



Cold Chain Qualification

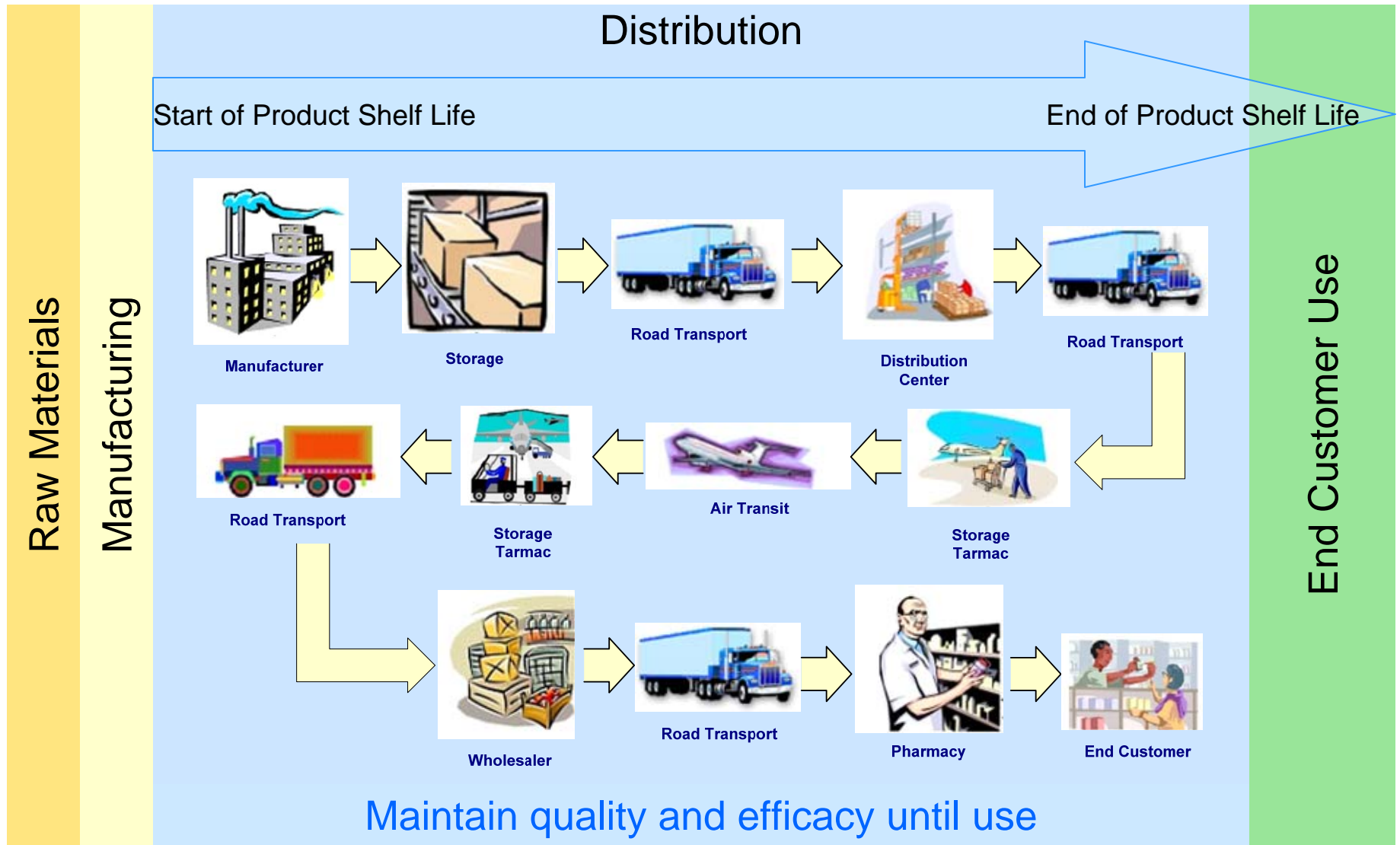
HPCLC at Johnson & Johnson Headquarters
New Brunswick, New Jersey
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Technologies



