

Setting a Standard



Edward A Church at the International Safe Transit Association (ISTA) reviews the new ISTA Standard 20 and discusses how it will impact the industry, the market, and the future transportation of temperature-sensitive pharmaceuticals

The research and development projects that were required for ISTA Standard 20 were a huge undertaking for ISTA. For far too long there has been a gap between what the global regulatory bodies want to see from the industry by way of proof that their products are protected during transportation, and a standardised methodology by which industry can go about providing the required information. ISTA had the vision of developing the first global method for standardising the measurement of the performance of insulated shipping containers (ISCs)

transporting high-value, temperature-sensitive pharmaceuticals. In addition to this, ISTA is taking it one step further by reviewing and independently certifying the ISC to its performance under the standard. Standard 20 is the realisation of that vision.

SPECIFICS

Of course, there are the technical aspects of the initiative to consider. Don Wilson at Amgen explains: “ISTA Standard 20 is a validation process that provides the structure and path to design, test, verify and

independently certify a specific ISC for use. The Center for Drug Evaluation and Research (CDER) guidelines on process validation as applied to ISC performance validation is central to the standard: design of ISC (in lab); qualification of ISC (in lab); and verification of ISC (real-world). While CDER brings the process, ISTA brings the testing parameters: ISTA 3A or 2B for physical stress testing and ISTA 7E for thermal stress testing.

Housed in Standard 20 is the first set of global thermal profiles – ISTA Standard



7E. The development, inclusion and application of the first statistically validated thermal profiles are critical to standardising how ISC performance is determined. Under Standard 20 you have it all: the ISC in question is thermally and physically stressed under established standards (7E profiles and ISTA 3A or 2B) and validated in accordance to best practice: CDERs guidelines on process validation.”

The infrastructure is clearly all in place, but how will ISTA Standard 20 actually benefit the pharma industry, suppliers and

the end users? EnviroCooler’s Rod Derifield explains the advantages: “By having a true industry standard to comply with, comparison of solutions can be performed in a more meaningful fashion. For biopharma, this will ultimately result in the best and most cost-effective solutions being highlighted and used by industry. For the supplier, both big and small, it will mean that the market will open up and provide them with a more level playing field to compete – if their ISC has been certified independently by ISTA and it performs better than a

competitor’s, then they will have an equal opportunity to win accounts based on proof of performance, cost-effectiveness and service levels. The ‘smoke and mirrors’ and ‘magicians’ tricks’ afforded by subjectivity and interpretation will be removed, and like for like comparisons of ISC performance will become the new benchmark. For patients, independently certified ISCs will result in the pharmaceutical product reaching them in the best possible condition for use.”

BENEFITS TO SUPPLIERS

In light of this, it may appear that, although the benefits to industry will be great, ISC suppliers may lose out. This is certainly not the case. Stuart Long at Life Packaging Technology points out the benefits to those that design and manufacturer ISCs: “I believe that Standard 20 will have a very positive impact on the ISC manufacturers that have built their businesses on sound engineering and scientific models. The consistency built into the Standard 20 will yield a common approach among ISC manufacturers and their presentations. In my opinion, those businesses that have been built on sound engineering and scientific practices will stand to gain the most from the introduction of the standard. There is too much at stake in the shipment of temperature-sensitive products to leave to chance. I believe this is positive for ISC manufacturers and consumers alike.”

GLOBAL REGULATION

One of the standout features of Standard 20 is that it contains the first set of standardised real-world shipping-lane global thermal profiles. But, since the accompanying study was performed in the US only, how can the profiles truly be classified as global? MoonJelly Inc’s Jim Cox, an ISTA certified auditor, clarifies the situation: “It is very important to understand that it is the profiles that represent the ‘shipping’ environment and not the ‘ambient’ environment. The ISTA 7E thermal profiles are the product of a three year shipping-lane study. A total of 82 shipping lanes were used covering all of North America, Puerto Rico, Alaska and Hawaii during winter and summer seasons. From this data, a profile was developed and validated statistically for

