

PlasmidFactory GmbH

The CDMO and service provider for plasmid and Minicircle DNA

Your trusted CDMO Partner

Why choose PlasmidFactory



- 25+ years of DNA manufacturing expertise
- Independent, flexible & trusted European CDMO
- Scalable production: Research → High Quality → GMP Grades
- Proprietary technologies: Minicircle, ITRPROTECT®, ITRRESCUE®, POLYARESCUE®
- 3,500+ plasmid & Minicircle projects delivered, incl.136 GMP-like projects & 5 production runs in the GMP facility
- 99.9% success rate

Company info

Minicircle info

Comprehensive DNA Portfolio

PlasmidFactory®

Custom DNA

- Plasmid DNA
- Minicircle DNA
- MIDGE® vectors

Tailor-made DNA vectors produced from Research to GMP Grade.

In-Stock DNA

- Reporter & pEPito plasmids
- AAV plasmids and Minicircles
- Molecular size markers

Ready-to-use plasmids & Minicircles · reporters, AAV tools, markers

Services & Analyses

- Capillary gel electrophoresis (CGE)
- GMP-compliant DNA storage
- DNA linearisation, cloning & synthesis
- **ITR**PROTECT® / **ITR**RESCUE® / **POLYA**RESCUE®
- Fill & Finish; Stability Studies

Proprietary technologies and QC services · ensuring stability, purity & compliance

Available Quality Grades

Scientific Quality (SQ) Grade

Advanced research standard.

- 4 parallel production lines
- Scalable process starting from 0.5 mg
- 2 options available:
  - *Research Grade* for basic requirements
  - *CCC Grade* with ≥ 95% supercoiled DNA

Key features
- Bioreactor fermentation

High Quality (HQ) Grade (GMP-like)

Highest non-GMP standard.

- 2 HQ facilities
- According to EMA guidelines
- Production scale 10 mg – 10 g
- Also available as "HQ in GMP“ Grade

Key feature
- Complete traceability

GMP Grade

Full clinical & commercial compliance.

- Dedicated state-of-the art GMP facility
- GMP / FDA-compliant
- End-to-end single-use processes
- Late-stage clinical trials and commercial supply

Key feature
- Single use equipment

GMP Manufacturing You Can Trust

Designed for highest plasmid & Minicircle DNA quality requirements



Status: Commissioning completed
First GMP batches successfully produced

State-of-the-art GMP facility

- Dedicated building for GMP Grade plasmid & Minicircle DNA
- 450 m^2 cleanrooms suites (grades C & D)
- Facility designed to prevent cross-contamination

Flexible manufacturing with highest safety standards

- End-to-end single-use USP- and DSP- process
- Ph. Eur. / USP grade WFI supply
- EU GMP-Part 2 and 4, Annex 1 & 2, AMWHV
- Various fill & finish options
- QP batch release

Full GMP compliance

- Data integrity measures and systems in place
- Appendix 11/21 CFR Part 11

GMP info

Minicircle DNA: Clinical Footprint

Snapshot of registered and planned clinical trials using Minicircle for cell engineering

Registered clinical trials

2020 — **CARAMBA-1 - SLAMF7 CAR-T (Multiple Myeloma)** — Recruitment ended

- Phase I/IIa (FiH) • EUCT 2024-512643-23-00 • NCT04499339
- Virus-free Sleeping Beauty gene transfer using Minicircle DNA + transposase mRNA
- Opened Jun 2020 • 33 participants • DE site (multi-country approvals reported in EU project updates)

2024 — **TranspoCART19 - CD19 CAR-T (r/r B-cell Lymphoma)** — Recruiting

- Phase I/IIa • EUCT 2024-514544-90-00 • NCT06378190
- Non-viral Sleeping Beauty transposon delivered as a Minicircle + SB100X mRNA
- Start Mar 2024 • 27 participants • 9 sites (Spain)

2025 — **LION-1 - ROR1 CAR-T (ROR1$^+$ tumors)** — Recruiting

- Phase I (FiH) • EUCT 2024-512019-36-00 • NCT pending (CTIS)
- Start Apr 2025 • 46 participants • 1 site (Germany)
- Includes hematologic + solid tumors (e.g., MCL, CLL, TNBC, OC, ACC)

2026 — **TCX-001 - Siglec-6 CAR-T (r/r AML & CLL)** — Recruiting

- Phase I (FiH) • SNCTP000006901 • BASEC2026-00192
- Non-viral Sleeping Beauty CAR-T program using Minicircle DNA
- Recruiting • 1 site (Zurich)

