

Researchers develop a new approach to scale-up manufacturing of life-saving oligonucleotide therapeutics

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Scientists have developed a new approach to produce life-saving oligonucleotide therapeutics on a large scale, in high purity, and with

minimal environmental impacts. The finding, by The University of Manchester, will facilitate large-scale production of oligonucleotides to ensure the widest possible access of these drugs for patients.

Therapeutic oligonucleotides are an emerging class of drug molecules that have the potential to treat a wide range of diseases. Oligonucleotides are short sequences of DNA that can modulate or control gene expression. In this way, they have the potential to address the underlying causes of various diseases such as heart disease, cancer, and muscular dystrophy.

Over recent years, there has been an increasing number of approved [oligonucleotide](#)-based therapies, but widespread use of the drug has been limited in part because of difficulties in its manufacturing process.

Current methods rely on [chemical synthesis](#) that requires large amounts of solvent, generates substantial waste, and delivers final products with low yield and modest purity. Reactions are performed on solid supports or columns, which limits scalability, making them suitable only for producing oligonucleotides in small batches.

The new research, published in the journal *Science*, presents a sustainable and scalable approach to oligonucleotide production, addressing the challenges associated with current methods. The findings could have major implications for the [pharmaceutical industry](#).

Sarah Lovelock, Senior Lecturer at the Manchester Institute of Biotechnology at The University of Manchester, said, "Therapeutic oligonucleotides are an exciting new [drug](#) modality with huge potential to treat a wide range of diseases, including genetic disorders and viral infections.

"Many [pharmaceutical companies](#) have therapeutic oligonucleotide

candidates in their pipelines, including those for common diseases. The development of more scalable and sustainable approaches to oligonucleotide production will be key to ensuring the widest possible access to this powerful class of therapeutics."

In nature, DNA can be copied or amplified using enzymes called polymerases. The new approach uses these polymerases to amplify a catalytic DNA template to make a high volume of therapeutic oligonucleotides in a single step. This contrasts the iterative rounds of chain extension, capping, oxidation and deprotection associated with established methods.

More information: E. R. Moody et al, An enzyme cascade enables production of therapeutic oligonucleotides in a single operation, *Science* (2023). [DOI: 10.1126/science.add5892](https://doi.org/10.1126/science.add5892)

Provided by University of Manchester

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