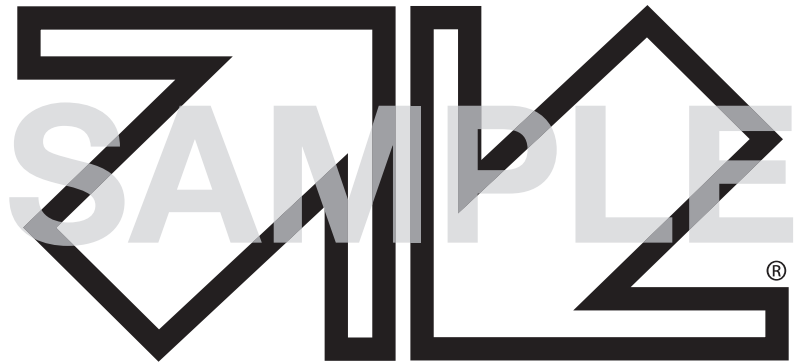
‘hot’ and ‘cold’ shipping conditions. These real-world profiles are representative of day to night and latitudinal variations within the shipping environment. They are not ‘climate data sets’, but instead are a reflection of the conditions in trucks, transit storage facilities and air cargo spaces – that is, those conditions experienced by the ISC during transportation, and not those of the weather at that particular geographic location on that day of shipment.”

FINANCIAL CONSIDERATIONS

Of course, no initiative brought into the industry at this time can ignore the impact of the recent economic downturn. However, the poor economy has not served as a driver for the standard, according to Paul Harber at Eli Lilly & Company: “When the Steering Committee for this project met four years ago, the economy was good so we couldn’t say that was a driving factor. To say that it is a coincidence doesn’t ring true either. What we could say is that the Steering Committee was made up of those that have been part of the driving force within the industry since its inception. Only if you have been there can you possibly anticipate market change – hindsight leads to foresight so to speak. All members of the committee agreed that it was time for standardisation of how ISC performance was determined, verified and marketed. The fact that the release of Standard 20 comes at a time when cost-to-market and cost-of-compliance during transportation needs to be minimised only validates the rationale behind the project and standard. Standard 20 and the independent certification of ISCs by a industry body is a surefire way of optimising your supply chain and minimising transportation and compliance costs.”

In terms of the impact on pharmaceutical companies themselves, Amgen’s Gary Hutchinson feels that Standard 20 has certainly been a positive development: “The biggest advantage is the innovation

TRANSIT TESTED



INTERNATIONAL SAFE TRANSIT ASSOCIATION



PACKAGE NUMBER: SAMPLE

The package supplier certifies that this package has been designed and tested following the ISTA Standard 20 process.

ISTA certification mark

and diversity of product offerings that this standard will drive. I really think the industry will unleash its creative energies to broaden and deepen its product offerings, available now that the requirements are well documented. We are close to the ‘Holy Grail’ – an off-the-shelf, independently certified packaging solution that meets industry requirements and has the necessary qualification data to support its use in the pharmaceutical industry already included!” Equally, though, there is awareness that there will always be obstacles to the introduction of any new regulation. “In my opinion,” says Rod Derifield, “change will be the biggest obstacle, followed closely by fear. Any significant transformation or change is inherently unsettling for people at all levels of an organisation. That is why it is important that the leaders of an organisation take the time to review Standard 20, assess what it brings to their organisation, identify how they will benefit from its success, and create the transition plan to the new standard. It is natural for individuals to question to what

extent change is needed and whether the reward is worth the investment. They will look to the leaders for answers.”

In order to support the change and transition to Standard 20, ISTA has appointed three independent auditors to provide training and education to the leaders within the industry and to support the integration efforts of suppliers, independent laboratories and pharma organisations. ISTA’s e-market is also offering an online tool to predict performance of ISCs against the 7E thermal profiles so that it is easy to predict the performance of an ISC under the new standards, or to identify any risk-exposure there may be due to potential non-conformance before investing in ISTA 7E certification testing. The third biggest obstacle will be those ISC suppliers that are afraid of head-to-head ISC competition. One can only question those that are reluctant to embrace Standard 20 and have their ISCs tested and independently certified under that standard.

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ONE SIZE FITS ALL

Global design, qualification and implementation projects for ISCs generally pose an impressive challenge for most large biopharma organisations, and Standard 20 will have an impact on this challenge not only for large globals but also the smaller biopharma organisations. Amgen's Brian Wallin points out: "ISTA Standard 20 should allow both large and small biopharma companies to choose among available solutions those which fit best with individual project requirements and finish their validation process in a shorter period of time and for less money. All of this can be accomplished by relying on proven processes, defined testing standards, and well understood testing parameters. For smaller biopharma companies, this impact will be amplified as the need for large resource investment, in order to qualify ISCs for their shipping lanes will be reduced, and the valuable capital of a one or two molecule company can be applied to product development, regulatory approval and launch."

