More Than Just an Insulated Box

Temperature-controlled Packaging:

The demand to frequently transport temperature-sensitive products with greater compliance and often in more difficult conditions is increasing. This places temperature-controlled packaging manufacturers under immense pressure to achieve temperature stability in more efficient and robust ways.

This has resulted in a marked shift in the temperature-controlled packaging sector, as manufacturers are having to provide increasingly more sophisticated packaging solutions, to ensure that the high-value payloads reach their destination on time and intact. More than simply just an ‘insulated box,’ temperature-controlled packaging solutions are highly engineered, innovatively designed solutions.

The purchasing of temperature-controlled packaging is often seen as a ‘second’ priority to decision-makers; behind the requirements placed upon them by their high-value payload, manufacturers are continually challenged to validate the cost of their services and the products they provide. Often this is characterised by an attitude that ‘it’s just an insulated box’.

The principal idea behind the GDP guidelines released in 2013 is that during the planning and execution of distribution, each decision must be undertaken with a ‘risk-based approach’, with the philosophy being that the sum total of the risk in the system must be below an acceptable level. It is the role of packaging manufacturers to design and provide solutions that help to minimise risk where they can.

Each product offered by packaging manufacturers has built behind it many hours of work to develop it to best meet the requirements of its user. Often this materialises into simplifying the appearance, as through this simplification one of the biggest risk factors is reduced – human error. However, this only serves to reinforce the impression that ‘simplified products’ are low-value goods.

Where Have We Come From?
Traditionally, passive temperature-controlled packaging utilised water/ice-based coolants and foam-based insulation (such as EPS or PUR) to maintain internal temperatures. These systems are still used effectively today, especially because their cost base is much lower than using the newer technologies available.

However, there are a number of limitations, one of the largest being that each design tends to operate in quite a narrow ambient temperature band. This means temperature-controlled packaging manufacturers have to utilise separate summer and winter packing configurations for optimum performance. The use of seasonality increases the risk of temperature excursions, as the wrong configuration can easily be used due to unseasonal weather, especially as the switch is often done on a predetermined date.

Furthermore, any ice-based system typically uses a combination of frozen and refrigerated coolant, plus the use of insulating spacers in order to control the flow of heat within the system. This leads these systems to ultimately be more complicated to pack, which means there is greater risk of human error. A single component forgotten or in the wrong place can have catastrophic consequences for the payload and a very high cost to the patient and/or the pharmaceutical company.

As the industry develops to demand more robust systems, the physical properties and thermal limitations of these materials leads to larger and heavier systems, which in turn leads to much higher freight costs for the user. It is estimated that for every $1 spent on packaging, $5 is spent on freight, so it is incumbent on packaging manufacturers to minimise that freight cost where possible.

The Challenge Grows
In recent years, the pharmaceutical industry has undergone significant changes, including stricter regulations controlling the conditions in which pharmaceutical products are distributed. As products have become more complex and costly, the need for stronger controls within the distribution network has also grown to ensure patient safety is maintained. In turn, this has led to a rise in the number of hazards that temperature-controlled packaging manufacturers need to overcome.

The publication of the GDP guidelines in late 2013 put more ownership on ensuring an intact cold chain on all parties involved in it. This meant that a lot of companies that had previously not used temperature-control are now using it, and everybody is viewing it in much more detail and gathering more data.

Historically, temperature-controlled packaging manufacturers could rely on a one-size-fits-all approach in the design of temperature-controlled packaging, with many manufacturers providing parcels that will protect payloads (whatever they may be) for 72 or 96 hours, against an internally created exposure meant to represent some sort of shipping, usually within/between the USA and Europe.

This model is no longer representative for a large proportion of movements within the pharmaceutical supply chain. It worked well when the pharmaceutical manufacturing and distribution market was more concentrated and shipping was required to relatively moderate temperatures. However, this is no longer the case.

Different stages of the manufacturing process can happen on different continents, often with a global shipment taking place as it moves between each step. The final market for a drug can now also be anywhere, particularly following the rise of the Indian and Chinese pharmaceutical markets.

