



MODALITY SOLUTIONS

You think you know Modality Solutions? Think again.

Modality Solutions is the leading engineering company that specializes in providing innovative and comprehensive solutions for cold chain management in the biopharmaceutical, food, and life sciences industries. With a strong focus on ensuring the integrity and quality of temperature-sensitive products throughout their supply chain journey, Modality Solutions offers a range of services and competencies that cater to the unique challenges and requirements of these industries.



COLD CHAIN CONSULTING:

- ⦿ **Engineering Consulting:** Modality Solutions offers in-depth expertise in designing, implementing, and optimizing cold chain processes, ensuring products are maintained within specified temperature ranges.
- ⦿ **Risk Assessment:** The company conducts thorough risk assessments to identify potential vulnerabilities and develop strategies to mitigate risks during storage, transportation, and distribution.
- ⦿ **Regulatory Compliance:** Modality Solutions helps clients navigate complex regulatory requirements, ensuring adherence to industry standards and guidelines.



TRANSPORT VALIDATION:

- ⦿ **Protocol Development:** The company creates customized validation protocols and testing procedures that validate the effectiveness of cold chain processes.
- ⦿ **Performance Qualification:** Modality Solutions conducts performance qualification studies to verify that temperature-sensitive products maintain their integrity throughout the supply chain.
- ⦿ **Data Analysis:** The company provides insights into temperature excursions and deviations through advanced data analysis, enabling clients to make informed decisions.



PACKAGING SOLUTIONS:

- ⦿ **Package Design:** Modality Solutions designs and tests temperature-controlled packaging solutions that protect products from temperature fluctuations, shock, and other environmental stresses.
- ⦿ **Thermal Testing:** The company performs rigorous thermal testing to ensure that packaging solutions maintain the required temperature profiles under various conditions.
- ⦿ **Sustainability:** Modality Solutions focuses on eco-friendly packaging options that reduce waste and environmental impact.



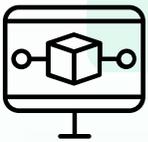
SUPPLY CHAIN OPTIMIZATION:

- ⦿ **Process Improvement:** The company identifies inefficiencies in supply chain processes and recommends strategies to optimize transportation, distribution, and storage.
- ⦿ **Technology Integration:** Modality Solutions leverages cutting-edge technologies to provide real-time monitoring of products in transit.
- ⦿ **Route Risk Assessment:** The company assesses different transportation routes and modes to mitigate risks associated with temperature fluctuations and delays.



REGULATORY EXPERTISE:

- ⦿ **Drug Stability Studies:** Modality Solutions reviews stability studies to assess the impact of temperature variations on drug efficacy and shelf life.
- ⦿ **Clinical Trial Support:** The company provides expertise in managing temperature-sensitive clinical trial materials, ensuring compliance and data integrity.
- ⦿ **Regulatory Strategy:** Modality Solutions assists clients in developing regulatory strategies that meet the stringent requirements of the biopharmaceutical industry.
- ⦿ **ASTM / ISTA Testing:** Modality Solutions helps biopharmaceutical companies complete the packaging qualification work needed for a successful regulatory filing. Our ASTM/ISTA Testing Solutions help drug developers obtain the robust data required to complete the packaging section of their IND, NDA, or BLA filings to regulators' satisfaction.



ADVANCED TECHNOLOGY SOLUTIONS:

- ⦿ **Simulation Modeling:** The company employs advanced modeling techniques to simulate temperature profiles and optimize cold chain processes.
- ⦿ **Risk Mitigation Strategies:** Modality Solutions develops risk mitigation strategies based on predictive modeling to anticipate potential challenges and prevent disruptions.
- ⦿ **Training and Education:** The company offers training programs and workshops to educate clients about best practices in cold chain management.



DRUG PRODUCT SAFETY ASSESSMENT:

- ⦿ **Nonclinical Safety Assessment Programs:** In collaboration with ToxStrategies, Modality Solutions develops and oversees nonclinical safety assessment programs from discovery to registration.
- ⦿ **Toxicology and Carcinogenicity Risk Assessments:** The companies author expert summary reports and waivers for reproductive and developmental risks and neurotoxicological and behavioral effects of test articles.
- ⦿ **QSAR Modeling:** The companies focus on Leadscope Model Applier and other tools.
- ⦿ **Nonclinical Regulatory Submissions:** The companies specialize in Pre-IND, INDs/CTAs, NDAs/BLA, and CTDs coupled with nonclinical sections of investigator brochures and clinical protocols.

About Modality Solutions

Modality Solutions is a trusted partner for industries reliant on maintaining the integrity of temperature-sensitive products. The company offers innovative solutions that ensure product quality, regulatory compliance, and optimal supply chain performance through a range of services spanning from cold chain consulting and validation to packaging solutions and biopharmaceutical support. With its commitment to cutting-edge technology, expertise, and global reach, Modality Solutions remains at the forefront of safeguarding the cold chain for critical industries.

We are part of:
ToxStrategies

ToxStrategies offers a wide range of consulting services, leveraging the expertise of their team of health scientists, regulatory specialists, and engineers. They specialize in addressing environmental and human health challenges and collaborate with businesses, law firms, and government agencies. Their services include computational analyses and modeling, environmental science, exposure assessment, product safety, risk assessment, and toxicology.

ToxStrategies covers diverse areas such as air quality, animal feed and pet food safety, bioaccessibility and relative bioavailability of metals, biopharmaceuticals and pharmaceuticals, cannabinoid and industrial hemp safety, coal combustion residuals, computational toxicology, cosmetics and sunscreen safety, developmental, reproductive, and juvenile toxicity evaluation, endocrine disruption assessment, environmental justice, and environmental liability cost analysis.

Additionally, they provide services in environmental sciences, epidemiology, biostatistics, epigenetics, food and supplement safety, food defense, and intentional adulteration prevention, compliance with the Food Safety Modernization Act (FSMA), foreign supplier verification program, health economics, and outcomes research (HEOR) overview, IARC cancer evaluation, industrial hygiene, medical device qualifications, neurotoxicology, ocular toxicology, PBPK and IVIVE modeling, per- and polyfluoroalkyl substances (PFAS), process authority, microbial risk assessment, Proposition 65 compliance, quantitative structure-activity relationship (QSAR) modeling, radiation risk assessment and management, risk assessment, risk communication, sustainability, global product stewardship, systematic reviews, evidence-based toxicology, toxicology monographs, and services related to the Toxic Substances Control Act (TSCA).