COLD CHAIN
TECHNOLOGIES
Engineered Solutions for Thermal Packaging

Pharmaceutical Distribution Model



Cold Chain Distribution Reality

Expectations

- An increasing number of countries have the following requirements for temperature-controlled product shipments:
 1. Temperature records covering the entire transportation process
 2. Conformance with product label claim temperature

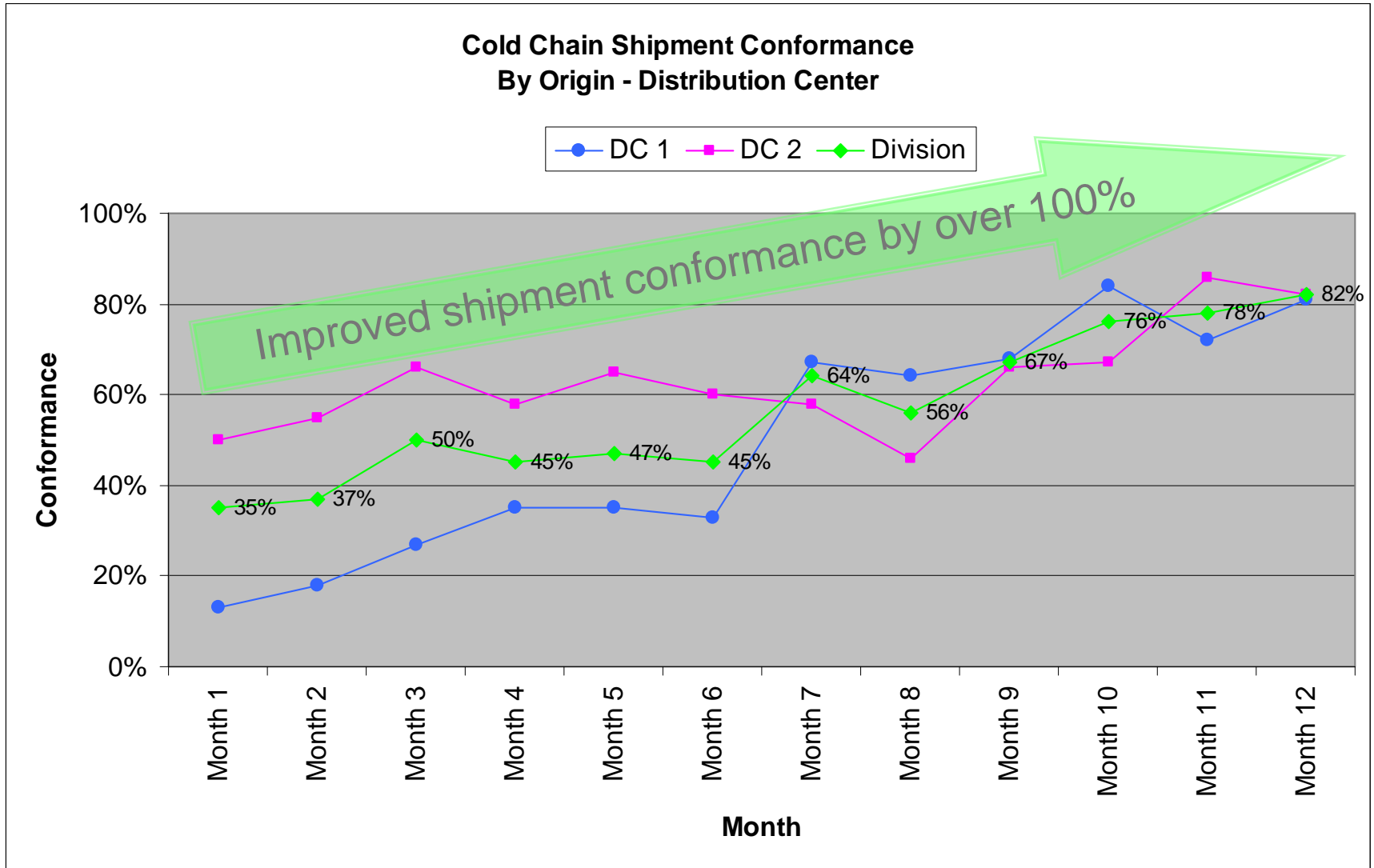
Temperature Excursions

- Temperature excursions occur and although generally supported by product stability data, some countries enforce conformance with product label claim temperature

