CASE STUDY

From Label to Patient: *Delivering Clinical Precision at -80°C"*

OVERVIEW

A biotech developing cancer vaccines was preparing to enter Phase I clinical trials and required a specialized partner to manage ultra-low temperature labeling, packaging, and global distribution. With product stored at -80°C, standard labeling methods would not be viable.

The company sought an experienced, flexible supply chain partner capable of designing and executing a compliant, reliable solution without compromising product integrity. PRONAV Clinical's -80°C labeling solution enabled the biotech to successfully progress into Phase I trials with a reliable, compliant supply chain.

OBJECTIVES

ENABLE ULTRA-COLD LABELING

- Design a labeling process that could be applied to glass vials at -80°C without loss of adhesion.

ENSURE GLOBAL DISTRIBUTION AT -80°C

- Safely package and ship ultra-cold IMP to clinical sites worldwide while maintaining product integrity.

MINIMIZE INVENTORY RISK

- Implement a pack-to-order model to reduce inventory losses and improve supply chain efficiency.

BUSINESS CHALLENGES

- Labeling at -80°C
- Adhesion failure risk
- Global ultra-cold shipping
- Regulatory quality standards
- Inventory loss exposure

SOLUTIONS IMPLEMENTED

PRONAV Clinical developed and qualified a manual -80°C labeling process for pre-frozen Biosafety Level 2 cancer vaccines. Working with specialist vendors, they identified a glue matrix that maintained adhesion at -80°C which ensured that the glue did not crystallize and validated the process through cross-functional collaboration, ensuring compliant labeling, packaging, and global distribution of the IMP

CONCLUSION

PRONAV Clinical's innovative -80°C labeling solution enabled the biotech to successfully progress into Phase I trials with a reliable, compliant supply chain. Their flexible, hands-on approach ensured product integrity, minimized inventory risk, and delivered global distribution with precision. As a result, PRONAV became a long-term strategic partner supporting the client's ongoing clinical development.

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