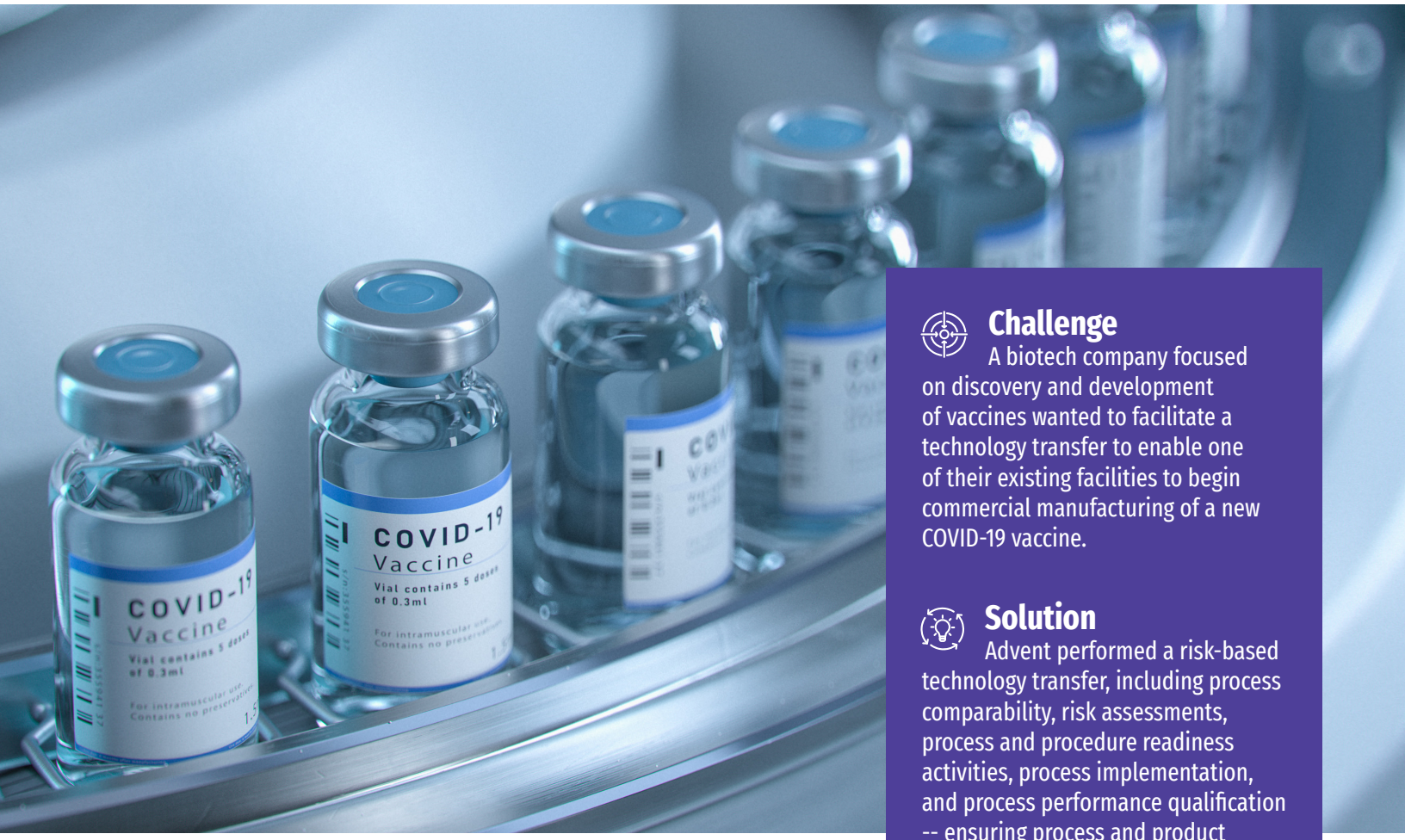
Case Study

# Biotech Company Scales and Commercializes Manufacturing in Record Time




A small biotechnology company focused on the discovery and development of vaccines and antibody therapeutics wanted to scale-up its processes to enable it to manufacture a vaccine for COVID-19 in quantities sufficient to meet commercial demand. The organization engaged Advent Engineering to help scale-up and commercialize its manufacturing processes through technology transfer to an existing facility.

