Transatlantic Bio-Pharma Marine Container Cold Chain Standard

GDP & FDA 21 CFR Part 11 Telematics Monitoring for Ocean Shipping

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SECTION 1: BIOPHARMACEUTICAL THERMAL SENSITIVITY

Oncology biologics, mRNA therapies, and vaccines require continuous temperature stability between 2.0℃ and 8.0℃ [or ultra-cold -70℃]. Marine transit introduces severe vibration, power cycle shifts, and estuarine ambient extremes.

SECTION 2: SMART REEFER TELEMATICS & COMPRESSOR REDUNDANCY

Mandates dual-sensor micro-datalogger placement, real-time satellite IoT telemetry pings every 15 minutes, automated battery backup systems, and electronic expansion valve failover circuits.

SECTION 3: DIRECT VESSEL DISCHARGE & IMMEDIATE REEFER HOOKUP

Outlines SOPs for priority berthing, direct vessel-to-chassis crane discharge, and immediate connection to mobile refrigerated generator chassis to ensure an unbroken cold chain.