Studies in preparation

Oncology (engineered cells)

- ROR2 CAR-T (Uniklinikum Würzburg; Phase I (FiH) start planned in 2026)
- FLT3 CAR-T (Uniklinikum Würzburg)

Autoimmune / gene therapy

- Nimvec™ AM510 (Amarna; Type 1 Diabetes)

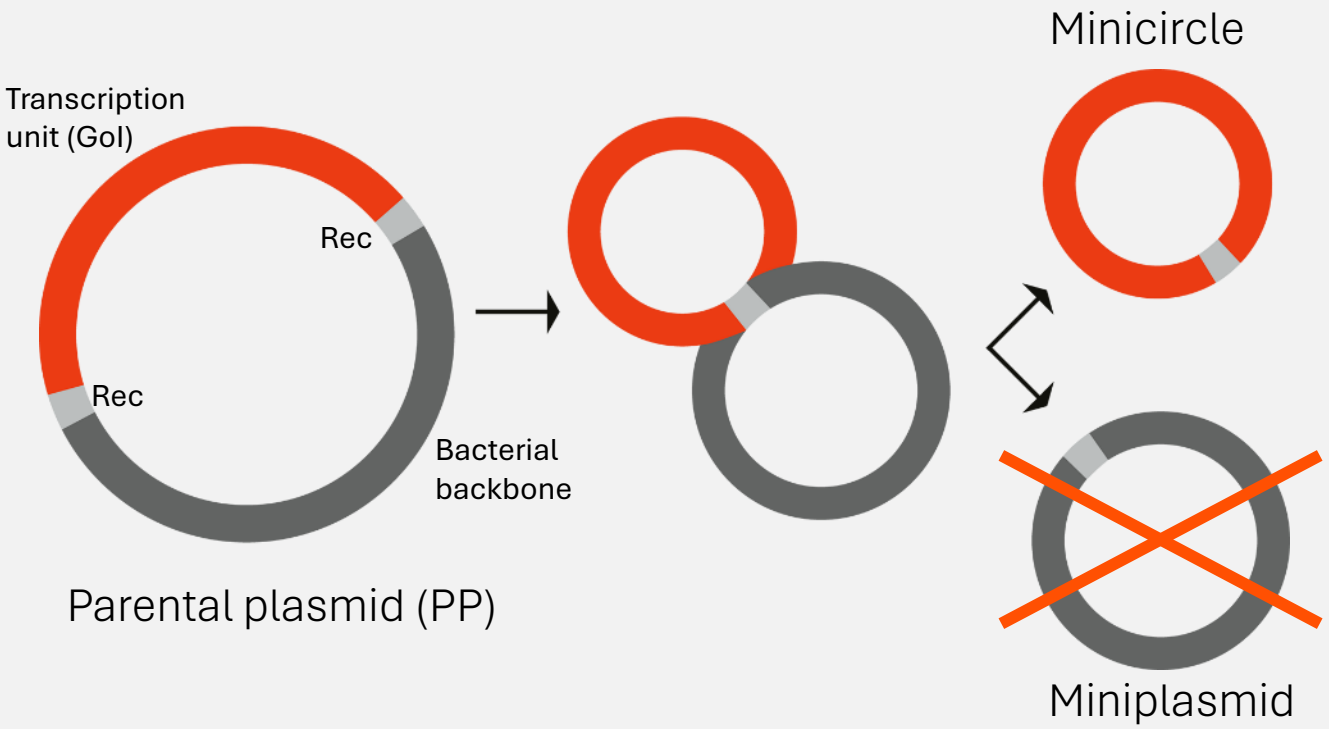
Undisclosed / confidential

- At least 4 additional clinical studies in preparation

Minicircle: Proprietary Production Method

Minimalistic DNA vector reduced to the gene of interest (GoI)

Minicircle production

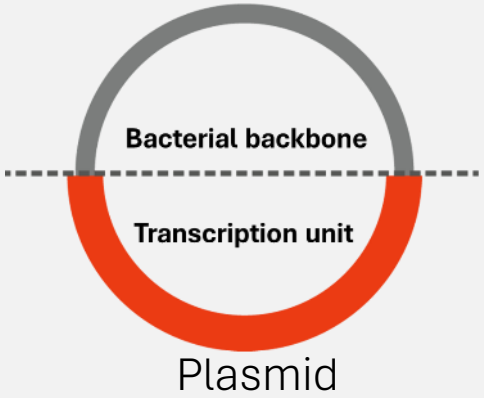


Minicircle vs. plasmid features



- No bacterial backbone
- Small, supercoiled

- Bacterial sequences
- Larger size



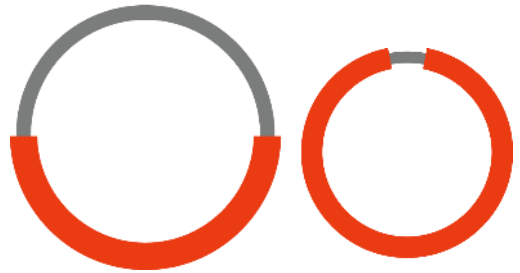
Minicircle: Small, monomeric, supercoiled

