PHARMACEUTICAL & MEDICAL Packaging NEWS
THE PACKAGING MAGAZINE FOR THE HEALTHCARE INDUSTRY

Sharing the Ride

Partnering with a provider of transportation packaging for temperature-sensitive products has given a drug manufacturer solutions for clinical trial products and pallets.

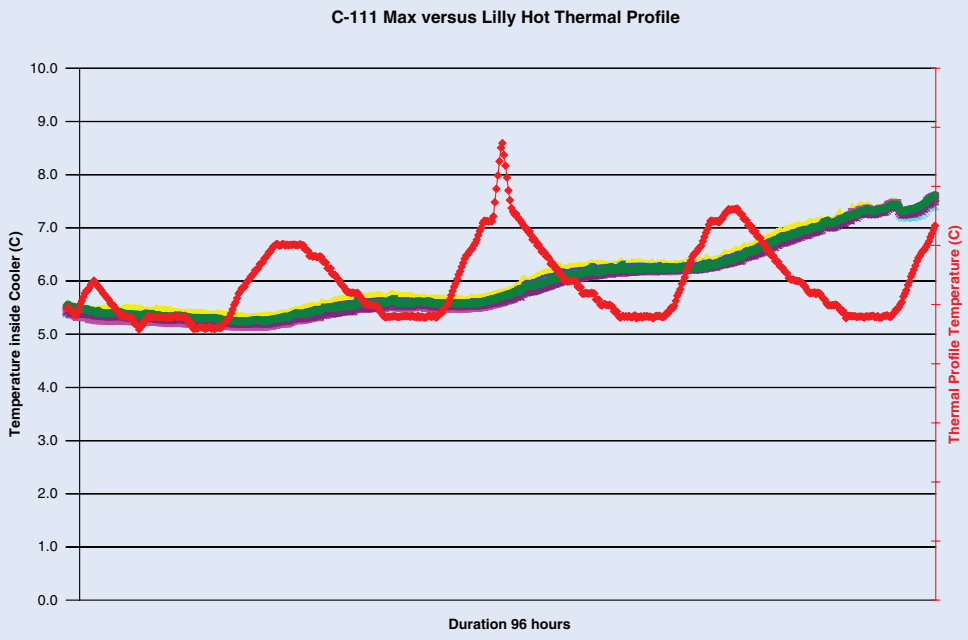
Eli Lilly and Co. is a leader in researching and developing pharmaceutical-based healthcare solutions that enable patients to live longer, healthier, and more active lives. In the five years from 2001 to 2005, when FDA approved nearly 40% fewer new molecular entities than it did in the preceding five-year period, Lilly has launched nine new products.

Partnering has enabled Lilly to selectively add molecules, capabilities, and muscle to create additional value. In fact, biotech companies that took part in a respected IBM survey ranked Lilly number one for its partnering capabilities.

Clinical trials (CT) are the Achilles heel of new drug development; it is the point of greatest vulnerability for biopharma organizations and the point where mistakes have extreme consequences. With the cost of drug discovery to launch so high, and the rate of approval so low, the importance of ensuring safety and efficacy during clinical trials could not be greater. It will come as no surprise that when Lilly's clinical trials division faced serious nonconformance/nonperformance issues when transporting its temperature-sensitive products (TSPs) to clinical research sites around the world, the company looked to collaborate.

"Why reinvent the wheel?" asks Paul Harber, associate engineering consultant, Eli Lilly. "Why not take the wheel, add to it a chassis and an engine—at least then you will get somewhere!"

The wheel in this instance is the map of the thermal profiles through which Lilly needed to ship its CT-TSPs. "We knew that our distribution centers were, geographically speaking, almost identical to those of Amgen's, so my team and I worked very closely with Don Wilson's group at Amgen to map and validate our transportation thermal profiles for our products. The preliminary review of our data matched well with the Amgen findings." Adds



Verified clinical-trial shipper performance for over a period of 96 hours. Shown in various colors on the primary y-axis are product temperatures inside the shipper and in red on the secondary y-axis the temperatures of the thermal profile (which are not provided because they are confidential.)

Harber: "And not surprisingly so, because our distribution centers are clustered in the same three regions of the country."

A validated temperature profile mapping study would have taken Lilly months or years to complete if the company did not collaborate. "At the end of the day, it is our job to provide the highest level of confidence so that investigative products reach CT patients in optimal condition," says Harber. Their condition cannot "compromise the possible outcomes of the clinical trial or the potential approval of new critical treatments. Unlike commercial shipments of TSPs, the shipment value for CTs is not a reflection of the value of the product, it is the ability to deliver the TSPs safely and keep the trial supplied."

