

Case Study

Accelerate Commercial Manufacturing of a Single Strand DNA with WuXi Speed

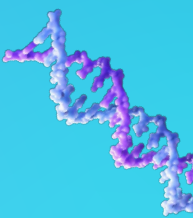
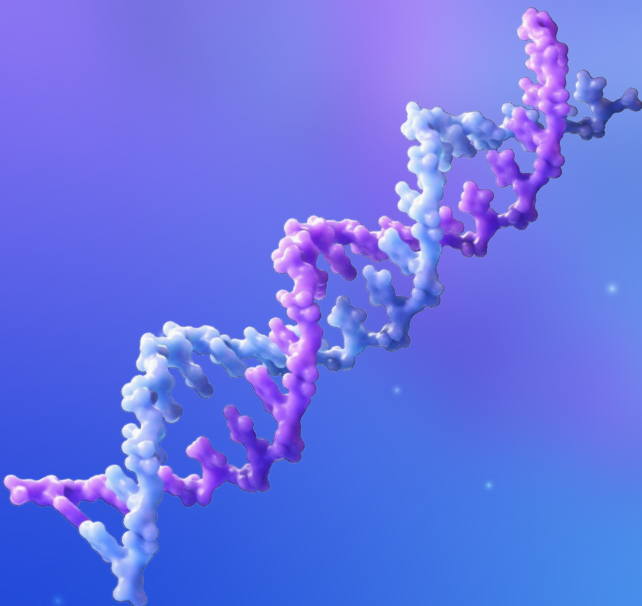
Introduction

In 2021, a biotech company was developing a vaccine that needed large scale oligonucleotide production capacity and rapid turnaround to produce hundreds of kilo oligonucleotide adjuvant. From May 2021 to September 2022, in 16 months with COVID interruptions, WuXi TIDES completed the technology transfer and delivered over 400kg of oligonucleotide product, as well as Process Performance Qualification (PPQ) enabling and PPQ campaign. Moreover, WuXi TIDES developed a robust commercial supply chain to support large-scale oligonucleotide manufacturing.

Manufacturing Efficiency

The single solid phase synthesis batch size was set to 900 mmol using OligoProcess™. To maximize efficiency, our manufacturing team successfully developed a process to complete solid phase synthesis, cleavage and deprotection, and purification of five 900 mmol batches continuously. The five sub lots were then combined into one batch for further downstream processing including ultrafiltration and thin film evaporation. Overall, the production cycle time was reduced by 50% compared to the original process.

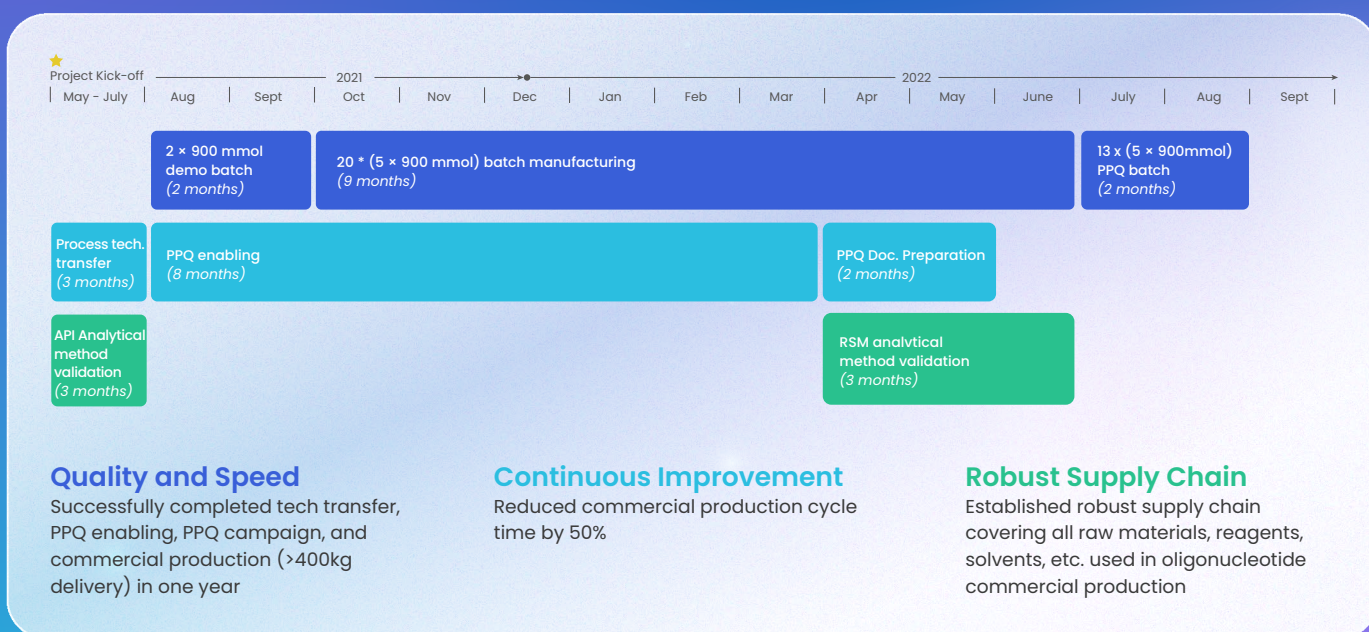
In just nine months, over 400-kilogram (20 X 5 batches X 900 mmol) oligonucleotide were delivered to the customer. To secure manufacturing continuity, in particular, to deal with long lead times of certain raw materials during COVID supply chain interruption, WuXi TIDES also established a robust supply chain covering all the raw materials and consumables by manufacturing some key materials in-house, enabled by strong chemistry capabilities.



Process Efficiency

To manufacture this oligonucleotide adjuvant efficiently, the team incorporated several new technologies, including Thin-Film Evaporation (TFE). TFE enables a more efficient concentration process with faster drying time, less thermal degradation risks, and reduced solvent loss. More importantly, it can deliver the oligonucleotide adjuvant in high-concentration aqueous solution, which can be readily added to the vaccine without additional processing steps.

Although the large-scale production was performed before PPQ due to the special regulatory process for the vaccine, the team needed to complete the PPQ as soon as possible. In parallel with manufacturing, the oligonucleotide R&D team and analytical team completed all PPQ enabling studies and full analytical method validations, as well as all PPQ documentation preparation. Once the production of 400 kilograms of the product was completed, PPQ campaign was continuously carried on without any pause.



Result

WuXi TIDES completed the entire project, including technology transfer, large-scale multi-batch production, PPQ enabling and PPQ production for this client in just 16 months with over 400 kg of the oligonucleotide adjuvant delivered. The client was highly impressed by the speed and quality of this project and recently awarded WuXi TIDES the “Outstanding Contribution Award.”



Contact Us

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