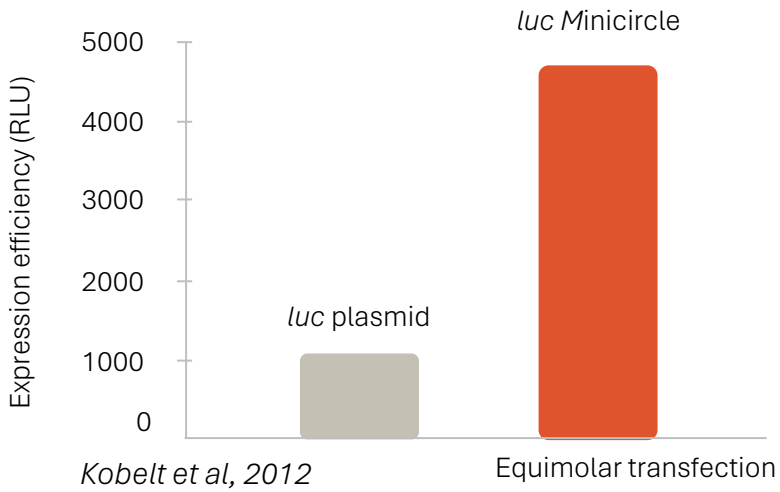
Minicircle: Advantages at a Glance

Bacterial backbone-free Minicircles

- No antibiotic resistance or other bacterial markers
- Less immunogenicity
- Lower DNA toxicity
- Higher transfection efficiency
- Reduced transgene silencing
- Stronger, more stable gene expression
- Almost no cargo size restriction,
- **Improved yield – minimized costs**
- **Ideal for virus-free gene transfers**
- **No "back-packing“ & enhanced safety (AAV)**

