

UK collaboration leads the way on revolutionising oligonucleotide medicines manufacturing



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CPI has announced the launch of a project in the Medicines Manufacturing Innovation Centre that aims to revolutionise the manufacture of oligonucleotides, through a collaboration with AstraZeneca, Exactmer, Novartis and UK Research & Innovation.

The development of a scalable, sustainable and more cost-effective oligonucleotide manufacturing process will enhance the production capacity and viability of this exciting new class of medicines. With production facilities based in Dagenham, London and later in Renfrewshire, Scotland, this global leading collaboration demonstrates the capability and power of UK innovation in the life sciences.

Oligonucleotide medicines work by interfering with how genes are expressed and have shown success in the treatment of rare diseases. This next-generation therapeutic class is now being explored to treat chronic diseases that affect much larger patient populations. Their utility, however, is currently limited by inefficiencies inherent in the existing manufacturing process. With many prospective oligonucleotide-based medicines already in development and clinical trials, a cost-effective, sustainable and scalable manufacturing method is required to meet current and future manufacturing needs. Inclisiran, an innovative small interfering RNA medicine from Novartis, approved for the treatment of atherosclerotic cardiovascular disease, would be the first medicine to be produced at scale as a result of the collaboration. AstraZeneca has a rich pipeline of oligonucleotide-based drug candidates that have the potential to benefit from overcoming the

challenges of large-scale oligonucleotide manufacturing that this collaboration seeks to address.

The collaboration will enable the partners to utilise their combined expertise across scale-up, analytics and process development with the goal of transforming the oligonucleotide supply chain. Known as Grand Challenge 3, the project is one of a series of 'Grand Challenges', designed to tackle industrial hurdles currently limiting pharmaceutical manufacturing, being explored in the Medicines Manufacturing Innovation Centre.

The initial phase of the project will focus on the development of scale-up strategies for liquid phase processes exploiting Exactmer's Nanostar Sieving technology, which is based on membrane separation. In the first year, the collaboration will concentrate on a proof-of-concept programme run by Exactmer with support and expertise provided by the other partners. The collaboration will also aim to enhance the efficiency and yield of the manufacturing process and reduce the consumption of a critical raw material (acetonitrile) of which global supply challenges the feasibility of large-scale manufacturing of oligonucleotides.

Initial activities will take place at Exactmer's facilities in Dagenham, London, with the large scale later phases taking place at the Medicines Manufacturing Innovation Centre in Renfrewshire, Scotland. The project is expected to span three years, with the final output being the demonstration of the commercial feasibility of manufacturing large-scale oligonucleotide batches using these improved methods. In addition to the founding partners, the Medicines Manufacturing Innovation Centre is seeking additional partners for its Grand Challenge 3 programme, particularly those with pharmaceutical or technology expertise, to support the development of this large-scale oligonucleotide technology.

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Press Contacts

1. **Alison Lancaster**

Editorial

editorial@pressat.co.uk

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