

## EDITORIAL FEATURE

It has been seven months since the implementation of the European Union GDP. The consultation period for these new guidelines generated a considerable amount of feedback....

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## CUSTOMER QUOTES

“ Long term leases are what we are moving towards. Controlling our own destiny related to equipment availability as well as the opportunity to increase margins just makes good business sense.”

– Product Manager at a Major Airline

“ The drug we ship in the CSafe Global RKN is not a drug that just enhances the quality of life, it is a drug that saves lives. We have been using CSafe exclusively now for over five years and have not lost a single dose! Because the product we ship takes so long to manufacture and is always in limited supply, we will only use the CSafe active pallet shipper.”

– Assoc. Dir., Global Supply Chain,  
Global Pharmaceutical Company



## NEWS FROM THE CEO

We just returned from a cold chain packaging show in Luxembourg where the major topics in conversations and presentations included regulatory updates with emphasis on the recent European guidance and its impact on CRT shipments as well as opportunities to identify lower cost transportation options such as sea freight and greener packaging options. The synergism around these topics continues to be the need for performance

and regulatory compliance, at the lowest possible overall cost.

“There is only one boss. The customer. And he can fire everybody in the company from the chairman on down, simply by spending his money somewhere else.”

Sam Walton, Founder of Wal-Mart

**Brian Kohr,**  
CSafe Global President and CEO

## NEWS UPDATE

### C.A.L. Airline Cargo MLA and EQUIP Accreditation



C.A.L.'s ongoing commitment to quality has been rewarded with an accreditation under the CSafe EQUIP program for their TLV, LGG and JFK stations. Our mutual customers

can rest assured that C.A.L.'s handling of CSafe containers ranks among the best in the industry.

### CSafe Director of Service Partners



Rick Rackley has accepted the promotion to Director of Service Partners. With a person solely responsible for our service center network, CSafe Global continues to insure the quality and integrity of the CSafe RKN is maintained globally.

### EQUIP Training Update

From 2011 to 2012 there was a 151% increase in individuals gaining EQUIP certifications. This significant growth in training continued to increase from 2012 to 2013 with a further 94% increase in participation. The popularity of the free EQUIP training is evident by the active enrollment by over 60 organizations. The EQUIP training is a modular, easy-to-use program that allows individuals to complete according to their availability and automatically schedules and notifies users for yearly re-certification. **Contact EQUIP@CSafeGlobal.com**

## SPOTLIGHT

### IQPC Luxembourg



Edwin Visser, Director of Sales EMEA

In January, CSafe exhibited their passive and active solutions at Cool Chain Europe 2014, where supply chain and quality assurance leaders gathered to discuss the future of the

temperature-controlled logistics industry. One topic of concern was the GDP guidelines and how shippers would build or rebuild their ambient supply chains in a cost-effective and compliant manner (see Editorial Feature).

Contingency planning situations under discussion were related to severe cold weather outbreaks and natural disasters and how to reduce the related risk and planning delays. Is your temperature-sensitive shipment protected with packaging qualified to -30°C? How will your shipment be protected when encountering weather related shipment delays? The CSafe RKN utilizes ThermoCor® high performance insulation, high efficiency and refrigeration and heating systems to ensure, no matter the ambient, the payloads are maintained at the selected temperature.

One topic of interest shared by all attendees related to partnership strategies and how to manage the myriad of touch points along the cold chain including subcontractors, airlines, ULD suppliers, security and custom agents. These partnerships and collaborations are required to ensure a thorough understanding and agreement of risk as well as the execution of a quality supply chain security program.



CSafe Team and IQPC attendees

## EDITORIAL FEATURE



### State of the Union for EU GDP (2013/C 68/01)

#### Excerpt from ColdChain.co blog

After a six-month implementation period, the latest version of the European Union Guidelines on Good Distribution Practice of Medicinal Products for Human Use (2013/C 68/01) came fully into force. The original set of GDP guidelines had been in force for almost two decades, and clearly revision was needed to reflect the considerable changes that had taken place in European distribution, import and export of medicinal products and particularly those requiring temperature-control.

Everyone wanted to have their say and there was much discussion about Guideline practicality and their economic implications. Many from the distribution and logistics sector felt that in the draft form, the new rules represented a considerable cost burden especially with the guidelines that required creating additional 'wholesalers' who would hold shipments ready for transportation for more than 24 hours.

Imagine – it is Friday evening and that pallet delivered today for shipment on Sunday morning suddenly requires a transportation company to hold an expensive distribution

license with all that entails. This element was thankfully dropped in the final GDP document.

What the new Guidelines have done is strengthen the process of control and responsibility that needs to be in place for effective and safe distribution. It aims to create a clear sense of ownership. Though originally suggesting it would 'police' compliance throughout the supply chain, that burden is clearly on the shoulders of healthcare manufacturers, wholesalers and brokers who must audit their supply chain and all its elements.

Packaging remains a vital part of supply chain integrity, particularly since the new guidance requires that "...for temperature-sensitive products, qualified equipment, (e.g. thermal packaging, containers or vehicles) should be used to ensure correct temperature...". Currently, only CSafe has focused on being able to offer both active and passive solutions, thereby giving manufacturers the surety and benefits that a single approved supplier can bring.

Manufacturers beware – your audited supply chain needs you!

For the complete editorial, visit [www.coldchain.co](http://www.coldchain.co)

### IQPC Comments

The January 2014 IQPC Cold Chain event in Luxembourg has been an excellent opportunity to connect Pharma Companies, Airlines and Freight Handlers. It is very clear that we all face the same challenges in driving down costs without compromising the product quality through the complete temperature-controlled supply chain.

We continue to keep an interest in any thermal protection system that meets these requirements and various shipping scenarios (high value, high-volume, time and/or temperature challenges etc.) The IQPC continues to be an open platform to bring together those involved in cold chain logistics.

– From Top Global Pharmaceutical Manufacturer

## News Update

CSafe continues to promote training in conjunction with partner sponsored events. Mark Mohr, CSafe Director Partner Management and Customer Support, visits a new MLA partner to demonstrate the benefits of the CSafe RKN.



### What's Going on at CSafe

During the last two years, CSafe extended their family of AcuTemp temperature-sensitive hand-held Couriers to include 2°-8°C, frozen and CRT. The Courier was developed for pharmaceutical representatives, healthcare providers, pharmacists, physicians and public health vaccine providers who are making "last mile" deliveries of temperature-sensitive products. Available in three sizes – PX 3, 6 and 12L, they feature adjustable straps, handles for easy carrying, as well as customizable options. Only standard refrigeration and freezing conditioning is required. The couriers are now in use globally.



## NEXT ISSUE

Guest Editorial

MLA announcements

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