# Refrigeration-Free Vaccine Transport: Early Regulatory Strategy

## The Situation

The client is an award-winning biopharmaceutical company committed to advancing global health through innovative drug delivery solutions. The founders established the company to overcome critical logistical barriers in healthcare. The company is currently developing a pioneering refrigeration-free transport system for vaccines and other temperature-sensitive biological materials.

The client's core innovation focuses on a revolutionary cold-chain-independent transport solution. Consequently, this enables the storage and shipment of vaccines and other biopharmaceuticals without the need for refrigeration. This technology aims to significantly reduce costs, expand global access—especially in low-resource settings—and improve the reliability of pharmaceutical delivery.

In its early growth stage, the company has secured £1.2 million in pre-seed funding to accelerate its research and development efforts. Additionally, the team is composed of experienced scientists, engineers, and entrepreneurs with a shared vision of reshaping healthcare logistics.

Our client specialised in:

- Cold chain disruption technology
- Biopharmaceutical formulation and stability
- Global health innovation and access
- Sustainable, scalable transport solutions for sensitive materials

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## DLRC's Solution

DLRC helped out early on by reviewing the company's technology through the lens of a regulatory authority, looking at how regulators might receive it down the line. As a result, this gave the team a clearer idea of what to focus on as they developed their product. We also joined meetings with potential investors, helping to explain the regulatory context and reassure them that the approach was realistic and had a clear path forward. Our involvement helped give investors more confidence in the team and the technology.

One of the main hurdles was uncertainty around how the product would be viewed by regulators, especially since it's a new approach to transporting vaccines. That kind of innovation can raise questions early on, and investors often want to know how risky the regulatory side is. Therefore, by offering a clear, informed perspective and answering investor questions directly, we helped the company overcome those early doubts and keep conversations moving forward.

Our support has been hands-on and strategic. Specifically, we didn't just give advice, we reviewed their technology like a regulator would and helped them translate that into clear messaging for investors. This level of involvement is quite rare, and it's helped the company make faster, more confident progress. Our support was unique in combining technical regulatory expertise (including an ex-MHRA assessor) with proactive investor engagement.

We didn't just provide guidance behind the scenes—we also became advocates for the technology. As a result, this helps to articulate its viability and compliance potential in investor discussions, which isn't something every support organisation offers. That level of involvement showed that the company had credible, experienced backing behind it.

## The Outcome

We are now guiding them through the process of engaging with the EMA. We are also directly supporting their preparations for a meeting with the Innovation Task Force.

Our work gives them the foundation to take a significant step toward regulatory validation.