

Mitigating Risk: Safeguarding Commercialization Timelines with Shipping Validation

Transportation is often overlooked during drug development, yet it remains one of the most common and preventable sources of product variability, delay, and loss.

Transportation sensitive modalities such as biologics, mRNAs, ADCs, and cell- and gene-therapies can experience stresses in transit that bench-level studies cannot replicate. With increasingly sensitive materials entering shipping lanes and global demand for pharmaceutical transport services growing rapidly, reliable and data-driven shipping strategies have become essential rather than optional.

Regulatory expectations have also been heightened. Agencies are increasingly emphasizing shipping validation, environmental hazard testing, and structured risk assessments as part of a defensible product. Standards such as ASTM and ISTA provide frameworks for evaluating key transportation risks such as temperature, shock, vibration, and pressure, strengthening stability programs and ultimately supporting patient safety.

Transportation Simulation De-Risks Drug Development & Commercialization

Most temperature failures do not result from dramatic single-point excursions but from gradual or repeated fluctuations during transfers, hand-offs, or delays. Even brief deviations can influence degradation pathways or alter product attributes.



Potential consequences include but are not limited to accelerated degradation or potency loss, aggregation or particle formation, phase separation or precipitation, rheological changes, freeze-thaw-related damage, and/or stability data no longer represents real-world conditions.

Transportation exposes drug substances and finished products to continuous vibration and occasional shock or drop events. Vibration, shock, and drop often negatively influence product aggregation, particulate generation, and compromise container closure integrity.

Furthermore, air shipments introduce pressure changes that can affect pre-filled syringe plungers, vial stoppers, and headspace dynamics. Changes in pressure can affect or compromise lyophilized cake integrity, impact seal compression and plunger movement, and container closure integrity.

Understanding the effect of transportation stress on a product is critical for programs working with extremely limited, high-value batches, where the impact can be disproportionately severe. Transportation Simulation studies help quantify the effect of these mechanical stresses, enabling teams to select or refine packaging before material is placed at risk.

The Impact of Late Packaging Decisions

When racing towards commercialization, the later a decision is made, the more significant the impact can be. Packaging and pack-out strategies are often finalized late in the drug development lifecycle and typically after stability programs and shipping expectations have already been defined. This can lead to costly delays caused by avoidable requalification activities, misalignment with real-world route conditions, and inconsistent product protection that impacts product quality and performance. Making packaging decisions earlier and grounding them in real-world data helps to avoid both costly reworks and surprises once product is in transit.

Transportation Simulation Matters

Transportation simulation provides a controlled, repeatable, and data-driven method for evaluating how materials respond to expected shipping hazards. Transport simulation studies focus on understanding the product-relevant impact of the most common and relevant stress profiles affecting stability: temperature

cycling, shock, drop, vibration, humidity, and pressure.

A comprehensive transportation simulation program will typically include:

- **Shipping Lane Mapping:** Identifying environmental conditions, dwell times, and hand-off points across intended routes.
- **Cold-Chain Strategy Development:** Designing realistic thermal management processes aligned with stability data.
- **Packaging and Pack-Out Design:** Evaluating primary, secondary, and tertiary packaging, including palletized configurations.
- **Protocol Development:** Creating ASTM- or ISTA-aligned test profiles that represent real-world hazards.
- **Controlled Execution:** Applying the profiles in environmental chambers under repeatable, documented conditions.
- **Post-Test Inspection:** Assessing packaging performance and product condition to identify design or process vulnerabilities.
- **Regulatory Documentation:** Preparing data and reports that support qualification, validation, and future regulatory submissions.

For pre-commercial teams working with scarce, often irreplaceable material, simulation substantially reduces risk and increases the likelihood that shipments reach their destination intact.

Unique Challenges in Pre-commercial Drug Development

Pre-commercial drug development programs moving towards commercialization also frequently rely on small, high-value batches produced after months of upstream and downstream activity. In these scenarios, a single shipping failure can jeopardize the entire project and create an uncertain path forward. Material lost in transit, whether due to shipping or stability failure, often cannot be replaced quickly, or at all. Earlier incorporation of transportation simulation as a part of understanding a drug product's stability profile can mitigate these vulnerabilities and strengthens long-term commercialization planning.

Leveraging Singota's Expertise in Transport Simulation

Singota Solutions' Transportation Simulation Lab (TSL) was built to address precisely these challenges by offering a seamless, end-to-end on-site service that is often unavailable through traditional

outsourcing models. While many teams rely on multiple external vendors to handle route mapping, packaging design, simulation testing, and qualification, this outsourcing adds variability, delay, and risk.

Singota Solutions 20+ years of experience with Transport Simulation and Shipping Validation delivers an integrated, end-to-end approach, bringing together the critical capabilities our clients need under one roof, including:

- 1. Route-Specific Distribution and Lane Mapping:** Highly customized environmental profiles reflecting real-world conditions encountered along intended shipment routes.
- 2. Cold-Chain and Thermal Strategy Development:** Support for designing temperature-controlled workflows aligned with product stability and operational realities.
- 3. Packaging and Transport Recommendations:** Data-driven guidance on primary, secondary, and tertiary packaging solutions.
- 4. Pack-Out SOP Development:** Validated, repeatable pack-out procedures informed by controlled testing - not assumptions.
- 5. Simulation Protocol Creation & Performance Qualification:** Protocols tailored to each product's characteristics and shipping journey, ensuring consistent performance under defined stresses.
- 6. On-Site Environmental Hazard Testing:** Faster turnaround times and



immediate iteration compared to traditional outsourced models.

7. **Post-Test Product and Packaging**

Evaluation: Clear, actionable insights that help refine strategies before clinical materials are placed at risk.

8. **BLA-Ready Validation**

Documentation: Structured, forward-looking documentation that reduces future rework as programs advance toward regulatory submission.

These capabilities support a broad range of modalities including biologics, mAbs, cell and gene therapies, mRNAs, vaccines, ADCs, combination products, powders, liquids, and tablets.

Focused on Faster? Choose Singota.

Transportation simulation and shipping validation data are essential for maturing programs from both practical and regulatory perspectives.

By integrating controlled environmental stress testing, data-driven packaging design, and route-specific risk assessment into development workflows, teams can better protect limited material, maintain timeline integrity, and meet evolving regulatory expectations.

Singota's Transportation Simulation Lab provides the structured, end-to-end support required to make informed decisions before product is placed in transit. The result is fewer uncertainties throughout the approval cycle, reduced risk to commercialization timelines, and greater confidence that these lifesaving products will reach their destination safely.

If developing a safe, reliable, and data-driven transportation strategy is a priority for your program, Singota Solutions' team can help.

Contact us at solutions@singota.com to discuss how our TSL services can support your development needs.