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## **DEVELOPMENT OF A NEW MAGNETIC BEAD PLATFORM FOR USE IN GMP PRODUCTION OF MRNA VACCINES**

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The success of mRNA vaccines in fighting the SARS-CoV-2 pandemic has brought the world into a new era of vaccine development. The production methods are not yet standardized and the need for flexible and highly scalable production of mRNA is still urgent.

We have previously presented our magnetic bead technology, including solid-phase in vitro transcription and generic capture purification on carboxylic acid activated beads, enabling different flexible strategies for scaling up mRNA production. The same technology is easily adapted from research scale volumes to industrial volumes.

For use in the manufacture of Therapeutic agents, there are high regulatory demands for documentation of both safety and performance of the technology. We are therefore developing a new Dynabeads magnetic bead platform and two new products, designed to be suitable as raw materials/ancillary materials for use in GMP manufacturing of mRNA vaccines. The beads are in compliance with ISO13485 and ISO20399 and regulatory support documentation will be available

The two Dynabeads products on the platform include a streptavidin conjugated bead for solid-phase in vitro transcription and a carboxylic acid activated bead for generic capture purification of mRNA. The beads are optimized for magnetic separation and workflow performance.

Manuals for a complete mRNA synthesis and purification workflow with performance data and analytical data on mRNA yield, integrity and purity will be presented.

For research use or further manufacturing. Not for diagnostic use or direct administration into humans or animals.