

How pre-qualified packaging increases speed-to-market for pharma products

Pharma is turning to packaging manufacturers to solve its distribution challenges for vaccines, medicines and other temperature-sensitive pharma products, while customer demand soars

Inside:

- › How the global pandemic transformed attitudes and approaches to packaging solutions
- › What manufacturers and 3PLs should do to ensure distribution channels remain open
- › Why pre-qualified thermal packaging offers a winning solution for pharma products

Brought to you in association with:

Introduction

Finding solutions in a strained supply chain

Challenging border restrictions, climate change and a global pandemic have, over the past two years, led to strains in the pharmaceutical supply chain and lengthy delivery delays. Increases in home-based clinical trials and direct-to-patient services has seen demand increase for quality packaging products, forcing the market to flex and adapt to changing requirements. Meanwhile, extended distribution durations have created further bottlenecks.

Secured pharma packaging plays an essential role in protecting the integrity of drug products and facilitates authentication. Its role in providing verification and product traceability means pharma companies around the world rely on authentication and traceability measures to ensure their products make it to their purchasers.

Ruud van der Geer, Associate Director Global Delivery Strategy Team – EMEA Product Handling Lead at MSD, remarks: "Covid-19 has changed our perception of testing, qualification and approval, along with overall time-to-market and scaling.

"We have had to prepare for pre-license shipping without the long-term stability for standard supply chains, so there has been a need to expand the offerings for low-temperature solutions in supply chains, all while the collection of long-term data has been pending."

In respect to the challenges facing manufacturers, Richard Harrop, Product Director at thermal packaging solution manufacturer Topa Thermal, notes: "We've found ourselves working with a number of companies that would be expecting to ship something within two days, but now these shipping durations are taking up to three or four days."

In this report, *Pharma Logistics IQ* highlights the issues affecting pharmaceutical product delivery across the globe and explains why pre-qualified thermal packaging may offer a sound solution for potential stakeholders.

Contents

- 3 Overcoming pandemic-era challenges
- 5 Solving bottlenecks with inventive designs
- 6 Latest advance in thermal packaging unveiled
- 7 Conclusion: Collaborate to innovate



Increased demand for cold-chain products has forced the pharmaceutical supply chain to develop innovative solutions to sustain the distribution of vaccines. Beyond the pandemic, supply chain issues such as managing regular temperature excursions during product transport and cutting costs remain at the forefront of customers' minds. Duration and distance increases have led to further packaging complexity, resulting in over-engineered thermal packaging products that have been over-specified for the ambient climate requirements of pharma's cold chain.

Luiz Alberto Barberini, Head of External Manufacturing Organization – Latin America for Bayer Consumer Care and a *Pharma Logistics IQ* Advisory Board member, agrees that thermal packaging products are being over-engineered – especially for temperature-sensitive drugs. He says: "Current processes already guarantee adequate time-to-market and delivery of medicines in top-quality condition."

Topa Thermal's Harrop adds: "Increased duration does not always mean a more challenging ambient environment is experienced. Quite often, the increase in time for a user of pre-qualified thermal packaging results in them needing to switch to a more-advanced and complex packaging solution due to many of the pre-qualified offerings today being designed around duration only.

"We opted for a different approach to pre-qualified packaging due to customers wanting to increase the duration of their distribution," Harrop continues. "Their only option shouldn't have to be a more complex thermal packaging solution."

