

# Cold Chain Compliance Services

## A quick reference guide

Logistics and quality assurance requires tradeoffs and testing to assure a balance between cost, safety and quality. There are a number of services available to help provide that balance and mitigate risk. The following is a quick reference of those services on the market today:

Service	Definition	Who needs it	Why you need it
 <p>Temperature Mapping</p>	Document temperatures within defined areas where temperature sensitive products are stored or shipped. Can range in size from small refrigerators to transport trailers & large warehouses.	<ul style="list-style-type: none"> <li>Manufacturers</li> <li>Wholesalers</li> <li>Transport companies</li> <li>3PLs</li> <li>Laboratories</li> <li>Blood &amp; tissue banks</li> </ul>	<ul style="list-style-type: none"> <li>Comply with regulations &amp; customer requirements (Quality Agreements)</li> <li>Develop compliance related documentation</li> <li>Understand storage environment &amp; seasonal effects</li> <li>Identify hot &amp; cold areas for ongoing monitoring</li> <li>Improve operations &amp; efficiencies through better temperature management</li> <li>Expand customer base (enter niche markets)</li> </ul>
 <p>Transport Mapping &amp; Validation</p>	Document & test environmental conditions inside trailers and transport containers where sensitive products are shipped. Empower staff with the know-how to improve processes & environments.	<ul style="list-style-type: none"> <li>Transport companies</li> <li>3PLs</li> <li>Wholesalers</li> <li>Manufacturers</li> <li>Companies owning fleet or air cargo containers</li> </ul>	<ul style="list-style-type: none"> <li>Comply with compliance regulations, provide documentation &amp; meet customer requirements (Quality Agreements)</li> <li>Better understanding of trailer / truck operation</li> <li>Improve efficiency of insulation &amp; operation</li> <li>Increase customer confidence &amp; loyalty</li> <li>Expand customer base (enter new markets)</li> </ul>
 <p>Qualification (IOQ)</p>	Evaluate goals & objectives, including enumeration and explanation of control parameters: Protocol writing, execution, & report writing for Installation Qualifications (IQ), Operational Qualifications (OQ) 7 Performance Qualifications (PQ).	<ul style="list-style-type: none"> <li>Manufacturers</li> <li>Wholesalers</li> <li>Transport companies</li> <li>3PLs</li> <li>Companies owning a fleet or air cargo containers</li> <li>Blood &amp; tissue banks</li> <li>Software companies (21 CFR Part 11)</li> </ul>	<ul style="list-style-type: none"> <li>Dev't. documentation &amp; comply with regulations &amp; customer requirements (Quality Agreements)</li> <li>Better understanding of equipment operation</li> <li>Qualify storage areas</li> <li>Security &amp; integrity of product</li> <li>Increase customer confidence &amp; loyalty</li> <li>Test equipment operation (Performance Qualification)</li> <li>Expand customer base (Entering niche markets)</li> </ul>
 <p>Data Logger Calibration</p>	Extend measurement confidence by conducting periodic calibration of your data logger through compliant monitoring aligned to NIST traceable standards.	<ul style="list-style-type: none"> <li>Manufacturers</li> <li>Wholesalers</li> <li>Transport companies</li> <li>3PLs</li> <li>Laboratories</li> <li>Blood &amp; tissue banks</li> <li>Hospitals &amp; pharmacies</li> </ul>	<ul style="list-style-type: none"> <li>Obtain traceable documentation that sensors have been test to meet compliance standards</li> <li>Test packaging, transport methods, and environments against environmental factors such as usage, stress, temperatures, &amp; time that may affect products</li> <li>Comply with customer requirements</li> </ul>
 <p>Shipping Studies</p>	Document the environmental hazards to which products may be exposed inside your distribution system. Information you'll need to stay in control of your unique cold chain environment.	<ul style="list-style-type: none"> <li>Manufacturers</li> <li>Wholesalers</li> <li>Transport companies</li> <li>3PLs</li> <li>Laboratories</li> <li>Blood &amp; tissue banks</li> </ul>	<ul style="list-style-type: none"> <li>Comply with customer requirements</li> <li>Develop documentation to support compliance with regulatory guidelines</li> <li>Better understanding of supply chain &amp; seasonal effects (documents temperature &amp;/or humidity over time)</li> <li>Plant to shelf audits identify gaps in there supply chain</li> <li>ROI through improved process (reduced loss &amp; claims)</li> <li>Increase customer confidence &amp; loyalty</li> </ul>
 <p>Packaging Design &amp; OQ</p>	Test & qualify existing systems, or design new packaging methods. Monitor and confirm temperature compliance across a distribution system. The evidence needed to evaluate effectiveness of packaging.	<ul style="list-style-type: none"> <li>Manufacturers</li> <li>Wholesalers</li> <li>Transport companies</li> <li>3PLs providers</li> <li>Laboratories</li> <li>Blood &amp; tissue banks</li> </ul>	<ul style="list-style-type: none"> <li>Comply with regulations &amp; customer requirements (Quality Agreements)</li> <li>Develop documentation to support compliance with regulatory guidelines</li> <li>Understand seasonal effects on shipping container &amp; pack outs</li> <li>Create documentation for data logger placement</li> <li>Minimize returns &amp; loss with more robust packaging</li> <li>Save cost on packaging material (Recycling programs)</li> <li>Expand customer base (Enter new markets)</li> </ul>
 <p>Qualification (IOQ)</p>	Identify current & near-term regulations and guidelines that apply to your supply chain and distribution systems. Prepare for changes and associated costs, highlighting critical parameters & identify necessary upgrades.	<ul style="list-style-type: none"> <li>Manufacturers</li> <li>Wholesalers</li> <li>Transport companies</li> <li>3PLs providers</li> <li>Laboratories</li> <li>Blood &amp; tissue banks</li> </ul>	<ul style="list-style-type: none"> <li>Understand and document compliance with global regulations</li> <li>Comply with customer requirements</li> <li>Gain a complete understanding of gaps in processes along with remediation</li> <li>Develop risk management program</li> <li>Increase customer confidence &amp; loyalty</li> </ul>