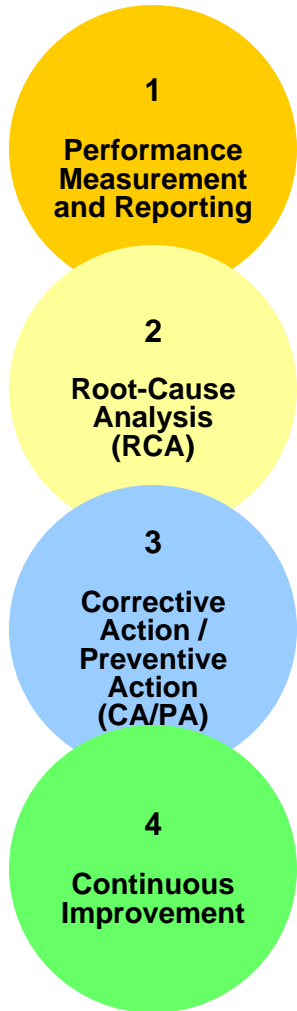
Supply Chain Interruptions

- Shipments may be delayed and/or rejected due to temperature non-conformances

Shipment Conformance Improvement – Results

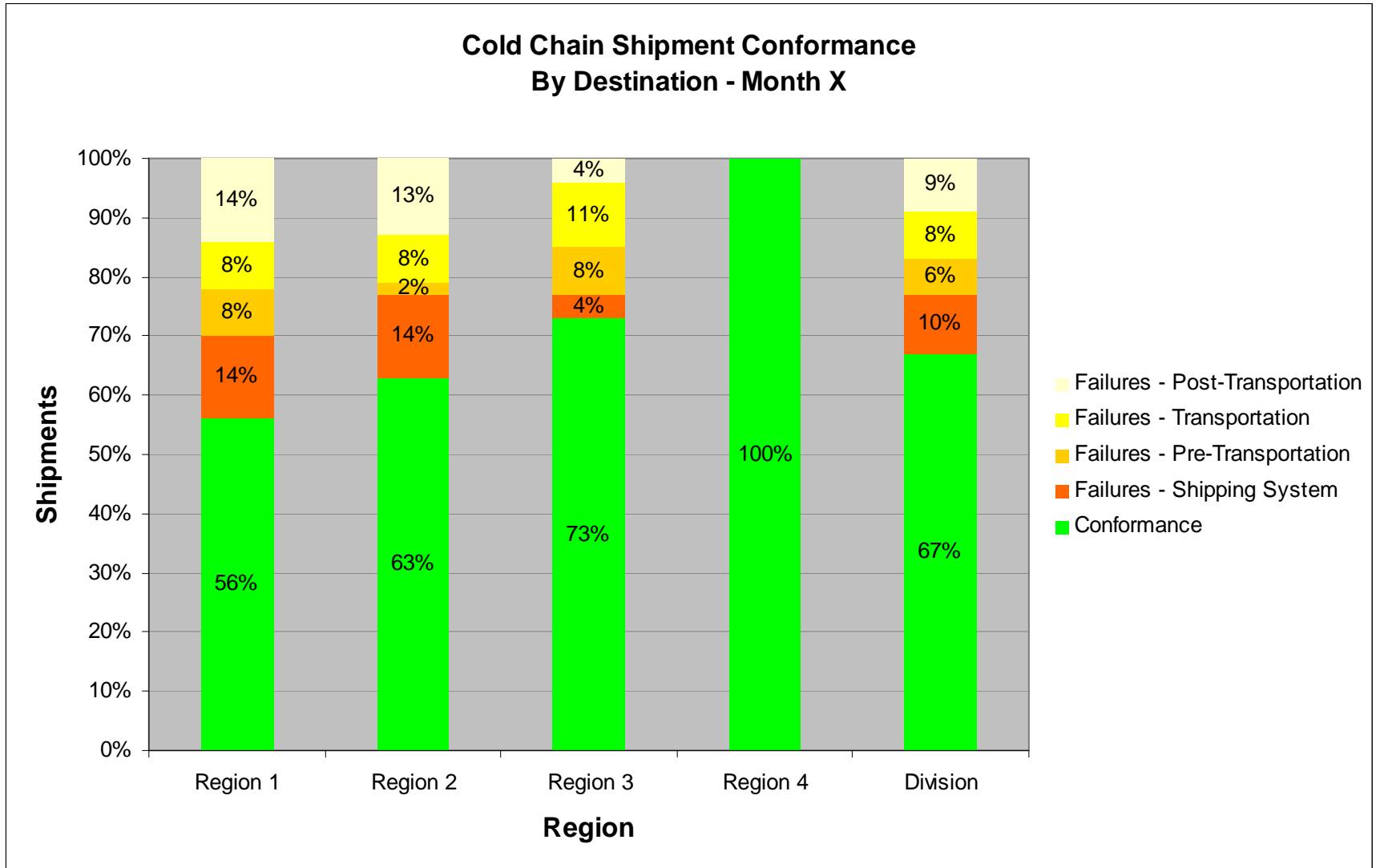


Shipment Conformance Improvement – Process

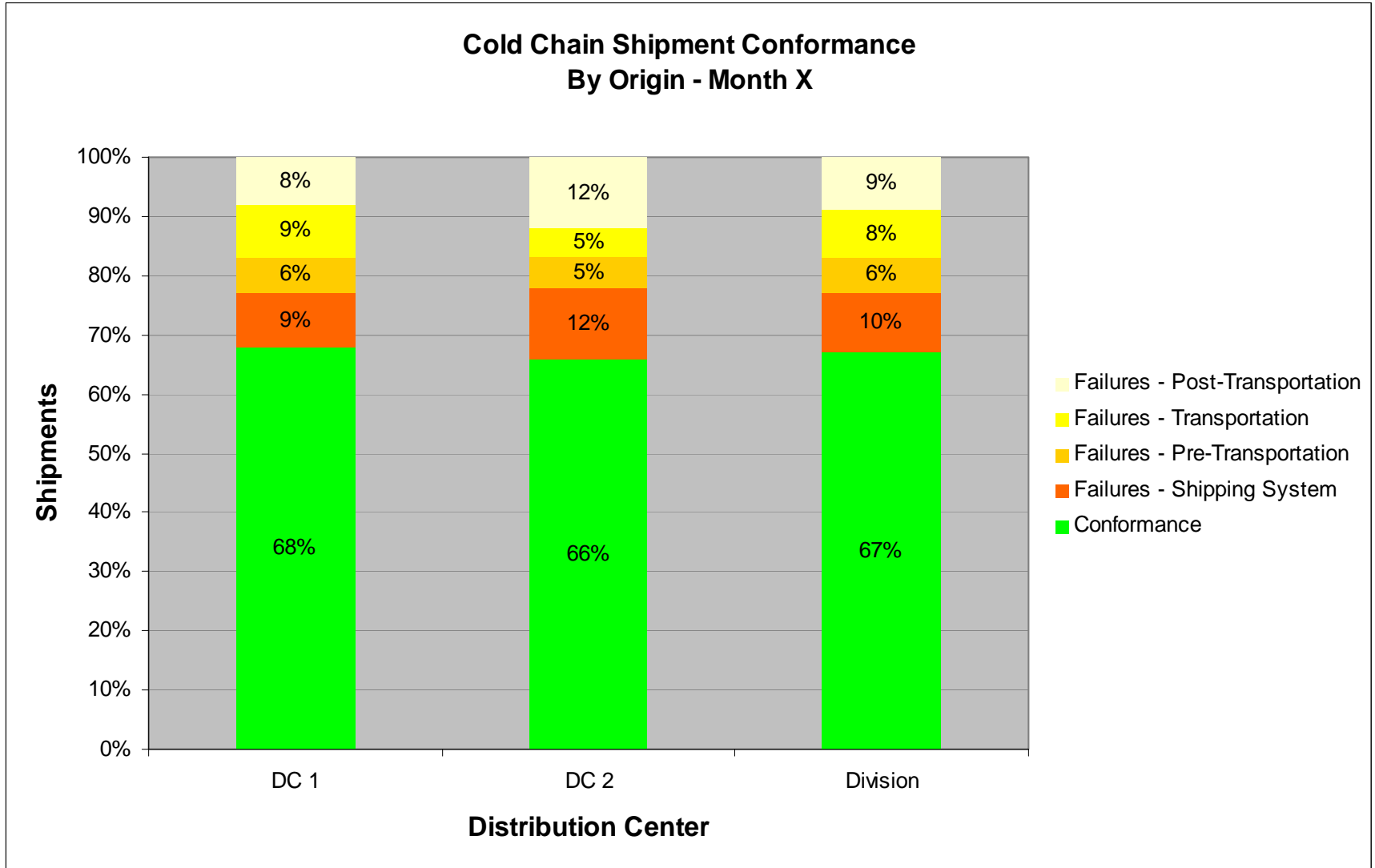


- Collect temperature data (product and ambient temperatures); measure and report performance
- Analyze temperature data to determine root-causes of excursions
- Establish and implement corrective actions/preventive actions based on root-causes of excursions
- Identify and implement process improvements (compliance, customer, cost)