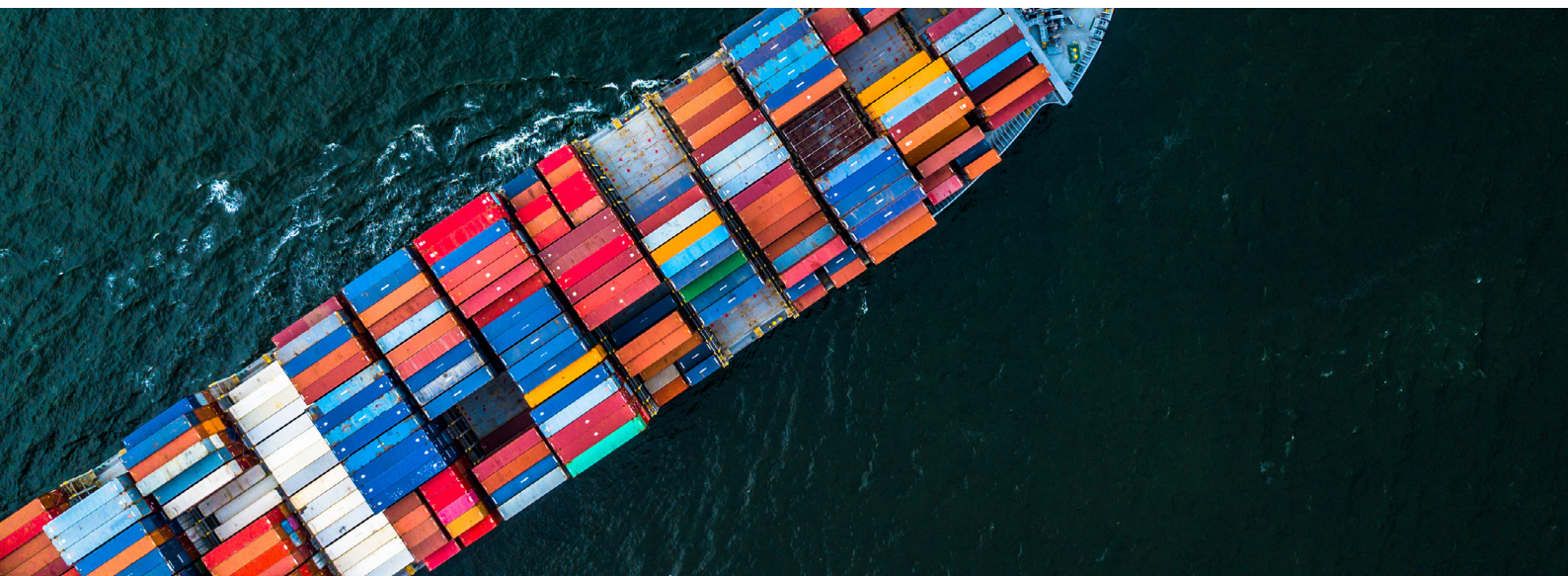
The strategy of collaboration, along with significant investments from 3PLs in building out their cold-chain storage and distribution capabilities, have all proved key to successful vaccine roll outs in many regions of the world, fueling process improvements throughout the supply chain.

Ann Pham, Director of Business Development at third-party logistics (3PLs) provider ICS, notes: "At the 3PL level, refining and renewing previously developed supply chain, risk management and business continuity planning strategies has become a focus, as well as storing products across multiple locations to decrease the risk event."



Cold-chain conundrums and complexity

A 2021 survey of 3PLs on the cold chain, conducted by NTT Data, Penske and Pennsylvania State University, revealed that 31 per cent of respondents believe "proper packaging is the biggest issue" they face. *The 26th Annual Third-Party Logistics Study* also found that 56 per cent of shipper respondents with cold-chain products either fully outsource or partially outsource packaging.



Tom Madrecki, Vice-President of Supply Chain and Logistics of US-based Consumer Brands Association, notes: "Demand for cold-chain services is so high that finding available, cost-effective services is difficult. There is increased demand for services that are more specialized."

An example of the specialized solutions and services being deployed include Johnson & Johnson's use of security seals on vaccine boxes and traceability measures on vials. Other companies have equipped vials with black-light verification to curb counterfeiting, while smart labels provide time-temperature indicators that react to heat and time.

In respect to the value of products such as pre-qualified thermal packaging and the solutions they offer for today's supply chain, Bayer's Barberini says each case should be viewed on its merits.

"Some requirements are not met with pre-qualified cases and may need to be reviewed, but it depends on the product and its respective lane," Barberini explains. "Pre-qualified solutions, however, do offer an advantage to companies throughout the supply chain."

"Increased duration does not always mean a more challenging ambient environment is experienced."

Richard Harrop

Product Director at thermal packaging solution manufacturer Topa Thermal

Topa's Harrop says: "If you need a packaging solution that's already qualified and ready-to-use for specific pharmaceutical distribution, there's so much choice available. The duration-centric design approach for pre-qualified solutions, however, serves only to streamline supplier offerings, resulting in the limitation of suitable user choice and selection compromise.

"An approach where all stakeholders stand to benefit from carefully considered products offering new dimensions of flexibility and portability will be a route

toward enhancing the supply chain of temperature-sensitive products," he adds.



Streamlined solution

Harrop describes pre-qualified thermal packaging as a ready-to-go thermal packaging solution, usually developed and qualified by a thermal packaging provider. These companies, among which Topa Thermal can be counted, compile all parts of the final product, from design and testing, through to qualification and supply.

