Bred for the Outdoors

Successful product distribution begins with the correct system design. However, ensuring the right temperature-controlled packaging specification, the correct system optimisation and the necessary parameter identification, should be top of the list for any packaging company

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The correct temperature-controlled packaging solution is the one that keeps your product secure and ensures its integrity is maintained. Beyond that, there are a large number of factors to consider when determining the best solution for your specific needs. Choosing the wrong system and specifications can lead to packaging failures, product recalls, or years of operational and logistical difficulties, not to mention the associated costs of such failures. Finding the right temperature-controlled packaging solution lays the foundation for a system that works best for both the product and the company.

Thermal Properties

To achieve the correct specification, there are a few key factors to consider. First, it is imperative to conduct an assessment of the thermal characteristics of the product to determine the level of performance a system needs. These thermal characteristics will determine what to specify for the performance qualification (PQ), as well as indicate the operational qualification (OQ) and validation parameters. A distribution model will also have a significant impact on the scope of the packaging specifications, as it will indicate the relevant markets and the volumes anticipated for transportation.

Performance Level Required

The necessary performance level for a particular temperature-controlled packaging solution is determined by the product. The system's temperature range, which considers the potential negative impact upon the product in adverse exposures, is determined by the stability data held on the product and the regulatory controls regarding the maximum and minimum temperature exposures, or the acceptable time out of refrigeration. In addition, the packaging, dimensions and materials used will all pose significant factors in the final specification. For example, the movement of bulk, active pharmaceutical ingredients (APIs) will pose a very different challenge to low volume microgram dose transdermal patches. These product details, including the pack contents, dimensions, variable doses and saleable units for distribution, all influence the final specifications.

Ambient Profile

Specifying the ambient profile – the likely temperatures the packaging system will be exposed to – is not a trivial matter. The distribution plan and established or proposed distribution partnerships have an important impact on the likely exposures. When the routes are fixed using an established distribution partner, the time and temperature mapping of the route and the likely controlled and uncontrolled exposures can be identified. An assessment of the probability of adverse exposures in both the controlled and uncontrolled sections can be carried out, and in light of the product properties, a suitable route profile can be specified.

In a complex logistics plan, the specification process is often more

challenging, as it may involve thousands of routes to map and investigate. It is often best to assess all of the carriers and destinations as groups with common thermal exposures, in combination with durations, to define a number of specification brackets. These complex routes will then need to be carefully qualified and monitored to ensure the bracketing process has not mistakenly placed a route in the wrong performance specification.

Qualifying Systems

By first defining the product and its specific characteristics, and then identifying the durations and exposures it will be carried through, one can specify the thermal performance required.

This leads to the performance qualification for the packaging solutions. By now, the diversity of routes and the product will often require a number of specifications. Decreasing this diversity to a single solution may seem to simplify the process, but it may also leave you over-specified for most of your shipments or at a heightened risk of having the system fail during shipments. So, even if differentiating solutions is as simple as having a cold and a hot exposure system, any differentiation of the systems can help reduce costs, volume and system complexity.

The performance qualification specification must consider the most demanding combination of temperatures and time exposure a product may go through to protect it. It is important to be realistic at this stage in terms of percentiles of protection. If you combine the most extreme one per cent of expected exposures with the corresponding percentile of shipping durations, you could create a system that far exceeds the performance requirements of 99.99 per cent of your shipments. Using the harshest five per cent for each, you could exceed the needs of 99.75 per cent of the shipments. This assumes your most extreme durations and exposures don't happen to the same shipments.

Selecting the acceptable, probable exposures for the performance testing sets the standard for the systems your product requires. Short durations and relatively low challenges allow for smaller system-to-payload ratios, leading to generally fewer components and less complex packaging systems with less operational constraints. For systems with higher demands due to more extreme exposures and longer durations, more materials will be needed, as well as more complex preparation and packing configurations.

By defining the performance specifications of a system, you can also define the time and temperature resolutions of the data you wish to see, the standard of calibration, and the data handling and audit inspection to which the testing must conform. If you require independent testing or external verification of performance, this can be included in the performance qualification specification. This performance qualification should also include the physical protection required by the packaging. Again, the identification of the physical protection level needed should be done through an assessment of the routes and carriers to be used.

There are bodies and associations, such as the World Health Organization (WHO) and the International Safe Transit Association (ISTA), which produce standards on physical and thermal protection for transport packaging. As to whether these are a good match in their approach to the challenges faced in your specific temperature-controlled packaging situation, is a judgement your partner will be able to assist in making.

