



Ten Mistakes Companies Make When Specifying and Validating Insulated Cold Chain Shippers

Ryan Craft

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WESTPAK
TESTING. OWNERSHIP. INTEGRITY.

83 Great Oaks Blvd
San Jose, CA 95119
800.830.8021

10326 Roselle Street
San Diego, CA 92121
800.830.8021

westpak.com

Abstract

This article presents a list of common errors companies often make when specifying and validating insulated cold chain shippers. Keeping these mistakes in mind during specification development and package validation testing will help save you and your company money and time. The article also offers tips on finding the right testing laboratory for your validation testing needs.

“Just wanted to say that Michael and Josue have done an awesome job helping me test a number of different products during the pandemic. They have been really accommodating by taking pictures, videos, and conference calls as needed.”

T.W.

Background and Introduction

Insulated shipper validation is rightfully considered one of the most enigmatic and challenging packaging validations to complete. Many companies simply avoid opening this Pandora’s Box unless forced to by customers, auditors or supplier issues. The choice of which environmental test profiles to use and for what duration are two examples of test parameters teams must address head-on with a thoughtful test plan. However, insulated shipper validation does not need to be the elephant in the room. Once equipped with the correct information, requirements and engineering support, your team can effectively and efficiently design a package system that accomplishes the design objectives without too much hassle.

Top Ten Most Common Mistakes

We present these Top Ten Most Common Mistakes teams make which, when avoided or addressed proactively, can save your company money and time - not to mention helping you secure that promotion and raise you’ve been working so hard to get.

1. Overly-Specified Environmental Temperature Profiles

Teams often specify profiles that were previously used, what a supplier has “pre-validated”, or one arbitrarily selected because it was liked. By taking the time to speak with a technical expert, a profile recommendation can be made that is concise and aligns with the distribution environment the packaging system will encounter on its path to the end user.

2. Qualifying Only One Insulated Shipper Supplier

Qualifying a secondary supplier takes time that your project may not have, especially for a new product. Assuming the decision is made to qualify another supplier, even more time and effort is required to conduct performance validation testing on the insulated shipper they produce. Therefore, it's not surprising that many teams keep the focus on the primary supplier, get their shipper qualified, and move on. Without a qualified secondary supplier, buyers lose out on several benefits including a second source, competitive pricing, and another insulated shipper test result for comparison.

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3. Too Many Shipper Sizes

In all honesty, how many different package configurations does your marketing or clinical trial need anyway? We have had client teams come in with three and even five different shippers in an attempt to satisfy their organization's requirements. This adds significant complexity to the project not to mention cost and time! Keep your team informed of the incremental impact each additional shipper would have on the project and hopefully they will support your recommendation to minimize the number of configurations.

4. Acceptance Criteria from Purgatory

In the absence of data, it seems that some teams resort to believing their product will vaporize if it's allowed an excursion to 1.9°C or 8.1°C. But not knowing the perishability or excursion tolerance of your payload can be detrimental. By getting the facts and knowing the payload's actual perishability and fragility, you can allow for some wiggle room while understanding its limits. We suggest determining these limits by performing a perishability study on the payload in question. If time and money are an issue, another way to determine this is to put a small bit out Friday night, leave it over the weekend and test it Monday. This simple trick can at least give you a place to start and can be cost and time effective.

5. Insanely Tight Schedule that Doesn't Include Failure Risk

Insulated shippers have 101 ways to fail and only one way to pass. Many pre-validated insulated shippers perform as expected, but even validations that are optimized for cost take time. Depending on the length of the profile, this could be up to a week per run or more. Among the questions we get, a common one is from the client wanting to know the results from a 5-day profile validation test on Monday when the test had just started the previous Friday. A well communicated plan will keep everyone informed so expectations are properly set. Also, best practice includes a risk mitigation plan that accommodates failure if it should occur. Having a rock-solid plan in place before the validation testing begins makes you look like a hero if the wheels start falling off the bus.