"Using our industry experience and with input from our customers we've undertaken the industry's most extensive pre-qualified solution development program," Harrop claims. "The main benefit of these products is in what they offer users who don't want to go down the custom development route, but do want something that works for them immediately."

To ensure their packaging meets the needs of the user, manufacturers of pre-qualified thermal packaging require a sound knowledge of varying shipping environments, for which Bayer's Barberini recommends three golden rules manufacturers should be aware of.

"The first rule is to ensure a product's integrity all way to customer," Barberini begins. "The second rule is to provide necessary conditions to guarantee compliant shipping conditions. And the third and final rule is to ensure packaging protects goods from any changes.

"The need for competitive costs, associated with a higher demand for protection, may drive companies to strive for new materials or packaging manufacturing costs," he continues.

Solving bottlenecks with inventive designs

Big problems often require creative solutions. As supply chains strain, the need for products to remain safe and usable – especially during a healthcare crisis – represents a timely challenge. Adversely, it provides an opportunity for distributors to put the quality of packaging solutions to the test.

In the *Third-Party Logistics Study*, respondents reported that cold-chain services were “important to their company’s growth over the next three years”, with 62 per cent stating they are “moderately important” and 38 per cent claiming they are “critically important”.

The quality of the products 3PLs providers select should offer clients security and assurance. Throughout the pharma supply chain, the use of products such as pre-qualified thermal packaging can provide pharma leaders with clear market advantages, enabling medicine or vaccine manufacturers the ability to create wider choices of products able to meet the personalized needs of customers.

As MSD’s van der Geer states: “Manufacturers need to understand the demand well, not just from an operational point of view, but also from a tactical and strategic viewpoint.

“Covid-19 demonstrated the value that supply chain management brings to a company,” he adds. “It has highlighted the need to have a strong leadership vision, as well as specialists and experts on board to deal with disruptions without impacting the whole business. Bluntly, I say that our regulatory space and SKU’s have been over-engineered resulting in non-value-added process input for distribution and logistics in general.

“Increasing the focus on issues such as sustainability and re-use, however, will allow companies in the space to transition to higher-end solutions,” he adds.

Those selecting packaging that prolongs a product’s life stand to benefit commercially due to increased temperature-controlled distribution process efficiency and simplified designs. For example, Topa Thermal’s °Connex thermal packaging range, a pre-qualified thermal

packaging solution, offers a quick route-to-market due the lengthy qualifications having already been completed.

Another option, as ICS’s Pham notes, lies in engaging 3PLs early in the commercialization process, so that pharmaceutical companies and their partners can design and execute a robust supply chain strategy able to leverage flexibility, storage across different areas and packaging solutions that maintain product integrity across all conditions.

“Our regulatory space and SKU’s have been over-engineered resulting in non-value-added process input for distribution and logistics in general.”

Ruud van der Geer

Associate Director Global Delivery Strategy Team – EMEA Product Handling Lead at MSD

Such has been the innovation in packaging due to collaboration between various stakeholders that Pfizer’s Covid-19 vaccine can last for up to 30 days in boxes that only require the dry ice to be replenished every five days.

Whether pre-qualified or customized, Topa’s Harrop agrees that the quality of packaging solutions now available within the pharma supply chain is outstanding, noting that the very best solutions focus first on client needs and places the highest level of choice into the user’s hands.”



Never forget the simplistic options

Brie Carere, Executive Vice-President, Chief Marketing and Communications Officer at FedEx, comments: “We believe the most critical attributes needed to tackle the size and scale of [the Covid-19 vaccine] monumental supply chain initiative were visibility, extensive temperature control and intervention capabilities.”

While that particular roll out has been particularly impressive, simplistic solutions are also helping ease the

burden on the supply chain, helping to bring pharma products to customers sooner.

Harrop comments: "If you consider 3PLs, they need to have a wide variety of thermal packaging solutions ready to go to support the needs of all their clients. Our aim with the °Connex GEO pre-qualified thermal packaging line was to offer a straightforward model of fewer than 10 different container sizes covering parcel-to-pallet load distribution.

Topa Thermal took all possible packaging material options and load configurations, qualifying them all to three different ambient challenge levels, with each challenge level consisting of a hot and a cold profile. Geo Zone level 1 shows system performance when shipped in a more moderate climate or well-controlled distribution network.

