CRYOPDP

THE GROWING PRESSURES OF COMPLIANCE IN U.S. Cold Chain Logistics



When compliance becomes the moment problems surface.

For life sciences companies in the United States, compliance is no longer just a final check; it's often where problems first arise.

As therapies become more sensitive and time-critical,
the cold chain becomes harder to control.

More sites, more partners, more handoffs, and more data all create additional opportunities for something to go wrong. In many cases, non-compliance is not the root cause. It is the point where the weakness becomes visible.

Where control starts to slip



Alignment

Procedures must stay consistent throughout the entire process. Temperature control, documentation, qualification, and validation **need to be maintained from pickup to receipt.** When different teams and locations are involved, **small gaps can quickly lead to compliance issues and risk.**

Traceability & Visibility

Keeping a shipment within range is only part of the job.
Teams also need a clear and reliable record of every step, every handover, and every action taken throughout the journey. As decentralized models and direct-to-patient deliveries grow, maintaining that level of traceability becomes more difficult. And without strong traceability, **true visibility is harder to maintain.** Data only helps when it is accurate, complete, secure, and supports control across the full journey.



What happens when control slips

- Delayed Trials
- Wasted Material
- Repeat Work
- Financial Loss
- Regulatory Scrutiny

For advanced and personalized therapies, the stakes are even higher.
If the material cannot be replaced, the loss is final.

Why the margin for error is shrinking

In the U.S., keeping a shipment within range is only part of what needs to be maintained. FDA expectations also emphasize **traceability, documentation, and control** throughout the entire process.

Companies must demonstrate not only that the shipment arrived as planned but also **how it was handled, monitored, and recorded from start to finish.** That is where stronger control makes a difference. **CRYOPDP helps life sciences companies maintain consistency, visibility, and control across the full journey.**

