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Synthetic mRNAs in clinical trials: Manufacturing of high quality GMP grade synthetic mRNAs

Synthetic mRNAs from AmpTec have achieved a world-wide acceptance. AmpTec's mRNAs are available as GMP grade products and have been introduced in several clinical trials in Europe, Australia and USA. Availability of high quality synthetic mRNAs is crucial in enabling significant progress in this field. Worldwide, a very limited number of active manufacturers of high quality mRNAs, AmpTec continues to realize its obligation to support the entry of new players by providing customized, mRNA products at small and large scales, from mg to grams. Applications of synthetic mRNA include reprogramming of human cells; antigen expression for vaccination projects in oncogenesis, infectious disease and allergy prevention; protein-replacement therapies. In a recent overview, applications and corresponding synthetic mRNA quality requirements were presented by Quabius & Krupp in New Biotechnology 2015. Syn-mRNAs can be generated by in vitro transcription (IVT) from defined templates containing the synthetic gene of interest. Optimal mRNA activity depends on a long, unmasked poly(A) tail, but long hompolymeric sequence are not reliably propagated in E.coli. Our alternative procedure uses PCR products as IVT-templates resulting in very well defined and easily modified poly(A) tails. Possible problems: Challenging sequences can lead to poor results in generation of the PCR template (AmpTec workflow) or (ii) during in vitro transcription reactions (workflow of all current mRNA manufacturers). For both steps (i) and (ii), results and trouble shooting are presented. Quality requirements and QC methods for GMP-grade synthetic mRNAs in therapeutic applications are presented.

Biography

Guido Krupp is a CEO and President of AmpTec GmbH. He received his PhD Degree from Würzburg University and Max-Planck-Institute Martinsried in 1981. He was Postdoc at Yale University from 1983 to 1987. He was a Research Group Leader at Kiel University from 1987 to 2002 and Founder of artus GmbH, 1998 and AmpTec GmbH, 2005 and KSK Diagnostics GmbH, 2015. His research interests include nucleic acid technology with focus on RNA, plant pathogens (viroids), ribozymes and telomerase. He has more than 60 publications, Editor of "Ribozyme Biochemistry and Biotechnology" and Editorial Board of "*Biotechnology Annual Review*".

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