

As the days grow shorter and colder, the heat is on for pharmaceutical supply chains to comply with Health Canada's new GUI-0069 guidelines

VAUGHAN, November 9, 2020 — The final guidance of the revisions to Health Canada's GUI-0069 (Guidelines for Environmental Control of Drugs during Storage and Transportation) has been confirmed. So it's critical for companies that deal with temperature sensitive products to be prepared for an increase in challenges, scrutiny and inspections.

The new guidelines assign responsibility for GMP and GUI-0069 compliance to all parties involved in the supply chain, including product owners, 3PLs and carriers. It broadens the scope of the guideline, which now extends beyond human drugs to include veterinary, clinical trial drugs, drug samples and Active Pharmaceutical Ingredients (API). "Temperature" has also been replaced by "environmental control" that includes factors such as humidity, light and physical stress parameters.

"This is one of the reasons that Accuristix has continued to build expertise in temperature and environmental risk management over the years and more recently in the area of transportation," says Julie Carriere, VP of Quality Assurance & Regulatory Affairs at Accuristix. "From temperature mapping and shipping container qualification to transportation lane studies and calibration, we have the in-house GUI-0069 expertise to ensure our clients are successful in meeting the new Health Canada requirements."

Not surprisingly, temperature is a critical factor affecting the safety, efficacy and quality of pharmaceuticals, biologics, natural health and animal health products. Damage and loss can happen as a result of travel time and distance, the number of transfers, packaging type and inadequate temperature control. Thus the use of a qualified shipping container may be required to preserve the safety and quality of products in summer and/or winter conditions depending on the shipping destination and transportation modes. With billions of doses needed worldwide, cold chain controls and risk management will be crucial for a COVID-19 vaccine when it becomes available.

Across the world, it's estimated that billions of dollars of pharmaceutical products are stored and shipped at improper temperatures or past their suggested shelf lives, making some drugs not only ineffective, but harmful and possibly even life-threatening, especially for people who count on them for preventing viruses such as the flu to fighting diseases like cancer. (Pharmacy & Therapeutics)

According to the International Air Transport Association's Center of Excellence for Independent Validators in Pharmaceutical Logistics, 25% of vaccines are degraded by the time they arrive at their destination due to incorrect shipping procedures.

When products are shipped across Canada, they can experience environmental conditions that vary widely depending on the time of year and location. In fact daily average lows and highs range from approximately -30 °C to 30 °C (Statistics Canada). Despite these wide environmental variations, Health Canada still requires the temperature of drugs while in-transit, be maintained at levels consistent with what is described on the product label. Use of Mean Kinetic Temperature (MKT) is allowed for temperature monitoring only and must be done in accordance with recognized pharmacopeia.

"With the addition of a 16 cu.ft. environmental chamber in August, Accuristix has expanded its shipping container testing capabilities," says Carriere. "In addition to using this chamber for calibration of temperature sensors and loggers, we test shipping containers and assess their ability to meet GUI-0069 requirements in various conditions before engaging in a full transportation study."

A survey of supply chain experts found that of temperature sensitive products shipped, 51% were ambient, 31% were refrigerated, 17% were frozen, and 32% should not be allowed to freeze. (Pharmaceutical & Medical Packaging News)

“Our temperature services include designing shipping studies for your products, documenting high and low temperature fluctuations, identifying potential risks and providing actionable recommendations,” says Carriere. “It’s important to know what to test for and look for the right data at the right place at the right time or you won’t get the full story.”

Adds Carriere, “As an experienced service provider to the healthcare industry, Accuristix has built a strong understanding of temperature management both in storage and transportation, as well as covering different labeled conditions. We offer solutions to mitigate risk and ensure the safety of our clients’ products.”

Accuristix is Canada’s leading third-party logistics (3PL) service provider and has been a trusted partner to the Canadian healthcare industry since 1994. The company manages the logistics of storing and distribution of more than \$7 billion pharmaceutical, OTC, NHP, narcotics, controlled drug substances, precursors, medical devices and other healthcare products.

Accuristix is a member company of Andlauer Healthcare Group Inc. (TSX: AND), a publicly-traded company. AHG is a leading and growing supply chain management company offering a robust platform of customized third-party logistics and specialized transportation solutions for the healthcare sector.

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