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A scalable microfluidics platform for the development of nanoparticles

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Microfluidic devices have been broadly used to produce nucleic acid-delivery nanoparticles for genetic medicine because they offer control, reproducibility and scalability of the nanoparticle precipitation process to overcome a significant challenge in the translation of these therapeutics. Control over process parameters afforded by microfluidics, allows optimization of nanoparticle quality and encapsulation efficiency. Automation improves the reproducibility and optimization of formulations. The continuous nature of the microfluidic process is inherently scalable, allowing optimization at low volumes to conserve scarce or costly materials, and seamless scale-up of optimized formulations by employing multiple microfluidic mixers performing identical unit operations in parallel. In this study, we present a scalable microfluidic platform for producing nanomedicines. The platform includes a system designed for production under cGMP conditions employing eight parallel microfluidic mixers capable of producing a 25L formulation of RNA lipid nanoparticles (LNP) in ~4h. Seamless scale up of production was demonstrated by producing a test batches of siRNA-LNPs against the blood clotting protein factor VII (FVII) on each of three systems designed for different stages of nanomedicine development. The physico-chemical characteristics (DLS, and HPLC) and *in vivo* efficacy (FVII levels in murine models) of the formulations were consistent across the platform. Additional performance testing determined that 5L can be produced with a single mixer without loss of particle quality. These results suggest that parallel microfluidic formulation is a viable path forward for overcoming challenges in scaling nucleic acid LNP formulations for a variety of gene and cell therapies.

Biography

R Broadhead is a PhD with wide experience of both the business and academic areas of the biological and medical sciences to drive the success of a company. He has achieved excellence in research, having been first author of a paper in *Nature*. I now combine my knowledge and understanding of cutting edge science with my significant product management and global business development experience to achieve success in the commercial side of science.

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