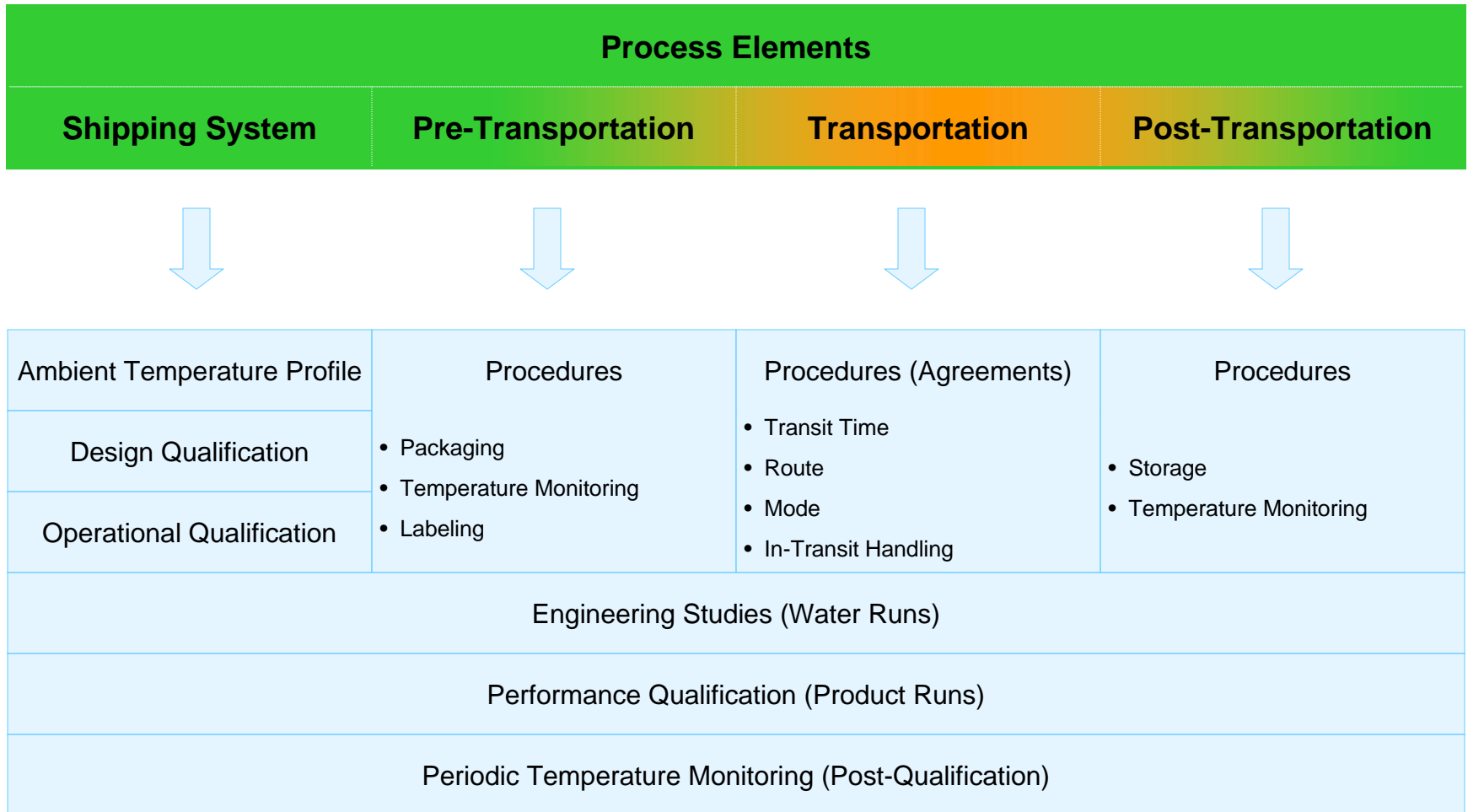
Shipment Root-Cause Analysis – By Destination



