

NEW OPTION

CUSTOM SERVICE PRODUCTS

Reference Nucleic Acids are manufactured in compliance with GMP principles

IVT-RNA, dsDNA and Plasmid DNA Products at AmpTec are manufactured under Good Manufacturing Practice (GMP) principles.

The challenging applications of AmpTec products require an outstanding product quality, high reliability and highly reproducible product properties. Our products are manufactured in a regulated environment to ensure continuity and traceability of all AmpTec products and product batches.

Our GMP system for these Custom Service Products includes these aspects:

Already in 2007 a Quality Management System was established at AmpTec, according to ISO 9001 and extended to ISO 13485 in the year 2008.

Raw materials used at AmpTec meet the highest quality standards.

Critical materials undergo rigorous in-house test procedures before clearance.

Each supplier is managed according to AmpTec's strict, documented and regularly updated qualification procedure.

AmpTec's manufacturing processes are clearly defined in SOP's and systematically reviewed.

Manufacturing and testing documentation is under strict Change Control.

Operators are trained to carry-out and document procedures.

AmpTec completely tracks products from raw material to final product. Records of manufacture demonstrate that all steps required by the defined procedures and instructions were taken, and that the quantity and quality of the product was as expected. These Batch Records enable the complete history of a batch to be traced and are retained in a comprehensible and accessible form.

Manufacturing processes take place in dedicated and specifically designed laboratory environment. Our facilities are designed to a defined and strictly controlled flow of personnel and material.

All equipment that has direct contact with the product is decontaminated with evaluated procedures or it is disposable. All equipment is qualified to fulfill the process requirements and is dedicated wherever possible for a single product.

These aspects and AmpTec's strong commitment to the highest quality standards guarantee that you will receive a product that consistently meets your requirements.

AmpTec products manufactured using Good Manufacturing Practice (GMP) Principles are intended for further processing by manufacturers or specialised laboratories for implementation as components in laboratory-developed tests.