

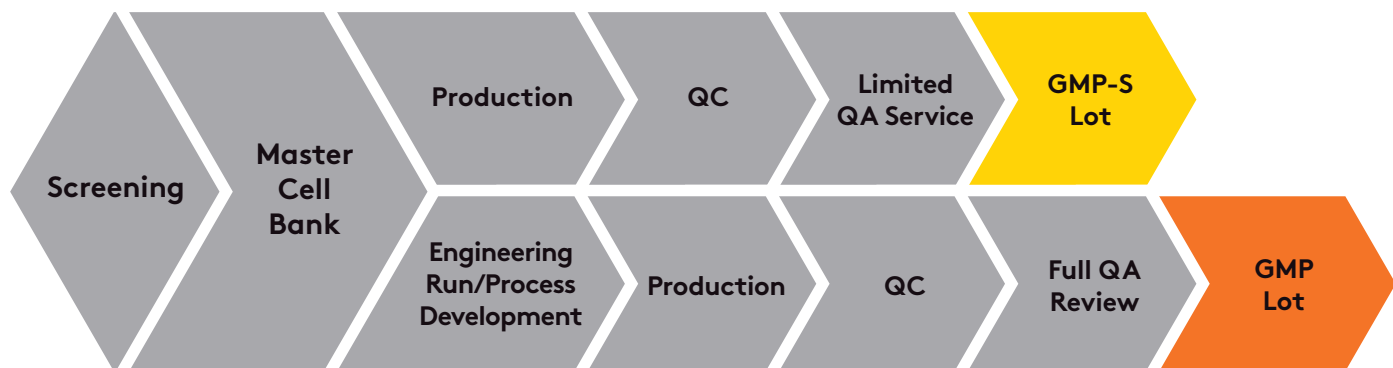


Our GMP-Source™ (GMP-S) service is a unique manufacturing solution enabling you to reach early clinical milestones while exceeding budget and timeline goals. You can then transition seamlessly into late phase clinical trials and commercialization using our full GMP service. With Aldevron as your manufacturing partner, save money and time without putting your plans at risk.

GMP-S advantages

- Retains key hallmarks of GMP service manufacture
- Allows clinical grade products to be manufactured in a shorter time frame
- Lowers costs and delivers material faster
- Easily transitions to GMP service for later clinical stages

GMP-S versus GMP production



Contact us for detailed development timelines

How is GMP-S different from GMP?

Manufacturing environment	GMP-S	GMP
Segregated manufacturing suites	✓	✓
Standardized cleaning processes	✓	✓
Bulk product fill in ISO 6 clean room, with ISO 5 Biological Safety Cabinet	✓	✓
Controlled manufacturing environment, unclassified	✓	
Controlled manufacturing environment, ISO classified under full environmental monitoring program		✓

Manufacturing process and documentation	GMP-S	GMP
Client-driven release specifications	✓	✓
Testing of growth conditions and cell strains	✓	✓
Process development and at-scale engineering run		✓
Client retains process control and authorization for change control activities		✓
Product-specific Client Master Batch Records		✓
Equipment/software/assay/process/facility validation		✓
Optional working cell bank		✓

Quality assurance batch record review process	GMP-S	GMP
Critical manufacturing processes and full QC documentation review	✓	
Comprehensive, full manufacturing and QC documentation review		✓

Contact us about Aldevron's GMP-Source

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