

**Name** • AmpTec GmbH  
an ISO 13485:2007 Company

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**Areas of Activity** • | Contract development and manufacturing of synthetic nucleic acids (RNA & DNA) for diagnostic and therapeutic applications  
| cGMP manufacturing of messenger RNA (mRNA) therapeutics for preclinical-and clinical studies  
| Process Development  
| Development and establishment of cGMP compliant customer specific QC-tests

AmpTec GmbH, is a Hamburg, Germany based international active contract manufacturing company (CMO) with comprehensive services for cGMP manufacturing of synthetic nucleic acids for biotech and pharma companies. The company was founded in May 2005 by Dr Guido Krupp and Dr Peter Scheinert and has a proven trackrecord of almost 15 years right now.

Key products are synthetic RNAs and DNAs for *in vitro* diagnostics as well as fully functional mRNAs as drug substance or active pharmaceutical ingredient (API) for the pharmaceutical industry using mRNAs to develop a new category of medicines.

## Regulatory history

- Manufacturer in compliance with ISO 9001 since 2008
- Manufacturer in compliance with ISO 13485 since 2010
- Compliance with cGMP since 2012 (regulations of FDA 21 CFR Part 820)
- Compliance with cGMP FDA 21 CFR Part 210 and ICH Q7 (section 19: APIs for use in clinical trials) since 2016
- In 2018: IND submission for clinical trials. FDA Clearance in 2019

## cGMP biomanufacturing

AmpTec provides customized solutions for each client and offers guaranteed product quality according to international cGMP guidelines. All AmpTec products are produced in a highly regulated state-of-the art GMP environment.

## Products and services

Customized Long single stranded RNAs (ssRNA) and DNAs from any sequence at any length and scale

*Key applications:*

- Reference material for the development of *in vitro* diagnostic assays
- Therapy-accompanying diagnostics (companion diagnostics)
- Internal controls for *real time*-PCR diagnostic kits

# Therapeutic mRNAs made in Hamburg.



We provide  
the **quality** you need.

Or visit us on the web:  
[www.amp-tec.com](http://www.amp-tec.com)



**Customized Long RNA Oligos fully enzymatically produced at any length and scale**

*Key applications:*

- Guide RNAs for CRISPR
- RNA therapeutics
- RNAi applications
- Short RNA controls

**Customized Long double-stranded RNAs (dsRNA) at any length and scale**

*Key applications:*

- dsRNA as tool for gene-specific silencing of gene expression
- Long dsRNA is substantially more effective than short dsRNA

**Customized fully functional messenger RNAs (mRNA) from any sequence at any length and scale**

*Key applications:*

- Highly specific vaccination
- Individualized tumor therapy with patient-specific tumor neo-antigens
- Cellular reprogramming
- Genome editing
- Protein replacement

## Capabilities

AmpTec has a highly motivated team of currently 38 employees with outstanding experience in GMP-compliant manufacturing of synthetic nucleic acids.

## Experience

AmpTec offers complete customized solutions for its customers worldwide since almost 15 years and is a highly reliable partner for the biotechnology & pharmaceutical industry.

mRNA batches manufactured at AmpTec are already used by our customers for Clinical Trials (ex vivo), Pre-Clinical Trials (in vivo) and Clinical Trials (in patient).

AmpTec offers excellent customer contact and flexibility to make our customer projects successful.