These elongated supply chains are now much more likely to pass through regions with more challenging ambient temperatures, whether it is from an API manufacturing site in Korea, a layover in Dubai, or landing in Washington in the...
As temperature-logging has developed, and manufacturers have been able to see how their products have performed, and the challenges the packaging actually faces, there has been a move towards needing to design solutions that are more effective at combating these risks. With the introduction of the new GDP guidelines, this has taken a further step forward with visibility of the supply chain taking ever greater importance.

Along with increased ambient temperature challenges, the logistics network handling conditions is also a factor that needs to be considered. A system that may have worked flawlessly in Europe and the USA may not be robust enough for a country such as China, where the network infrastructure outside of the central cities is not as well developed.

With GDP emphasising a risk-based approach, there has been a trend to over-specify the packaging requirements as, justifiably so, quality departments are unwilling to determine an acceptable risk level, instead trying to find a near-zero-risk solution. But demanding a package perform to a higher level, by allowing additional safety factors, does not necessarily provide greater useable protection or added value, but does ultimately increase costs.

The healthcare and clinical trial industries are constantly evolving and pharmaceutical companies will always introduce new challenges through new products with different requirements – in particular, the introduction of more personalised medicines. This means ‘last mile’ logistics is becoming increasingly more important, perhaps delivering to individuals rather than a hospital pharmacy and certainly introducing more diverse shipping conditions. Currently, this final mile after pharmacy isn’t covered by GDP, but it is expected in the future there will be more attention paid to it by the regulators.

So What Can We Do?
The key to selecting the right packaging is to accurately identify what the hazards are, such as destination, touch points and modes of transport, when identifying the route. This is the difference between utilising good and efficient products and services to protect pharmaceutical payloads, compared to selecting packaging that will either under-protect the product, or incur unwarranted extra cost. However, when identifying the route it is often difficult due to a lack of real-time insight data into the challenges a package expects to face. Hence the requirement for packaging to not only be thermally qualified by manufacturers, but also undertake operational qualification through the chosen logistics channel, before shipments of expensive product.

The two main causes of temperature excursions are shipments experiencing temperatures they haven’t been designed for – so the wrong packaging has been selected for the challenges it faces – and human error.

The risk of human error can be largely reduced through user-centred design. With many companies’ high performance passive systems, they can generally only be packed one way. Furthermore, temperature-controlled packaging manufacturers may also include added safety measures, such as specialist labelling to visually indicate and verify the readiness for packing, so that there’s a secondary safety check to ensure that things are prepared properly before packing.

As the challenges faced evolve, temperature-controlled packaging providers are having to evolve with them. This decade has seen the introduction of ‘high-performance passive systems’ which utilise new techniques and materials, but also require new ways of thinking about packaging in order to get the greatest cost benefit.

Demonstrating the Difference
Today, the new generation of high-performance temperature-controlled packaging solutions are not too dissimilar in appearance from the outside to more traditional passive solutions, which relied on water-based coolants and foam-based insulations. However, this jump in technology has not only resulted in easier to use systems and greater protection, but also greater capital expenditure for the end user, causing re-use to become a growing sector of our industry.

The new generation of systems comprise of similar key design components: an outer case, insulation and coolants in the form of bottles or bags.

An outer case can be made from a range of materials, depending on the intended use: low-cost corrugate fibreboard, through corrugated plastic, up to high-specification rigid containers (typically moulded plastic for smaller units and metallic for the very largest).

The case is then typically ‘lined’ with VIPs to give a very high degree of insulation. These panels are usually made from compressed silica boards placed within a pouch with an
impermeable metallic membrane. This is then evacuated and sealed to create a very low-pressure environment within the panel. The advantage of these is that the VIPs offer five to seven times as much insulation, compared to the same thickness of foam.

