PlasmidFactory®

Starting material for mRNA vaccines

The COVID-19 pandemic has pushed vaccine development and production to their boundaries and resulted in the first mRNA-type vaccine that has been officially approved and authorised. Efforts to develop mRNA vaccines and associated research started long ago, however, the pandemic catalysed the development and market launch enormously and associated with this the need for adequate starting material.

As plasmid DNA serves as a template for mRNA production it is one of the key factors for an effective and save vaccine product. Particularly for mRNA production the plasmid manufacture is subject to essential requirements that are indispensable for a secure end product. This includes a homogenous plasmid sample without host cell RNA contamination and naturally, no RNase. In this context of homogeneity, the preservation of intact polyA sequences present an additional challenge as these repetitive sequences are usually quite unstable. At the same time, it needs to be available in large-scale while retaining highest quality.

PlasmidFactory has progressively increased production to address the DNA manufacturing needs of our customers. A key requirement is the capacity to produce increasingly large quantities (10 g batches). This challenge has been addressed with the unveiling of a new, state-of-the-art dedicated HQ production facility during the pandemic that fulfils the requirements stipulated in the latest EMA Q&A document EMA/246400/2021, and integrates comprehensive QC including CGE service for DNA topology analysis. The here produced High Quality Grade plasmid DNA, generated using a proprietary production platform, meets the requirements for use as a starting material for GMP production of RNA for clinical application and enables the production of the large quantities of plasmid DNA. This year, our products will also be available in GMP Grade.

23 years of experience in the production of by now more than 3000 plasmids has formed our expertise in the manufacture of unstable and difficult-to-produce plasmids. E.g., our process is capable of retaining unstable polyA stretches (POLYARESCUE®), a prerequisite to obtain a homogenous RNA product. Moreover, we guarantee RNase-free plasmid DNA while host RNA is maximally depleted due to chromatographical purification. In this way, we ensure that we meet the requirements that apply in particular to the production of starting material for mRNA production.

By now, PlasmidFactory has establishes itself as a key contributor to mRNA vaccine manufacturing.

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