Ambient Temperature Profile Development: A New Approach for Qualifying and Defining a Shipping System's Performance

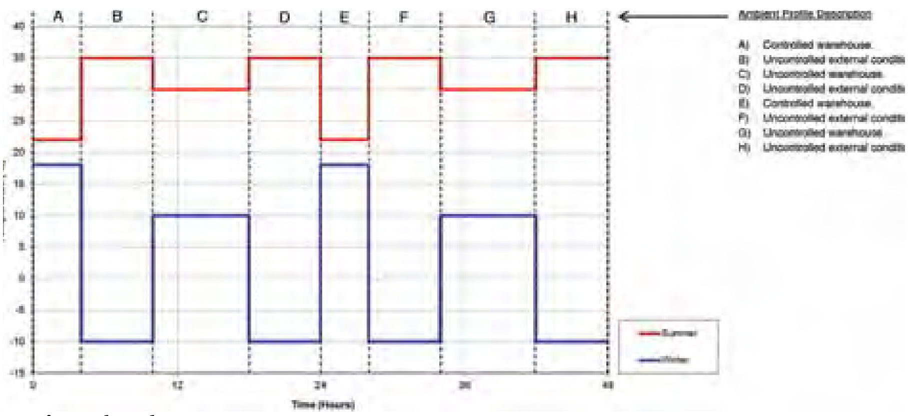
PEER REVIEWED

When developing an ambient profile for a temperature-controlled packaging solution to be qualified against, every Temperature Control Packaging (TCP) user has their own views on the best way to create a profile that accurately reflects a distribution process. Overall, each reaches the end result by a different method, meaning that companies often end up with very different ambient temperature profiles from each other. But shouldn't all profiles be created in the same way? Why do they differ so greatly? And is it actually possible to have one universally accepted formula, which could be used to help standardise the process? Richard Wood from DS Smith Plastics Cool Logistics discusses this burning issue.

The design and development of a packaging solution to manage products that require a temperature-controlled environment during transit, depends upon a comprehensive understanding of the distribution territory and challenges it could face during its journey. This knowledge will not only maximise the packaging's performance and minimise cost, it will maintain the quality of the product being shipped.

In order to build this picture, many healthcare companies collect temperature data and may take information from identical environments, on matching routes, with the same transportation method - but end up developing completely different ambient profiles. This is because there are many methods for establishing profiles, ranging from empirical analysis (direct or indirect observation or knowledge) to theoretical models (such as geography or historical weather data).

When taking into consideration geographic zones, seasonal variance and anticipated temperatures throughout the shipping process, many TCP users lack sufficient evidence-based temperature data within their supply chain. This can hinder the development of a profile or may lead engineers to adopt a 'worst case' approach; planning to extreme geographic ambient highs and lows. The use of a 'worst case' methodology in the design of TCP leads to ultimately increasing the packaging size and logistics spend. This is because it requires a higher level of thermal performance to overcome the external ambient stress in order to sufficiently protect the products being shipped. As a result, the added materials lead to heavier, larger systems, higher costs and increased freight spends.



A Pivotal Role

Indeed, successful product distribution for today's complex global healthcare industry begins with the sophisticated design and configuration of TCP, which ensure that the products inside maintain their efficacy during transportation. As such, creating an ambient temperature profile is no trivial matter, and is actually the most important factor when TCP manufacturers test their shippers for a customer. Ultimately this relationship between time and temperature is designed to replicate what the shipping system may be exposed to in a real world transit. It lays down the building blocks for the design and dictates how much phase change material the manufacturer has to put into a shipper to absorb the heat energy that it is exposed to on its journey.

The development of a realistic profile is essential in ensuring the right packaging solution is devised to maintain the correct temperature control that these products require. But, there are many views on what constitutes the 'right' method for creating an ambient temperature profile for any given shipper.

Understanding the Challenge

Professionals who design and qualify TCP solutions for healthcare products continually face a multitude of challenges in developing systems that suit the many demands of a distribution route. Exposure to extreme temperatures needs to be taken into consideration and can impose a significant hazard. Without the correct configuration of energy-absorbing phase change materials, the TCP may not offer the required level of thermal protection for the duration of their journey, which could result in temperature excursions within the packaging payload and could compromise the temperature-sensitive product's quality and efficacy.

It stands to reason that the more challenging the profile, the more robust the packaging needs to be, but as previously mentioned, the availability of 'real-world' data needed to create ambient profiles varies considerably. For example, when regularly shipping along predefined distribution lanes, such as Europe to America, there is an abundance of temperature data to support the way in which an ambient temperature profile is designed. However, when creating a profile for less familiar routes, such as Europe to remote parts of Africa or the Asia, TCP users often work with their TCP vendor to build an 'ambient challenge' that they feel will satisfy the new route.

Building the Picture

The largest user of TCP with the least amount of variability within the distribution channels includes the large pharmaceutical product manufacturers. When transporting products from the main manufacturing site to a pre-defined distribution hub, the shipping lanes are well mapped for times and temperature, plus the freight service is of a high standard. On these routes, it is possible to control certain temperatures; for example, packages could be stored in a controlled room temperature environment or a refrigerator. Likewise on flights, temperatures that the aircraft hold is controlled at can be prescribed, so therefore this distribution model faces a 'lesser challenge' in the industry.

The next stage of the route (from the distribution hub into clinics, pharmacies and hospitals) becomes a bit more challenging. While the duration of the shipment may be shorter, as delivery may be within the same country, the variables become a lot more inconsistent. For example, it could be transported via a standard delivery network, in a truck or van, where temperatures could vary if it is curtain-sided or has a solid wall and/or air conditioning. So this is where a shipper perhaps needs to have more robustness built into it, because there are more variables involved.