## Challenge

A biotech company focused on discovery and development of vaccines wanted to facilitate a technology transfer to enable one of their existing facilities to begin commercial manufacturing of a new COVID-19 vaccine.

## Solution

Advent performed a risk-based technology transfer, including process comparability, risk assessments, process and procedure readiness activities, process implementation, and process performance qualification -- ensuring process and product comparability between facilities.

## Result

Advent helped the client successfully complete technology transfer, while demonstrating comparability of process and product, enabling the client to complete the commercialization project in record time and within budget.

Trinity Consultants

Advent Engineering
Life Science Solutions

## Challenge

The client had developed manufacturing processes for process intermediates and bulk drug substance (BDS) at pilot scale, with Phase I clinical lots successfully demonstrating product safety and a proposed dosage schedule. The client chose one of its existing US sites for vaccine production; however, they needed support to scale-up and fast-track the commercialization of their first marketed product. With the COVID-19 pandemic well underway and vaccines in high demand, the clock was ticking to get the facility up and running.

## Solution

Advent built a team of process scientists and engineers with extensive experience in process development, technology transfer, and process validation to engage and drive the scope. The Advent team began by performing a process risk assessment to identify gaps in process knowledge that would require additional characterization to support process design efforts. Leveraging Computational Fluid Dynamics, Quality by Design, and Design of Experiment methodologies, Advent supported process design, troubleshot process problems, and improved the overall robustness of the processes.

Advent performed feasibility assessments of the new facility's capabilities, technical and operational resource capacity, quality system, and compliance risks. Gap analysis helped identify and analyze risks, while process criticality analysis and process comparability assessments identified which process steps were directly comparable and which needed to be modified.

These assessments informed the technology transfer plan as well as the creation of mitigation strategies and recommendations. In total, there were hundreds of attributes involved, each of which had to be evaluated to understand how they would affect scale-up activities. Advent developed a wide variety of process-related documentation, including standard operating procedures and protocols, and conducted training for operators on the transferred processes and documentation.

Advent also performed process shakedown to confirm that all systems were performing as expected, and engineering runs to demonstrate scalability of the process as well as provide additional operational experience prior to clinical lot manufacturing. Phase II and Phase III clinical lots were successfully manufactured at commercial scale. After clinical lot manufacturing, a final process and validation risk assessment ensured that all residual risks were acceptable and justified the number of lots required for process performance qualification (PPQ).

Advent then executed PPQ, including building out a sampling plan and defining criteria, to ensure that the transferred process can reliably and consistently manufacture product meeting pre-defined acceptance criteria and product release specifications. Product comparability was also performed to ensure there were no differences in product quality attributes and degradation pathway of product manufactured at the pilot versus commercial-scale facilities.

## Result

The partnership with Advent allowed the client to successfully take a manufacturing process and transfer it to a new site, in record time—going from a pilot scale Phase 1 process to a commercial manufacturing process in 18 months. After successfully completing PPQ, the manufacturing process received full regulatory approval, allowing for the manufacturing of millions of COVID-19 vaccines.

### About Trinity

Founded in 1974, Trinity Consultants helps organizations overcome complex, mission-critical challenges in EHS, engineering, and science through expertise in consulting, technology, training, and staffing. We support clients in geographies worldwide and across a broad range of sectors including industrial, energy, manufacturing, mining, life sciences, and commercial/institutional.

**HEADQUARTERS** 12700 Park Central Dr, Ste 2100, Dallas, TX 75251
P 800.229.6655 / P 972.661.8100 / F 972.385.9203

**trinityconsultants.com**