

Developing a C.U.R.E for Temperature-Controlled Packaging of Gene Therapy Products

Creating a compliant gene therapy cold chain packaging program is as easy as finding a C.U.R.E. Let's take a look at the steps to develop a smarter cold chain supply chain solution:



Check the stability data for material. Does your product:

- a. Need to remain below $\leq -60^{\circ}\text{C}$ in a dry ice shipper
- b. Need to remain below $\leq -150^{\circ}\text{C}$ in dry nitrogen vapor shippers
 - i. Do all packaging components withstand cryogenic temperatures?
- c. Remain unaffected when exposed to excessive shock and vibration



Understand which regulations apply based on jurisdiction and method of shipment. Understand the package design, process and testing requirements that must be considered



Refine requirements for package design. Check if:

- a. The package design is thermally and mechanically robust enough to withstand standard tests, such as
ASTM and ISTA standards
- b. Temperature traceability is feasible across supply chain routes
- c. Secondary and primary labels do not get compromised (i.e. flagging, smudging, smearing, etc. at
cryogenic temperatures)
- d. Tertiary packaging labels address all relevant regulations



Establish a testing strategy to:

- a. Eliminate the risk of thermal testing failure under simulated and extreme conditions
- b. Reduce the risk of temperature excursion, especially early stages of shipment and last-mile, during
performance qualification activity and actual shipments
- c. Address all thermal requirements addressed in URS and proposed actions in risk assessment plan
- d. Prepare for potential future package design modifications

About Adept Packaging

The gene therapy cold chain packaging experts at Adept Packaging are the industry leaders in providing simple, efficient, and effective packaging designs that maintain the potency of your drug product and intermediates. Don't let packaging predicaments prevent your product's success – solve them before they start with Adept Packaging. Our gene therapy packaging experts can create packaging programs for companies at every stage, crafting your packaging process so you can get on with saving lives.

Adept is the leading expert for packaging engineering and serialization, providing teams with flexible, scalable service through staffing, engineering services, business processes and technology. Our portfolio of accelerators and products capture and create value from packaging. Our collaborative team is always on top of the latest trends in packaging technology, while developing services and products geared toward the trends in our clients' industries.



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