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Common Oversights in Cold Chain Validation

Think your approach is sound? These strategies are often-missed:

1 Understanding Regulatory Jurisdictions

The agency reviewing your validation is as vital as the validation strategy itself. For instance, countries like Brazil & China have specific requirements for in-country testing and shipping, and pharma companies need to be aware of those specifications upfront.

2 Creating a Multi-Market Validation Plan

A Master Validation Plan for trial logistics and cold chain should cover as many country-specific jurisdictional requirements as possible so that you can extrapolate these for future expansion and market plans. This foresight is key to synchronizing efforts and maintaining an early validation effort's best ROI.

3 Accounting for Nuances of Weather

Cold chain validation must consider different weather patterns, geographies, topographies, seasonal trends. Understanding the weather patterns in your target markets ensures a thorough analysis of your shipping validation needs.

4 Building Sound Thermal Profiles

Developing a thermal profile involves gathering data from different weather/geography/seasonal patterns to determine your unique thermal profile. You need enough data points to make it statistically relevant, but don't overcomplicate it with hundreds of profiles that do not provide better results than one global profile.

ISTA Profiles

These are industry standards that pharmaceutical companies can utilize when developing their profiles. When selecting an ISTA Profile to use, the FDA will expect you to make a justification for why that standard applies to your transport lanes.

Insight from the Experts at Modality Solutions

Pharma companies make mistakes on both ends of the spectrum. Either they spend too much money collecting multiple data points when an ISTA profile would have sufficed, or they try to apply an existing ISTA profile that doesn't match their case. The key is to look at it from a risk-based system, determine your confidence interval, and if no standard profiles work, then you can create your own.

5 Trusting in Good Engineering Work

Proper statistics can make or break an application. You don't need tens of thousands of data points across all different seasons to develop a thermal profile for a lane; you need enough to make it statistically relevant and then compare that to the underlying data set to build a thermal profile. You need sound engineering with a statistician's eye to get this done right.