Operational Qualification

Once the specifications for the system's performance has been set, it is possible to define those for an operational qualification. They should include all of the unique internal and external operational factors specific to your product and operations.

With regard to the sites where the product will be shipped to and from, the sites in question must be able to both prepare and receive the systems respectively. Does your product require specific temperature-controlled facilities, refrigeration equipment and temperature management training? If so, can this be incorporated and assessed in the operational qualification process? If the product will be shipped from several different sites and in a variety of systems, with seasonality across a number of routes, then the operational qualification will involve a number of stages with potentially a summer and winter qualification. This can have a direct impact on the timeline for delivering a suitably qualified system to support the product.

It is important to have an agreement with your supplier and internal team of what you expect from the packaging solution's performance. An audit of the temperature-control and packaging preparation facilities can highlight the unique aspects of the specific operation and incorporate these into the performance testing and operational qualification process. The operational qualification can act as a confirmation of the data gathered in the initial route assessments and can reinforce the choices of the performance qualification specification.

The performance and operational properties can be used in conjunction with the information known about the properties of the product and the regulatory requirements to identify a system that meets these specifications, and can be validated accordingly.

Logistical and Material Restrictions

The above specifications will have defined a system that meets the product's needs and performance requirements; however there are other considerations. Is the system specified too large, in that it exceeds the limits of certain carriage methods? Does it trigger punitive charges from carriers? In these situations, it may be possible to reduce the physical volume using higher specification insulation materials. Conventional foam has a predictable thermal insulation, directly proportional to its thickness in most cases. Higher-grade foams offer fractional decreases in wall thicknesses, whereas vacuum insulation systems offer substantial

increases in insulation at a fraction of the thickness of traditional insulation materials. If a system is too heavy and is incurring shipping penalties and handling difficulties, you can look at specifying a suitable maximum system weight. This limit leads to pressures for more insulation or tailored phase change materials to reduce the need for greater mass water-based materials.

What to Do if the Operational Qualification Fails

If the performance you receive in the operational qualification does not provide the thermal stability the product requires, the performance has either been improperly specified, or has not been met appropriately. Typically, this requires an increase in the specification and use of larger systems with more components. This may not be possible due to established limits on the system mass and volume. To overcome this obstacle, high performance materials can again be specified to meet the dual challenges of system size and increase the performance.

The operational qualification can also indicate if the physical specification given for the system is appropriate. What may seem like minor damage or disruption to the packaging can have disastrous, exponential effects if the insulation is broken and air flows between the payload, or if the thermal media are in contact with external temperatures. This situation requires more physical protection, including conventional packaging solutions such as upgrading materials and increased monitoring by the distribution partners.

Other Key Issues to Consider

Additionally, certain questions should be considered when assembling the specifications for the system. These questions may also help address other concerns:

- Are there difficulties with the types of packaging materials being shipped and stored? Are they safe materials for travel and do they have compliant material safety data sheets (MSDS)? Will they cause concerns at customs checks? Are there any environmental issues with the materials chosen? Does the company or destination site have issues with disposal of the materials chosen?

- When attempting to reduce the carbon footprint of the packaging used, can the resources used in the packaging materials be reused or recovered? Is a life cycle analysis from cradle to grave – or alternatively cradle-to-cradle – required to ensure the impact of the packaging choices in the specifications (both explicit and implicit) are acceptable?

- Are the supply sites positioned to accept packaging of a certain size, and do they have the capability to prepare the materials needed to the right temperatures? If specialist materials with specific phase changes have been selected, they may need preparation at temperatures that are not common in storage and distribution environments.

- If employed, are recyclable, re-useable systems possible in the logistics operation? What kind of system recovery percentage is expected and is re-qualification for re-use possible? Are there ownership options that are unacceptable? Are there liabilities that must be accepted in the supply of the systems? Are there quality standards to be met by the suppliers?

About the Author

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Conclusion

If you can assemble the initial information, present a complete specification of your needs, then work together with a qualified partner in the supply of temperature-controlled packaging solutions, you can help identify the likelihood of meeting all of the criteria and thereby determine the key priorities. With proactive, intelligent system development and planning, you can move step by step towards a system that meets realistic expectations of performance. If you can specify your temperature-control and packaging requirements, then you can provide the protection the product requires and have confidence that you have the best temperature-controlled packaging for your specific needs.