

EDITORIAL FEATURE

IT'S A RISKY BUSINESS

In their recently revised GDP guidelines (2013/C343/01), the European Commission has a simple statement regarding the distribution of temperature-sensitive products.....

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CUSTOMER QUOTES

“As airlines place a greater commercial focus on temperature-sensitive specialty products, the role of the product manager will dramatically increase in importance.”

– Airline Industry Insider

“We have been utilizing the CSafe RKN into São Paulo, Brazil now for five years and continue to be excursion free.”

– Global Pharma Director of Supply Chain Management



NEWS FROM THE CEO

We are fast approaching the final quarter of 2014. It has been only nine short months since the beginning of 2014 and the creation of CSafe's New Year's resolutions and business forecasts. CSafe has had a great 2014 so thank you to our valued customers and partners. In this issue of E-Quips, we will share not only the news of our growth and expansion, but also review challenges that we all face in the biopharmaceutical market. As always, we appreciate the honest feedback we hear from our customers. Understanding what is working and what can be improved continues to be a recipe for success as we believe "what is right for the customer is usually what is right"!

"Growth is never mere chance; it is the result of forces working together."

James Cash Penney,
founder J.C. Penney stores

Brian Kohr,
CSafe Global President and CEO

NEWS UPDATE

RKN Fleet Expansion

In order to meet the growing demand for CSafe solutions over the last year, we've increased our RKN fleet size by 45% while also significantly increasing our AcuTemp® passive packaging capacity. We thank our customers and partners for trusting the CSafe team to continue to meet their expanding active and passive solution requirements.

Continued Expansion of Service Center Network

With the expansion of our fleet and customer base, we needed more servicing capacity to enable us to continue our high standards of support and maintenance. In June we announced our first wholly-owned and dedicated service center at SFO.

In September we subcontracted maintenance and repair services for the CSafe RKN at both SEA and IAD to support our growing biopharmaceutical customers in transporting high volumes of temperature-sensitive shipments. We are dedicated to opening new service centers as our partners and customers require.

CSafe Avianca MIA Training

CSafe and Avianca recently partnered in Miami to implement a "train the trainer" program to support the carrier's cold chain services. Avianca key market operations representatives attended the live training designed to supplement CSafe's EQUIP® online training program.



SPOTLIGHT

FAA Extends CSafe Approval to include Upper Deck

CSafe Global received the approval from the FAA for use of the CSafe RKN on the upper deck of aircraft, making the CSafe RKN the only FAA approved active ULD for use on both lower and upper decks. Being able to use the CSafe RKN on both the upper and lower decks will enable customers to transport temperature-sensitive products originating closer to the shipment point and to destinations closer to the receiving location, thus reducing road transport and providing faster delivery times. With this approval, integrators now have more flight options available to move precious high value temperature-sensitive products achieving more of an 'ideal' loading configuration mix between upper and lower deck containers on their aircraft.

Etihad MLA

Following the recent approvals granted by the aviation authorities in the UAE, Etihad Cargo becomes the latest air carrier to be welcomed into the CSafe family. Operating a diverse fleet of more than 100 aircraft and serving over 100 destinations, EY offers essential CSafe transportation and leasing services for customers seeking superior cold chain solutions.



EDITORIAL FEATURE



It's a Risky Business

It is evident when reviewing the Good Distribution Practice guidelines that there has been a shift in focus towards Risk Management in the distribution of temperature-sensitive pharmaceuticals. Whether it's the publication of the recent EU guidance, the revisions from USP or the PDA's technical report 58, there can be no mistaking one thing - shippers and manufacturers are ultimately responsible for examining their supply chains using a 'risk-based' approach. The definition of risk per the International Conference on Harmonization is:

Risk is defined as 'The combination of the probability of occurrence of harm and the severity of that harm'.

Harm is defined as 'Damage to health, including the damage that can occur from loss of product quality or availability'.

Hazard is defined as 'The potential source of harm'.

A 'risk-based' approach warrants an in-depth analysis including an evaluation of the elapsed time since the validation of the current temperature-sensitive shipping and packaging solutions. Some suppliers have utilized the same solutions for decades although technology, regulations and

guidelines have continued to evolve. The production process also has challenges related to contract manufacturing, multiple vendors and locations that are distant from the point of sale. Identifying the potential sources of harm to a product being transported through several temperature zones, multiple transit points and a variety of modes can be an exacting task.

The market for both passive and active solutions has expanded over recent years and there is now a comprehensive array of suppliers. Shippers should validate their choice of solution providers by predetermined criteria:

- Availability – is the solution always available at seasonal peaks and internationally?
- Solution range – does the supplier provide both active and passive solutions?
- Performance – have their solutions been qualified to your needs?
- Re-usability – does the supplier have a program for packaging re-use?
- Custom-built solutions – new/different products may need new solutions. Can the supplier respond to new requirements?

Risk management should not be centered only upon the choice of which route, which logistic provider and which type of packaging solution to use. Key to minimizing risk is to qualify more than one thermal shipping solution and preferably utilizing a provider that can offer both active and passive solutions to meet the specific needs of your product.

For the complete article see the unedited version of the white paper at www.CSafeGlobal.com

NEWS UPDATE

Production Facility Expansion

We have experienced a significant increase in the demand for our AcuTemp® brand passive packaging, including the REPAQ® program and courier solutions. As a result, CSafe has expanded our production facilities resulting in the creation of 30 new jobs in a 38,000 square foot facility which will be ISO certified and also provide an additional contingency manufacturing location. The additional space and equipment will significantly enhance CSafe's production capacity. The increase in manufacturing capacity, continuing expansion of our pre-qualified passive packaging offering and growing REPAQ program are examples of our commitment to continue to deliver value, quality and efficient temperature-sensitive shipping solutions to our customers and partners.

Vaccine Program Statistics

The Cost of a Broken Vaccine Cold Chain

With the advent of flu season, patients swarm to immunization programs throughout the country. Yet each year, some of those vaccinated succumb to life-threatening seasonal influenza. What is the financial cost of cold chain failure and more importantly, what is the human cost? CSafe's latest blog provides research from the Center for Disease Control and MILVAX and insight into cold chain failure in a vaccine program.



NEXT ISSUE

Preventative Maintenance
Re-use, REPAQ®, Recycle



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