

# Transport Simulation Laboratory



*Focused on Faster*

**Excessive temperature, mechanical shock, and vibration are just a few factors that can damage pharmaceutical biologics through aggregation and degradation. All of these factors are present in the distribution environment. Recognizing these vulnerabilities early in the development process gives drug developers an opportunity to take preventative measures, such as modifying the drug formulation or product packaging, to avoid unexpected and unwelcome downstream surprises.**

The Transport Simulation Laboratory (TSL) is located at Singota's facility in Bloomington, Indiana and consists of a large environmental chamber equipped with a control system, calibrated sensors, and a validated data collection system with mechanical and hydraulic equipment that can simulate a customized distribution environment profile. The simulated conditions expose products to typical as well as extreme conditions that may be encountered during transport prior to patient use. Testing can be conducted on product in different settings: its primary container or combined with selected protective packaging, including palletized formats. Plunger movement within syringes caused by changes in pressure can be evaluated. Test protocols can consist of recognized industry standards or custom designed profiles. Environmental hazards in transport that can be applied include:



Singota Solutions is a recognized leader in the pharmaceutical industry for specialty supply chain management services.

Singota and its partner, Modality Solutions provides BLA submission ready shipping validation studies

## Deliverables

- Protocol and Simulation Profile Development
- Shipping Validation,
- Regulatory Filing Support
- Package Testing/Mechanical Qualification
- Thermal Systems Qualification
- Cold Chain Management Process Design



## Support Services

- Materials Handling (receipt, storage, shipment)
  - 50,000 sq. ft. environmentally controlled warehouse with a range of storage conditions including **15-25°C, 2-8°C, -20°C, -80°C**
  - Technical expertise in cold chain processes
- GMP Analytical Testing
  - Product testing capability to assess degradation
  - ICH stability test studies
- Finishing Services
  - Label, kit, package, pallet building to support testing
  - Inspection (pre and post-test visual inspection of product)

0100619

[solutions@singota.com](mailto:solutions@singota.com)

4320 West Zenith Drive, Bloomington, IN 47404 | 812.961.1700

[singota.com](http://singota.com)