Part of several clinical trials





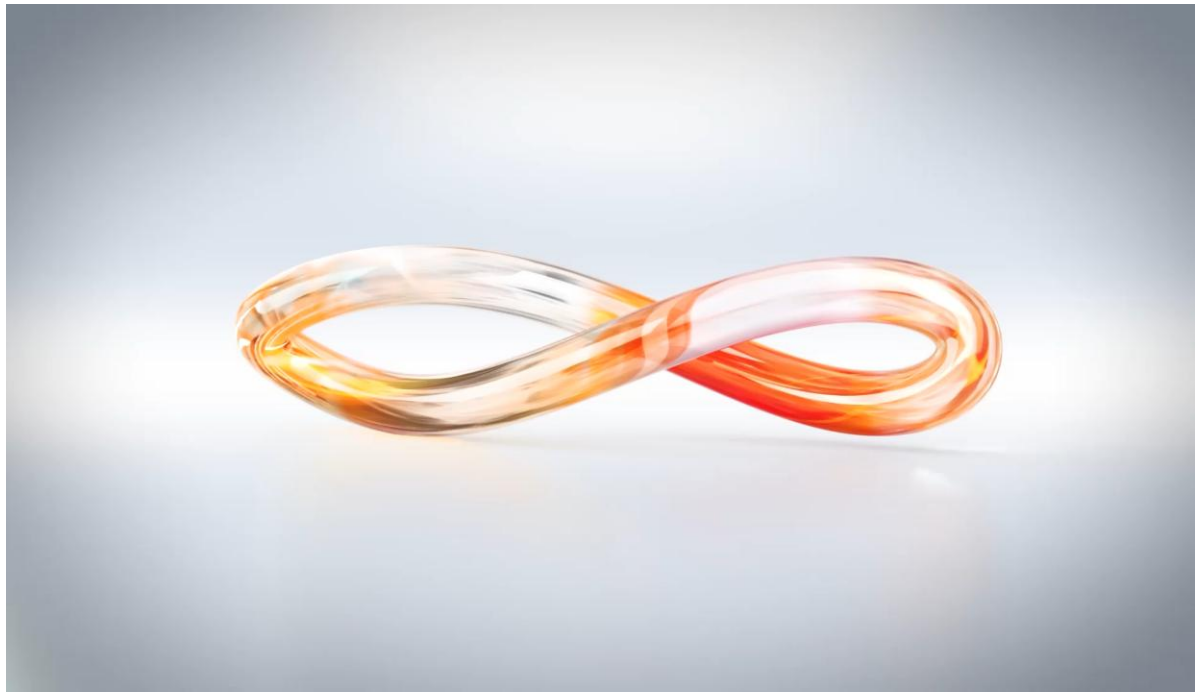
Kobelt et al, 2012

Minicircle: Small, monomeric, supercoiled

Minicircle info

Selected Focus Applications

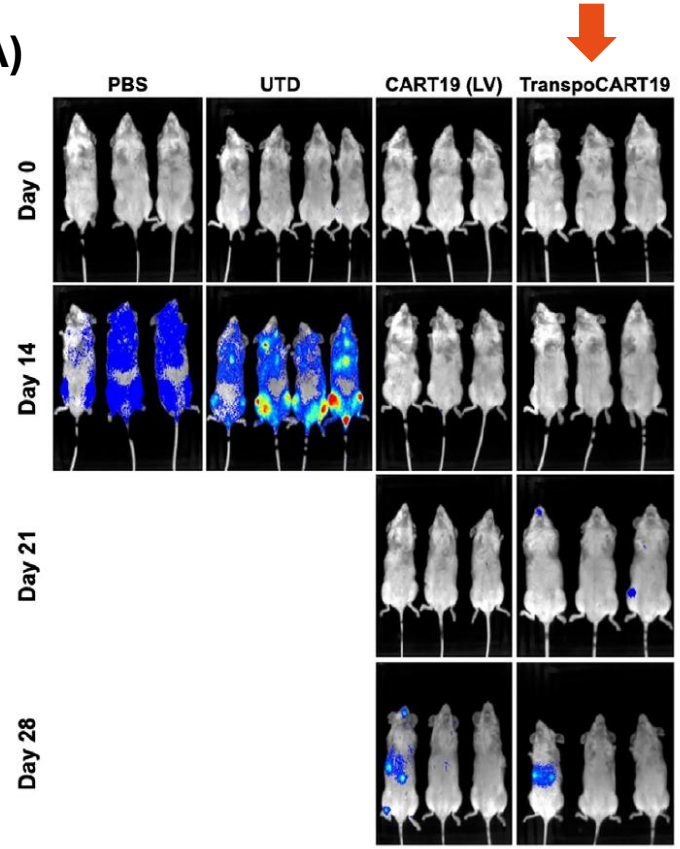
- **Virus-Free Cell Engineering**
  Clinical Scale Generation of functional CAR-T Cells using a Minicircle-based SB transposon system
- **Boosting AAV Production**
  Minicircles in AAV Production for higher vector purity and increased Titers
- **mRNA for Vaccines and other Applications**
  Clean, linearized and stable templates for reliable mRNA production



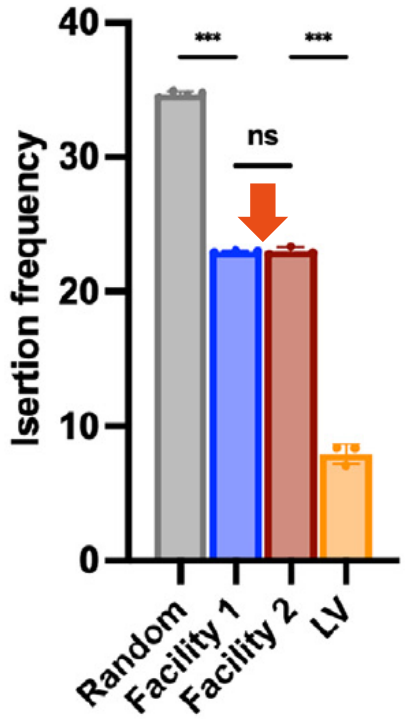
Clinical Scale Generation of functional CAR-T Cells using a Minicircle-based Sleeping Beauty Transposon System

PlasmidFactory®

A)



B)



