

# Integrate Your Cold Chain Management Systems



Simulated transport testing.



Decrease development cycle times.



Protect against environmental hazards.



## Take advantage of our insight. Work with subject matter industry experts.

You **get results** because we focus on implementation, not just defining regulatory requirements.

A properly integrated cold chain ensures regulatory compliance, product quality, and patient safety by providing a multi-layered approach that combines best practices of process validation, systems qualification and risk assessment with the most applicable monitoring, controls, and packaging technology aligned with the latest cGMP quality management systems guidance.

Our unique multi-modal Advantage Transport Simulation Laboratory™ provides valuable data on the impact of five environmental hazards of drug formulation—temperature, shock, vibration, pressure, and humidity.



### Gary M. Hutchinson

13+ years. Designs logistics networks. Focus has been on shock and temperature-sensitive, high-risk products and medical devices.



### Paul J. Harber

31+ years. Co-authored the PDA Journal of Pharmaceutical Science and Technology Technical Report No. 39 (PDA TR#39).



### Daniel J. Littlefield

19+ years. Leads successful projects in safety performance. Six Sigma Master Black Belt and expert LEAN Practitioner.



### Brian Wallin

10+ years. Authored the first global standards of insulated shipping container performance (Standard 7E) and testing methodology and lab certification (Standard 20).

**Services:** Product Characterization • Risk Management • Process Validation • Quality Management  
Packaging • Logistics • Training • Monitoring and Controls • Management Review

We offer **best-of-breed technology solutions** integrated together into your quality management systems with proper documentation for qualification, validation, along with training aligned with the necessary procedural controls, visual controls, and monitoring.



**Designing Confidence Into Your Product Pipeline.**

Call (214) 919-4629 or email [info@modality-solutions.com](mailto:info@modality-solutions.com)  
[www.modality-solutions.com](http://www.modality-solutions.com)