commercial applications have the option of transferring an existing process into Aldevron. Clients choosing to transfer an existing method will engage with Aldevron's protein manufacturing SMEs. Process optimization may be recommended to ensure a seamless transition. Regardless of the path taken, Aldevron's internal manufacturing readiness process ensures the successful transition and execution of both the engineering and manufacturing runs.





Research Through Clinical and Commercial Manufacturing

Aldevron provides timely, high-quality solutions for customized protein manufacturing. Proteins produced for research or diagnostic purposes benefit from Aldevron's ISO 13485 certification. cGMP manufacturing services are conducted in our FDA-inspected facility that provides the highest quality oversight and process control for any application.

Stages of manufacturing supported:

- Master/working cell bank production
- Analytical method validation & testing
- Fermentation
- Lysis & clarification
- Column chromatography
- Aseptic fill/finish

Quality System Application

	Product/Process Development	ISO 13485 Manufacturing	cGMP Manufacturing
Gene synthesis & cloning	✓		
Expression method development	✓		
Chromatography method development	✓		
Quality control method development	✓		
Standard quality control tests	✓		
Temporal segregation		✓	
Certificate of Analysis (CoA)		✓	✓
Vendor management & raw material traceability		✓	✓
Validated Equipment / Cleaning / Processes / Software		✓	✓
Change control notification		✓	✓
Non-conformances/ Deviations/ CAPAs		✓	✓
Internal audit program		✓	✓
Certificate of Origin (COO), BSE/TSE statement		✓	✓
QA review of all documentation		✓	✓
Validated quality control tests		✓	✓
Spatial segregation			✓
Master batch records			✓
Controlled classified suites & environmental monitoring			✓

ISO 13485 certified manufacturing facility

Highest level of quality controls

Scaling Operations

Aldevron protein manufacturing supports clients and partners at scales from milligrams to hundreds of grams using fermentation up to 1,000L. We also partner with clients to scale for future requirements of their important diagnostic, clinical, and commercial programs. Our goal is to provide the best client experience from concept through product release with clear communication and technical excellence.

Contact us about Aldevron Protein Production Services

**Aldevron Fargo – Corporate Headquarters
& cGMP Manufacturing**

4055 41st Avenue South
Fargo, North Dakota 58104, USA

**Aldevron Madison – Product/Process Development
& ISO 13485-Certified Manufacturing**

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Visit: aldevron.com/contact



Since 1998, Aldevron has been proud to support novel therapies and vaccines with the supply of plasmid DNA, RNA, and proteins. Produced to our clients specifications using a robust and scalable process, these biologics are available for research or manufactured using cGMP for clinical trials and commercial applications.