Geo Zone 2 ups both the high- and low-temperature spikes and provides clear performance data that could be used to support most international distribution requirements. Geo Zone 3 represents the highest challenge level, testing packaging capability all the way up to +45°C and down to -10°C, providing the highest level of shipping confidence when moving products through environments that can offer unexpected challenges.

"Optimal packaging selection is core to our beliefs as a packaging supplier and by deciding to take every pre-qualified system we create and test it to all three Geo Zones we never need to move our customers into using an advanced material packaging simply because they need more time," Harrop notes.



Latest advance in thermal packaging unveiled

A new concept in thermal packaging, demonstrated to the pharmaceutical industry for the first time in late-2021, was the °Connex thermal packaging range, which was developed to offer the widest possible choice of packaging solutions for shipping sensitive pharmaceutical and medical products.

Designed by Topa Thermal and utilizing its Geo Zone qualification approach, more than 250 pre-qualified °Connex GEO thermal packaging solutions have been developed, making it among the widest offering of pre-qualified thermal solutions on the market.

Topa Thermal Sales Director Paul Theuns remarks: "Our °Connex GEO pre-qualified thermal packaging solutions go beyond the standard two-profile qualification traditionally used by our industry, with each solution qualified to three Geo Zone ambient challenge levels."

"Our packaging systems are fully modular and designed to be warehouse and distribution optimized," adds

Jacques le Comte, Business Development Manager at Topa Thermal. "Our integrated parts and components are designed with customer operations in mind."

Topa Thermal's packaging design and qualification is undertaken at its state-of-the-art ISTA certified test center, the Topa Institute, located in the Netherlands.



Conclusion

Collaborate to innovate

By encouraging all stakeholders to work together, challenges within the pharma supply chain can evidently be overcome and products with short shelf lives can find their way to their destinations in the shortest possible time. By selecting the right packaging partners, pharma companies and their 3PL partners can enable process improvements, resulting in competitive advantages and fewer supply chain strains.

"There is a lot of value in pre-qualified systems if these meet the supplier requirements," says MSD's van der Geer. "There is a need for industry and regulatory acceptance of standards and virtual data-collection via simulations. But in 99.9 percent of cases, if a solution meets the standard requirements, it will be an external factor that drives performance.

"The risk is not always in the packaging solutions, but rather in external factors such as services, transport

agreements, communication and disruptions," he adds. "It is key to manage these well otherwise any solution will fail. To overcome supply chain challenges, one must make sure to undersell and overdeliver, because it will be an even more monumental task if suppliers cannot deliver what has been agreed."

Confidence in secured pharma distribution plays an important part in the process of ensuring the integrity of drug products and helps to facilitate authentication throughout the industry. The role of packaging manufacturers here is vital in ensuring the supply chain does not fail – especially in an industry where the timely delivery of products can be the fine line between life and death. In that respect innovative packaging designs and express options – such as pre-qualified thermal packaging – present solutions that can keep the entire supply chain flowing.



About Topa Thermal

Topa Thermal is a leading innovator and supplier of thermal packaging solutions and services for the life sciences industry and beyond, aiding access to medicines, vaccines and related healthcare products for patients around the world.

To us, protecting thermally sensitive pharma products means protecting consistently every part of the cold chain, from manufacturing and storage to transportation and global distribution. That's why our easy-to-use cold

chain packaging solutions offer our customers the highest standards of performance, at the best price, with the lowest impact.

With the largest selection of pre-qualified and custom-made solutions, thermal components and the most comprehensive engineering and testing services available in the industry, our temperature-sensitive packaging solutions are designed to work for your needs, to meet your specific distribution challenges.



[Learn more](#)



About Pharma Logistics IQ

Pharma Logistics IQ is an online resource for life sciences and biopharma supply chain professionals providing value-rich content and insight through industry reports, customer trends, best practice, latest industry news, interviews with pharma thought-leaders, online events and so much more.

Our focus is on the content that matters, providing our members with a primary resource to turn to and giving our partners a clear voice within a crowded spectrum.

By joining our growing network you will be able to connect, learn and interactive with other likeminded industry professionals and keep up-to-date with industry inside advice to help you achieve your business goals.

Become a member today to receive exclusive access to our content and regular industry updates.



Pharma Logistics IQ



If you are interested in becoming a *Pharma Logistics IQ* contributor, please get in touch with **Pharma Logistics IQ**.