## Top 5 compliance concerns in the pharmaceutical and life science markets (and a checklist for addressing them)

When clients contact us to talk about their concerns, we first look to regulatory compliance for the answers, and then break down your concerns from a compliance perspective. Below are the most common concerns and how you can address those concerns through a regulatory services program:

Customer Concern	What is needed to address them (what we supply to the customer)
<b>Security</b>	<ul style="list-style-type: none"> <li>• Security policies</li> <li>• SOPs related to security (transport)</li> <li>• Personnel training</li> <li>• Reporting system for incidents</li> <li>• Tracking system for products (RFID)</li> </ul>
<b>Quality</b>	<ul style="list-style-type: none"> <li>• Quality system (QMS)</li> <li>• Quality documentation (Policies &amp; SOPs)</li> <li>• Training (personnel, staff)</li> <li>• Quality agreements</li> </ul>
<b>Storage</b>	<ul style="list-style-type: none"> <li>• Seasonal mapping of all warehousing &amp; storage areas</li> <li>• Qualification (IQ/OQ) of thermal/storage equipment (refrigerated &amp; frozen)</li> <li>• SOPs relative to storage &amp; storage areas &amp; equipment</li> <li>• Engineering &amp; maintenance of storage equipment</li> </ul>
<b>Transportation</b>	<ul style="list-style-type: none"> <li>• Qualification (IQ/OQ) of temperature-controlled transport systems</li> <li>• Elaboration of seasonal temperature profiles (transport)</li> <li>• Design/optimization &amp; qualification (OQ/PQ) of packaging systems</li> <li>• SOPs relative to transport &amp; packaging systems</li> <li>• Validation of transport/shipping systems</li> </ul>
<b>Delivery</b>	<ul style="list-style-type: none"> <li>• Mapping of storage areas &amp; equipment</li> <li>• SOPs &amp; training</li> <li>• Delivery packaging systems (design &amp; qualification) to the patient</li> </ul>

If you are concerned with any of these issues and would like support, Mesa now offers a wide range of cold chain compliance services, packaging and intelligent monitoring solutions for the pharmaceutical, healthcare, food and life sciences industries. We are available to help you assure products remain in compliance with regulatory guidelines, and are stored or transported under ideal conditions.