6. Pack-Out Instructions Are Vague or Don't Exist

You can save money and time by addressing this in advance: specify pack-out instructions with exact details including Bill of Materials, CAD drawings, pictures with notes, arrows, or clear hand sketches if

Make certain the validation test samples comply with the pack-out documentation.

that's all that is available. A good BoM should be revision-controlled while providing part numbers, descriptions, quantity, and revision of each part. On the drawing or picture, clearly show the taping pattern and any pre-conditioning required. The objective is to have good documentation that

would enable you to ask your new intern to pack the payload on their first day and get the same exact shipper your operations team produces daily. Make certain the validation test samples comply with the pack-out documentation.

7. Consultants

Hiring consultants for an insulated shipper project can be the best or worst idea. Let's look at some of the items involved here: coordinating boxes, shippers, payloads, sensors, lot numbers, acceptance criteria, sample size, and pack-out are just a few. You can get help with these things but at the end of the day, many of these questions and tasks will come right back to you if you don't have a clear Scope of Work or detailed plan that specifies who is doing what and when. If you don't get your consultant fully involved with your team, you may end up doing the work yourself! Oftentimes, test labs can complete shipper validation projects faster and with less cost than involving a consultant because they have the resources readily available.

8. Reinventing the Wheel

At the end of the day, you are packing an ice chest - a need that has been around for hundreds of years. Just because you need an environmental thermal validation performed does not mean you need to challenge or reinvent the laws of thermodynamics or become a meteorologist. Thicker insulation is

better; the more surface area you have on your box, the faster heat will enter; more gel packs lengthen the allowable time and distance capabilities of the payload, etc. It can be incredibly difficult to design your own unique thermal profile but if you decide to try doing it yourself, pay attention to Mistake #1. If you want to pay somebody to do it, a qualified test lab will be able to assist you by providing an outside perspective and additional expertise.

9. Misinterpreting the Notion of Validation

We continue to challenge the notion that insulated shipper validation is an oxymoron. Ultimately, validation ends up being a business decision that needs to be addressed. Inevitably, there are distribution hazards that cannot be controlled in the real world such as weather and environmental conditions, the actual duration of distribution, mechanical shock, vibration as well as package handling. It might be worthwhile to include a ride recorder and, end user accept/reject criteria in your validation plan. A well-designed and executed validation will enable successful transits of your packages to the end user most of the time. Depending on the payload, it may be cost-prohibitive and impractical to design for the 1% that will eventually occur. Completing a good package validation will relieve a lot of pressure on your assumptions while enabling a higher product acceptance rate in the field.

Keeping these mistakes in mind during specification development and package validation testing will help save you and your company time and money.

10. Using Your Supplier's Lab

A pre- or free validation sounds like a good deal, but this usually includes only one supplier, no customer control, plus pushback when you ask to qualify additional samples. Consider using a third-party lab instead of, or in addition to, your supplier. Just like a fee-based versus commissioned stock portfolio manager, the advice and attention you receive will be different and should be unbiased with the third-party option.

“Another job well done. I really appreciate the help with the sample preparation this time around.”

T.M. _____

Finding the Right Test Lab

When it comes to finding a laboratory to test and validate your package, here are some questions to consider:

- Does the lab conduct cold chain validation tests regularly? Are they accustomed to the industry and the broad spectrum of product and package types that exist?
- Is the lab willing to consult with you at the beginning stages of development or revision, especially when shippers are failing validation tests on a continual basis?
- Are the staff members well-qualified, experienced, have expertise in testing, the right equipment, plus an understanding of the cold chain industry's techniques and standards?
- Is the lab ISO 17025 accredited? If so, are the test procedures planned to be utilized listed on the Scope of Accreditation?

If the answer to these questions is yes, then the test lab being considered for insulated shipper validation should be qualified to validate your company's insulated shippers.