The financial aspect of a cold supply chain is every bit as important as the efficient and compliant transportation of a product to the end user. Naturally, companies will be concerned that Standard 20 may have a negative financial effect, and similarly will be keen to see how the standard can benefit their revenue stream. Karen Greene at Life Packaging Technology sees the positives: "From an end user perspective, the internal validation costs are reduced, the engineering and supply chain staff can select certified ISCs and their Standard 20 qualification report package. Engineering staff headcount can be contained or reduced as the validation efforts can be shifted to the supply side or manufacturer."

Standard 20, along with ISTA 7E certified packages, can also aid risk management decisions when shipping temperature-sensitive pharmaceuticals. As Don Wilson states: "ISTA's Thermal Certification Mark, coupled with the fact that ISC performance has been independently verified and certified, will carry a lot of weight within any pharma organisation. The certification shows a certain level of commitment and transparency from a supplier, and a willingness to stand behind its ISC designs and their performance. If an ISC has been ISTA 7E certified to meet

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Edward A Church is President and COO of ISTA, serving in that capacity since 1995. He is a graduate of the Michigan State University School of Packaging, with both a BA and MSc degrees in Packaging. He is a Lifetime Certified Packaging Professional and has an extensive background in transport packaging performance testing. Edward was one of the founders of Lansmont Corporation, a distribution testing equipment manufacturer, where he served in several capacities, including President. He is a member of the ASTM D-10 and F-2, and represents ISTA at the International Association of Packaging Research Institutes (IAPRI). Edward is also a member of the Steering Committee for the Pharmaceutical Cold Chain Interest Group (PCCIG) in the PDA. He is a past President and Chairman of the Board of the Institute of Packaging Professionals (IoPP). He is a past Member of the Year and has been inducted into the IoPP College of Fellows and the MSU Packaging Hall of Fame. In 2007 he was inducted in the National Packaging Hall of Fame. He sits on the Packaging Advisory Boards at the Michigan State University, Rochester Institute of Technology and California Polytechnic University. Email: ista@ista.org

my acceptance criteria for example, the work required internally to approve the ISC for use will be greatly reduced. If it is not ISTA 7E certified or validated internally, it makes the approval process a much more difficult and lengthy exercise. The likelihood that a pharma company will choose an ISTA Certified ISC over a non-certified ISC is great."

THE FIRST ALL-ROUND INDUSTRY STANDARD

Standard 20 is the first standard relating to the thermal performance of ISCs, yet many suppliers have claimed that they are 'pre-qualified to industry standards'. But since no 'industry standard' has previously been in existence, this has been confusing to the industry. The establishment of a true 'industry standard' will allow companies to make true ISC-to-ISC performance comparisons to facilitate decision-making: a 96-hour ISTA 7E certified ISC from vendor A can be directly compared with a 96-hour ISTA 7E certified ISC from vendor B. Now the claims can only be 'certified' ISC.

'Audits' and 'certification' aren't exactly inviting words, but Jim Cox does not feel that it will take excessive work for a laboratory to become certified: "Any laboratory following good procedures with established SOP documentation will have minimal problems passing an audit." Stuart Long has similar thoughts: "All laboratories will be held to the same standards. The audit and certification

process will be made straightforward and uncomplicated due a pre-audit checklist (ISTA Form 0014), which will be the same checklist used by the auditor in the lab certification process. If all the checklist items are in order prior to the audit, you should expect a successful audit." Karen Greene points out that many labs are already in the right place through voluntary good practice: "The laboratory process is truly not that onerous. The majority of labs are already meeting most of the Standard 14 requirements due to their voluntary compliance to ISO 17025, general requirements for competence of testing laboratories and calibration labs."

CONCLUSION

While regulatory bodies are increasing their focus on all aspects of the cold supply chain, particular focus is on the ability of an organisation to defend the use of ISCs for the transportation of temperature-sensitive pharmaceuticals. Standard 20 will help biopharma companies manage the increased regulatory scrutiny. All regulatory bodies are looking for the proof that a company has validated its transportation solutions to the specific requirements for keeping products within acceptable temperature bands and protected from physical damage in their journey through the cold supply chain. Standard 20 and ISTA 7E certification of ISCs should provide all the documentation and testing support needed to show to any regulatory body in order to be compliant.