Phase change materials are currently derived from one of three sources; plant oils, paraffins or salt-based solutions. These are tailored to provide protection at various temperature ranges, such as below -20°C, +2 to +8°C and +15°C to +25°C, though in theory a PCM could be designed for any temperature you wish.

The strength of PCMs is that during a phase change (typically between solid and liquid) the temperature of the material does not change, essentially absorbing or releasing heat as required. By coupling the PCM with the payload, this means that the payload temperature is kept stable too, as the temperatures will always try to equalise. This removes the requirement for mixed preparation coolants or insulating spacers.

With the use of VIPs as high-performance insulation, this massively increases the length of time it takes the PCM to change phase and therefore prolongs the temperature-stability of the payload, even over longer distances and more extreme or varied climates. The combined benefit of using VIPs with PCMs therefore means prolonged duration, simplified preparation methods and reduced volumetric weight ratios, which brings shipping costs down.

It is, however, the relative cost of the raw materials of the new technology that has a direct impact on the costs of packaging solutions. Moving from some of the most common materials available, to those that require more work to obtain and process, can only involve an increase in cost.

Investment in this type of packaging can result in easier to use systems, and labour and stockholding efficiencies. Intelligent user-centred design, therefore, is becoming more and more of a key differentiator between systems on the market.

These high-performance systems are also typically backed up by rigorous thermal testing protocols and reports. Historically, packaging was qualified against proprietary testing profiles, which would demonstrate how a system performed against thermal challenges, but it was often difficult to compare systems from different manufacturers head-to-head due to variations in their protocols. The growing trend of different packaging companies testing their systems against ISTA 7D as a benchmark for thermal qualification has helped reduce this confusion for purchasers.

The relative high cost of this packaging, along with the sophisticated materials and robust qualification data, means end users are looking for a greater return on their investment and expect systems to be multi-use rather than single-use, whereas in the past, packaging was seen as being a single-use consumable product. Some high-performance temperature-controlled packaging solutions are developed for multi-use, rented by the shipper and reused by the logistics provider, to reduce the environmental footprint and decrease costs.

However, the reality is that they are not always used to their full potential and are sometimes only used once, therefore not achieving their maximum proficiency in terms of cost-saving and sustainability. With a lack of return logistics through some shipping lanes, hybrid systems utilising combinations of old technologies and new are becoming more commonplace, trying to bridge the price versus performance gap between the historical and current approach to packaging.

These products and services are constantly maturing, but we are a long way from anyone being able to offer a comprehensive global solution. When a network is able to do this cost-effectively, this is likely to be the next big revolution in our industry.

Conclusion

Cost will always be a key driver in decision-making and there’s a limit to what anyone is prepared to pay for what’s often a secondary consideration. However, by fully understanding the risks in the supply chain, temperature-controlled packaging is able to be a key pillar in avoiding problems, and generating overall cost savings.

Our industry is constantly changing and we are always looking for new materials and techniques. Finding and developing new alternatives will no doubt result in the next technology jump, but advancements in cross-border shipping and return logistics will ultimately be the next stage.

The challenge to create better products with different advantages, easier to prepare, more size/weight-efficient and more cost-efficient is paramount for temperature-controlled packaging manufacturers as drugs become more specialist and temperature-dependent.

However, without another step-change in technology, the market is moving towards making the existing packaging work more effectively. So the main differentiator between the many options on the market today is the added benefits of good design, quality thermal testing reports, operational efficiency, ease of use and reducing hazards.

It is now more pertinent than ever to demonstrate the value of temperature-controlled packaging as a product in itself and not just an insulated box.

Neil Sherman is Technical Services Manager at Intelsius, responsible for overseeing new product development, assessing new marketplace technologies, assisting with technical sales enquiries and managing the ISTA-certified testing laboratory. He is responsible for driving continuous improvement processes and managing technical testing and reporting activities. He also contributes to Intelsius’ business strategy, maintains accurate records and supervises staff within the technical team.

Neil holds a Master’s degree in physics from the University of York and has been instrumental in the design and development of some of Intelsius’ most innovative packaging.