But working with Amgen was only part of the collaborative effort to solve its nonconformance issues; Lilly also partnered with EnviroCooler (Huntington Beach, CA). Lilly was experiencing an unacceptable level of nonconformance with the prequalified insulated shipper it was using. "The shipper just wasn't performing for us. When that happens, you realize that your department is the one putting the trial at risk. No one wants to be in that position. So you have to do something to fix it—not fix it for now but fix it for good," says Harber.

Lilly realized that it needed a solution that would not only meet its immediate requirements, but that could also be flexible to meet its requirements as they evolved in the future. "We wanted something that was supported by science and designed with purpose," says Harber. "[We needed] a solution we could use as a platform when durations or payloads vary, so we could scale up or scale down where necessary. Again, avoiding reinventing the wheel!"

EnviroCooler's clinical trial shippers (C-111 and C-162) were selected by Lilly for thermal testing through its mapped thermal profile. "The CT shippers chosen by Lilly were already in use globally by another client of ours," states Rod Derifield, chief executive officer, EnviroCooler. "Some groups in the industry would try to classify these as prequalified, but what does that even mean? If you really want confidence in your shipments, you need to qualify your TSP solution against the thermal profile they will be transported through—your thermal profile."

The C-111 and C-162 shippers were tested under Lilly's thermal profile, using single pack-out formations and minimum and maximum mass loads. "This was important for us," states Harber. "We wanted to avoid the messiness of dictating the SKU combinations for the min and max load. So we stuck to min and max masses instead. This then gives us a greater degree of flexibility when it comes to implementing in our distribution centers, and in the future when new product lines are introduced."

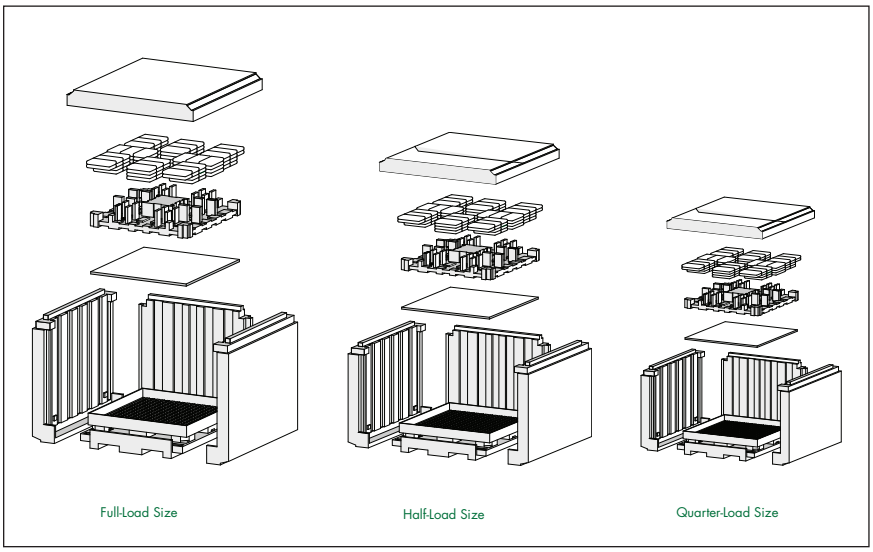
To date, Lilly has used EnviroCooler clinical shippers for more than 2500 CT shipments. "I have just reviewed a boat load of data," reports Harber, "and we only had one nonconformance resulting in loss to date, which was a seven-day shipment to northern China. The temperature dipped at the end of the trip because of a logistics breakdown that exposed the shipper to –10°C for more than 24 hours."

"Our CT partners appreciate that they can return the C-111 and C-162 to us and not be concerned with disposal issues," says Harber. "We reinspect the shippers and can reuse them, which allows us more cost-efficiency as well as being environmentally conscious."

Lilly also introduced the technology into its commercial business. Last year the firm launched Byeta in Europe using EnviroCooler's LD3-sized BioSphere (P-002). Adds Harber: "Like the clinical shippers, the P-002 was being used by other organizations, so all we had to do was qualify it through our four-day-plus thermal profiles. And it passed the first time."

Sending half-filled pallet shippers around the world is expensive business, so again Lilly collaborated with EnviroCooler and scaled the BioSphere (P-002) for half the load mass. "This gave birth to the P-022. Again, we didn't reinvent the wheel, just used what works and scaled it." Ken Lukes of EnviroCooler adds, "Because our technology is based on the science of thermodynamics, our shippers are designed with purpose. Because we know our science and purpose, we can scale up or down with ease."

"When you know how and why, it makes the whole process, from design to qualification, much more efficient," concludes Harber. "When Lilly makes the decision to collaborate, we make sure we select those that have proven they know how and why." ■



EnviroCooler's BioSphere is a scalable pallet platform.