However, it is the clinical trial sector that faces the biggest challenge of all TCP users. This is due to the fact that clinical trials for particular products have to be conducted in extremely remote areas of the world in order to assess 'naïve patient groups' who haven't already been exposed to certain types of pharmaceutical products. It is on these distribution routes that some of the greatest ambient temperature profile design challenges are faced. Here, it is not just the time duration of getting clinical trial material from Europe into countries such as West Africa or Africa, which generally speaking could take around 48 hours. One of the main issues faced is its management during customs clearance, where it could be held (and potentially mis-managed) for up to a week.

Setting a Standard

While in previous years, data-based standards by which to qualify a TCP have been created, currently there remains an absence of a reliable globally accepted industry standardisation. Standards organisations have attempted to address this issue by developing generic ambient profiles, whose objective was to function as a universal test profile for insulated shipping systems. Whilst these projects have been run in partnership with several pharmaceutical companies, packaging suppliers and global logistics providers in order to conduct this study, unfortunately these profiles have not fulfilled the demands of all regions. This meant that ultimately, the shipper designs were not robust enough or were over-engineered for the particular purpose they served.

Historically, these organisations that have created a 'one size fits all' approach to developing an ambient profile have always focused on the external temperature and the duration of the shipment. This information is then used to build an ambient challenge for a shipper to be qualified against.

However, this puts forward the question of whether we are looking at this the wrong way, and is it indeed possible to challenge this method with a new, completely different approach?

Instead, rather than focusing on what could be happening outside the shipper, why not look at the capabilities of the shipper itself…

A Different Approach

By using new virtual development design tools such as Multi-Physics (MP), which are beginning to be adopted by the industry, we can assess the energy-absorbing capabilities of a TCP system and match it to the average thermal stress that is going to be experienced during a distribution process. This can be applied to any region in the world and, based on certain key parts of information being made available by the industry, in theory perhaps offers a new way of looking at qualifying and defining a shipper's performance.

Firstly, by obtaining the temperature lane data and understanding the heat/thermal challenges faced whilst trying to distribute a product (information which is

likely to already be in the hands of many pharmaceutical companies), a single database of ambient statistics could be developed to build an accurate global map of distribution lane data.

For instance, if a TCP needed to be shipped from North America to Asia, the actual data collected in the field provides a very accurate view of what temperatures will be experienced during that distribution route and off the back of that, an average thermal stress score could be created that the shipper would be exposed to during its distribution.

Secondly, TCP providers would qualify shippers to demonstrate their basic performance and ability to withstand the external ambient conditions (either hot or cold) during transit. What this means is that the qualification style would change and stress tests would provide a Thermal Stress Score that the shipper would be able to overcome. TCP manufacturers could then take the Thermal Stress Score based on the real-world data (database) and match it to the Thermal Stress Score that the shipper can accommodate. That would give healthcare companies a clearer view of what configuration of passive shipper they should be using and thus remove the uncertainty from distribution chain challenges.

Let me explain, using cycling to illustrate (bear with me). In recent years it's become possible to measure a cyclist's overall performance (power output) when riding a bike. This helps these athletes train more effectively and understand what stresses they put their bodies under during competition. Special power-measuring cranks are attached to the bikes that constantly monitor the power output they are producing. This data, along with the heart rate, speed etc. are recorded on the bike using a data logger (cycle computer). After a training ride or race, the data is downloaded to an application that analyses and interprets the data. The software reviews the power output and the heart rate by using a special algorithm that produces a Training Stress Score. This offers a very simple way of assessing how hard the cyclist has worked during that event and is a training method that has been put to excellent effect in recent years by Team Sky, culminating in the success of Sir Bradley Wiggins at last year's Tour de France.

In a similar way, by understanding the stresses that a shipping system will be exposed to during shipments, we can use technology like MP simulation to design TCP that is specifically intended to overcome these stresses by means of controlling the amount of heat-absorbing material (power) designed into the shipper.

Like the subjective nature of ambient profiles for TCP, cyclists used to determine how hard they were working based on feel. The introduction of a system by which they can empirically assess the work they have done on the bike has significantly changed the way most cyclists now train. Perhaps by introducing such a 'data-based' system to the pharmaceutical industry it too can realise the benefits of looking outside the box!

Conclusion

This theoretical, fact-based approach is supported by a TCP system's capability to absorb and release energy in the form of heat over a time period. This is very different to the way ambient temperature profile development has always been approached previously in the industry. For the most part, certainly around domestic and clinical trial distribution, it has been built around perception of what the requirements might be, and not necessarily based on accurate data of what the challenge actually is within those particular lanes.

This would mean that customers could approach TCP manufacturers and select a shipper based on a Thermal Stress Score they expect to see on a particular route, and manufacturers would match their requirements with the appropriate system. This single tool could be used to define challenges that need to be overcome by a TCP shipper, and would potentially simplify and standardise the way in which packaging systems are designed to perform, as well as regulate the selection method for the shipper.

But in order for this approach to work well,the primary information needs to be sourced from as many different points in the industry as possible, and requires the collaborative working of the industry, as well as with academics, to understand and coordinate the collation and interpretation of data.

Perhaps this would then create a global thermal map of distribution lanes that would be far more comprehensive and fact-based that any previous universal formula for the development of ambient temperature profiles.

The debate continues…

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