CASE STUDY

A Global Need Meets a Large-Scale Solution:
Supplying CleanCap® Reagent for a COVID-19 Vaccine

CHALLENGE

A leading COVID-19 vaccine includes TriLink BioTechnologies' CleanCap® reagent within their formulation process. Rapid scale-up and development of analytical testing capabilities were needed to meet timelines and help end the global pandemic.

SOLUTION

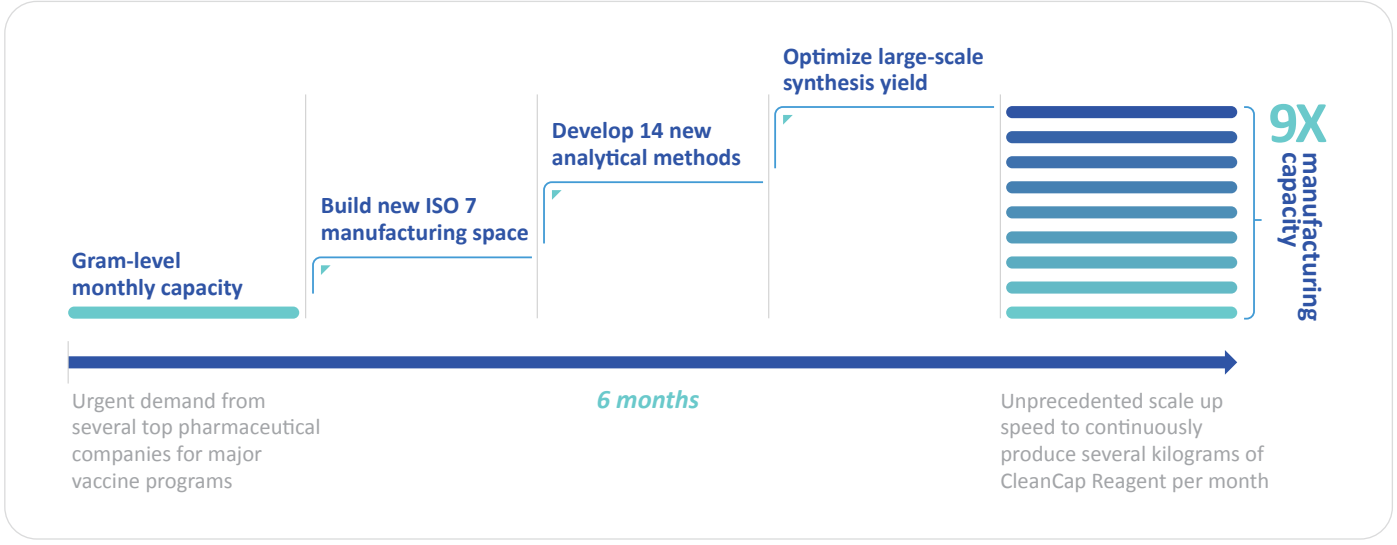
Increased CleanCap production nine-fold in 6 months via massive expansion of ISO-certified manufacturing space. Multiple kilograms of the highest quality product were delivered to facilities in the U.S., Asia, and Europe to meet the demands of a pandemic.

A Global Challenge

The World Health Organization declared COVID-19 a global pandemic on March 11, 2020. A major pharmaceutical company rapidly developed the first-in-class mRNA vaccine using TriLink's proprietary CleanCap mRNA Cap1 structure[1]. To meet global distribution goals to the tune of billions of doses, we had to significantly expand manufacturing capabilities within an ISO-certified space. Scale-up of mRNA supply chain, increased quality standards, and global supply capabilities were required within record-breaking time.

Production Ramp up of CleanCap Reagent

Through unparalleled analytical and manufacturing growth, TriLink met unprecedented timelines and scales. Abundant quantities of the highest quality CleanCap were available within months of the pandemic's onset.



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Massive Expansion Produces New Capacity for the Industry

TriLink exceeded the necessary production demands of the client with record growth of nucleoside triphosphate and CleanCap manufacturing capabilities. Over 3,300 square feet (300 square meters) of additional, dedicated CleanCap reagent manufacturing space was online 18 weeks after breaking ground. Fourteen new analytical methods were developed and validated to assist with a nine-fold increase in production yield. The ISO-certified small molecule space will continue to produce CleanCap reagents For Further Processing and support the manufacturing of new chemistries and modified nucleoside triphosphate products for clients for years to come.

Small Molecule Manufacturing at TriLink

- **ISO 9001:2015 certification**
- **3,000 sq ft of ISO-certified manufacturing space dedicated to CleanCap Reagent (300 m2)**
- **Multi-kilogram/month production capacity**
- **Release testing for purity, concentration, appearance, pH, ion content, residual solvents, endotoxin, bioburden, and contaminating nucleases**
- **Analytical and functional support laboratories to support product testing**
- **Routine monitoring of temperature, pressure, humidity, and particle count**
- **Comprehensive Quality programs and Quality systems for document control**
- **ISO Class 7 and ISO Class 8 clean rooms within the 118,000 sq ft facility**

Get Smarter Sooner: Scale up with TriLink

With the dramatic growth of TriLink's ISO-certified manufacturing space, we are poised to address your most difficult scalability challenges early in process development. You'll make significant progress faster by leaning on us for standardized processes with increased flexibility. By successfully facilitating global COVID-19 vaccine distribution, we have set the precedent for a strong commitment to furthering the application of mRNA-based therapeutics and vaccines for the treatment of the deadliest acute, chronic, and rare diseases.

References

Sahin U, Muik A, Derhovanessian E, et al., COVID-19 vaccine BNT162b1 elicits human antibody and TH1 T cell responses. *Nature* 2020; 586:594-599.

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