Díez *et al.*, 2025, Mol Ther Methods Clin Dev

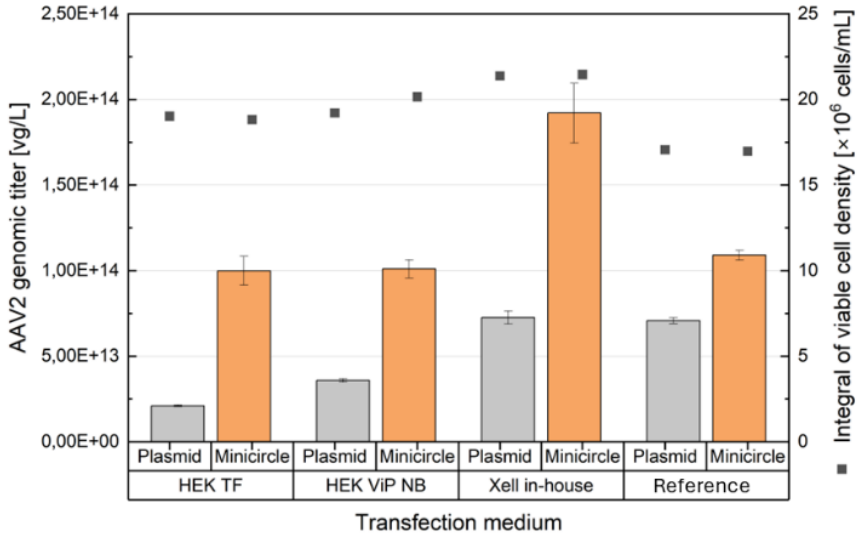
- MC approach results in equal tumor eradication to LVV (A)
- MC shows improved genomic safety vs. LVV (B)
- MC approach results in prolonged survival equal to LVV (data not shown)
- MC un-detectable in final CAR T product (data not shown)

Article title: Generation and GMP scale-up of human CAR-T cells using non-viral Sleeping Beauty transposons for B cell malignancies

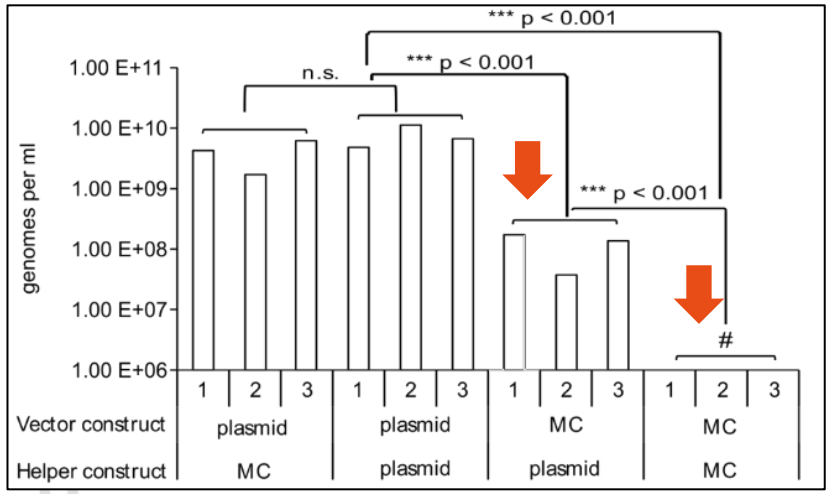
GMCT Webinar

Minicircles in AAV Production for higher Vector Purity and increased Titers

A)



B)



Kraemer et al., ESGCT Annual Congress 2021
Schnödt et al., Mol. Ther.-Nucl. Acids 2016

- **Marked increase in viral titers**: 3 to 4-fold (A)
- **No back-packaging**: higher vector purity and product consistency (B)
- **Improved transduction efficiency**: up to 30× higher (scAAV; data not shown)
- **Cleaner & safer** – lower immunogenicity, less silencing, up to GMP Grade (data not shown)

Article title: DNA Minicircle Technology Improves Purity of Adeno-associated Viral Vector Preparations

AAV webinar

Selected Testimonials

PlasmidFactory®

> The gene transfer rate we accomplish [with Minicircles] in primary human T cells is quite impressive and is always in excess of 50 - 60%, which is **5 to 6-fold higher** than with plasmid DNA.“



Prof. Dr. Michael Hudecek
Universitätsklinikum Würzburg & Fraunhofer IZI

> Minicircle DNA addresses one of the key sources of plasmid-derived impurities in AAV manufacturing and can be integrated without disrupting established production platforms.”



Dr. Eduard Ayuso
CTO at DINAMIQS, Zurich, Switzerland

> We indeed have a very fruitful and productive scientific collaboration with PlasmidFactory for **more than 10 years** now.”



Prof. Dr. Michael Hudecek
Universitätsklinikum Würzburg & Fraunhofer IZI



Thank you for your interest!

PlasmidFactory.com

PlasmidFactory 25 YEARS

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