Shipment Root-Cause Analysis – By Origin



Shipping Lane Qualification Model



Shipping System Qualification

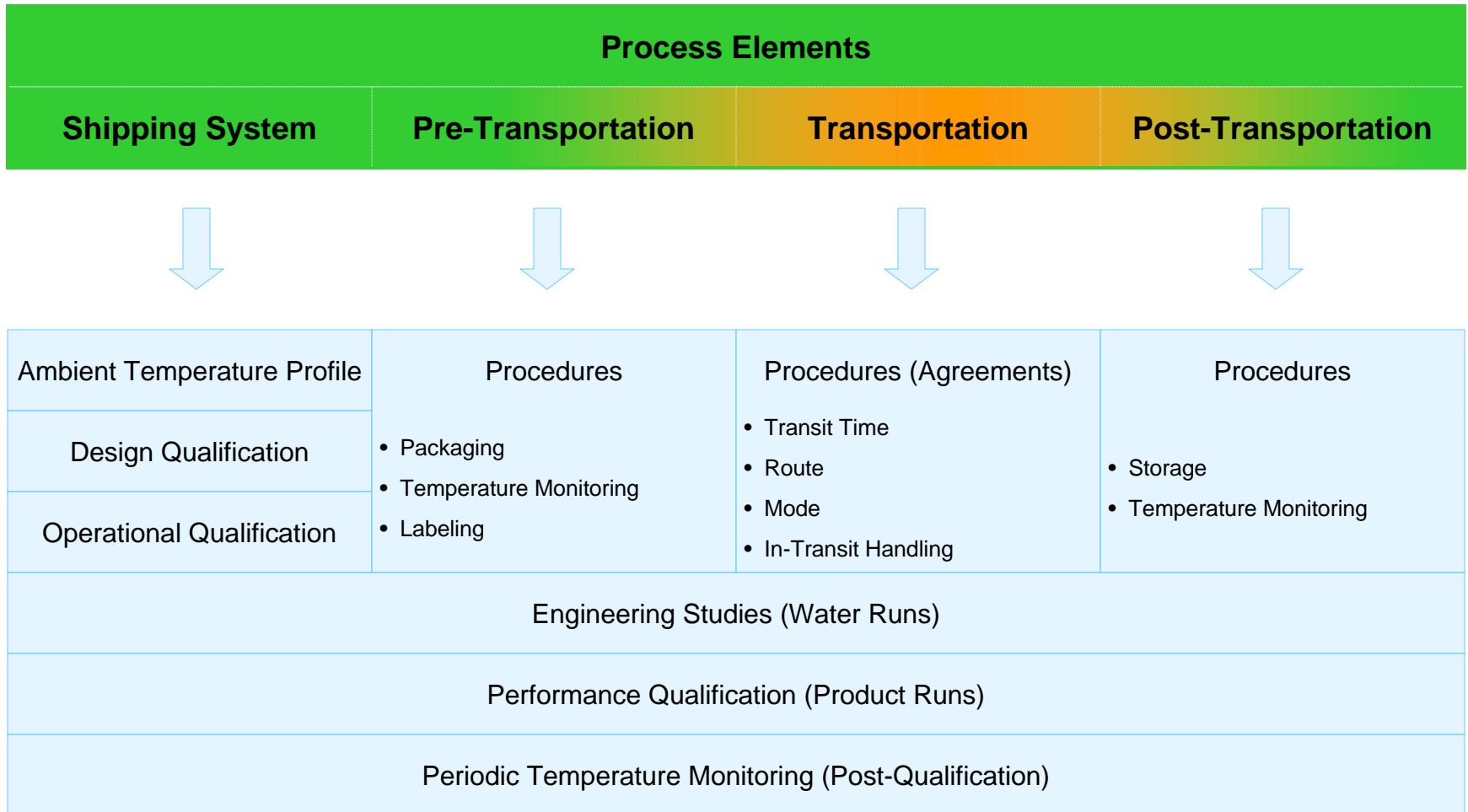
HPCLC Seminar Cold Chain Qualification June 2009.pptx



Summary



Shipping Lane Qualification Model



Cold Chain Management Model

Cold Chain Management

Maintain product quality and ensure compliance with global regulations and industry standards for the storage, handling and distribution of temperature-sensitive products



Product Requirements	Qualification / Validation	Supply Chain Partner Management	Performance Measurement and Reporting	Communication and Education	Continuous Improvement
<ul style="list-style-type: none"> ➤ Long-Term Stability Studies ➤ Accelerated Stability Studies ➤ Temperature Cycling Studies 	<ul style="list-style-type: none"> ➤ Ambient Temperature Profiles ➤ Shipping Systems ➤ Temperature-Controlled Vehicles ➤ Facilities / Equipment ➤ Periodic Temperature Monitoring ➤ Distribution Validation Master Plans 	<ul style="list-style-type: none"> ➤ Quality Questionnaires ➤ Quality Agreements ➤ Standard Operating Procedures ➤ Business Review Meetings 	<ul style="list-style-type: none"> ➤ Exception Management ➤ Conformance Measurement and Reporting ➤ Root-Cause Analysis and Trend Analysis 	<ul style="list-style-type: none"> ➤ Policies / Procedures ➤ Training Modules ➤ Management Review Meetings 	<ul style="list-style-type: none"> ➤ Shipping Systems ➤ Temperature Monitoring ➤ Transportation ➤ Regulatory and Industry Trends Monitoring ➤ Benchmarking

Summary

- Qualification is one element of cold chain management in ensuring that the quality and efficacy of temperature-sensitive products are maintained
- Understanding/improving cold chain shipment conformance requires structured problem-solving approach and implementation of processes/procedures to ensure sustainability
- Shipment conformance is part of cold chain management program, which in turn supports supply chain business objectives (compliance, customer service, cost)