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Winter Mapping: Ensuring Pharmaceutical Integrity in Cold Environments

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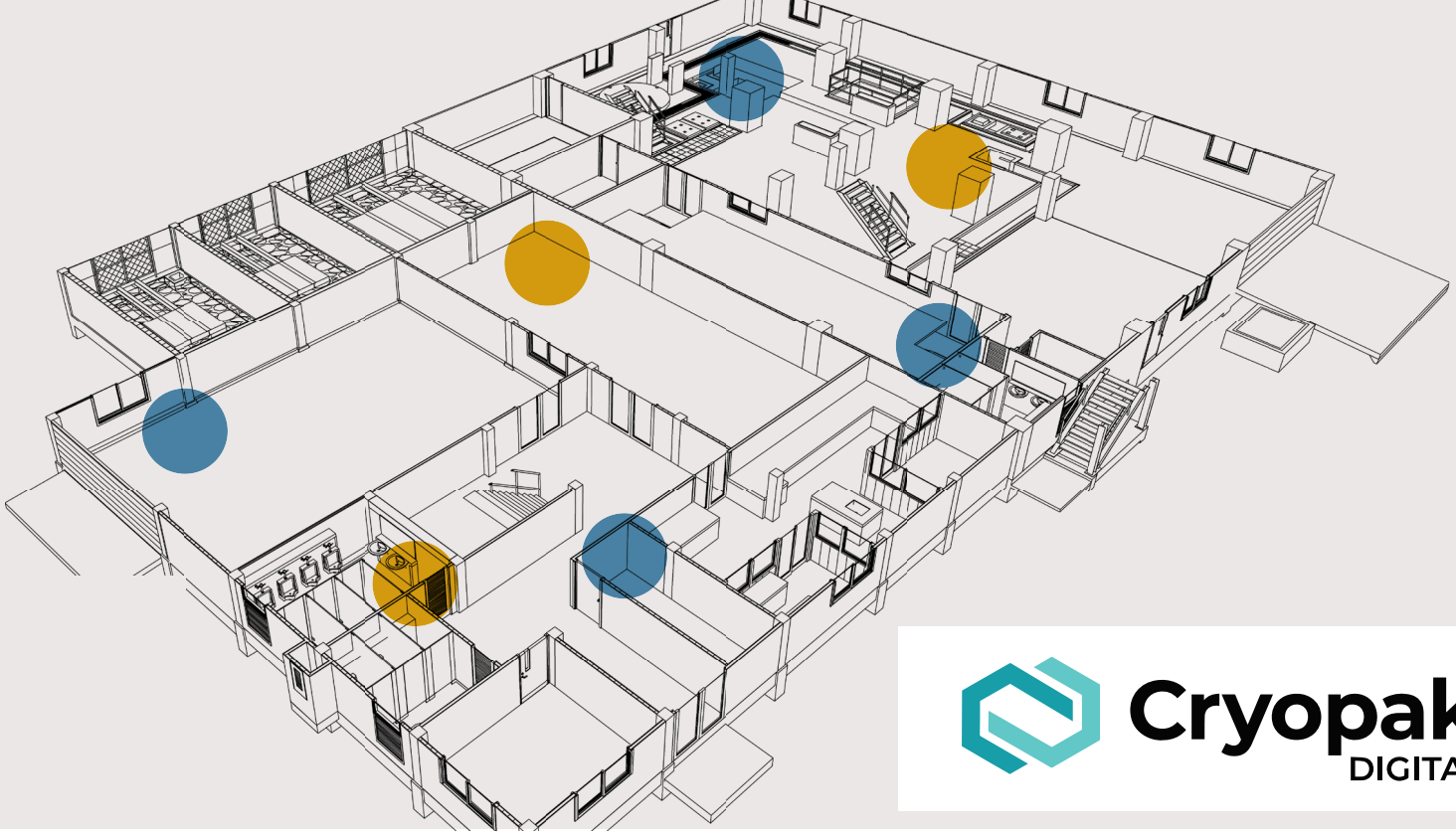


Cryopak DIGITAL

Winter Mapping: Ensuring Pharmaceutical Integrity in Cold Environments

INTRODUCTION

The pharmaceutical industry faces unique challenges during the winter months, primarily due to the harsh environmental conditions that can significantly impact the stability and integrity of pharmaceutical products. As temperatures drop and fluctuate, and as heating systems struggle to maintain a consistent environment, the risk to temperature-sensitive medications increases. This paper discusses these challenges and introduces Cryopak's Winter Mapping Service, a solution designed to ensure the integrity of pharmaceuticals in cold environments.

WINTER CHALLENGES IN PHARMACEUTICAL STORAGE

Temperature Fluctuations and Heating Systems

Winter is characterized by drastic temperature fluctuations, which can pose a severe risk to pharmaceutical products. Many medications and vaccines require storage at specific temperatures to remain effective. Heating systems in pharmaceutical storage facilities, while necessary to combat the cold, can sometimes lead to uneven temperature distribution. This inconsistency can result in certain areas within a storage unit becoming too warm or too cold, thereby compromising the stability of stored pharmaceuticals.

Impact of Dry Winter Air

Another critical factor is the effect of dry winter air on humidity levels. Most pharmaceutical storage facilities require controlled humidity to maintain product stability. Dry air can lead to lower humidity levels, which can, in turn, affect the moisture content of products. This alteration in humidity can have adverse effects on the physical and chemical stability of pharmaceuticals, potentially leading to reduced efficacy or shelf life.

The Role of Temperature Mapping in Regulatory Compliance

Storage conditions for pharmaceutical products and materials should be in compliance with the product labelling, which is based on the results of stability testing storage conditions. All drugs should be stored according to the conditions described on the label. Pharmaceutical facilities are required to maintain specific environmental conditions for storing medications and vaccines. Maintaining a uniform temperature is not just a best practice; it's a regulatory requirement, essential for compliance with Health Canada and the FDA guidelines. The recent changes in the FDA and Canadian regulations (GUI-0069 and various federal CFR codes), along with the objective to eliminate the waste of time and money to fix environmental conditions failures has made temperature mapping an integral aspect of any storage area operation.

Regulatory authorities underline the importance of storage and transportation temperature in maintaining drugs and temperature sensitive products' quality within distribution network. Temperature mapping is required to assess the ability of the facility to maintain its required temperature range.

Figure 1: Installation of data loggers, hanging from rope in open spaces and attached to stationary objects.

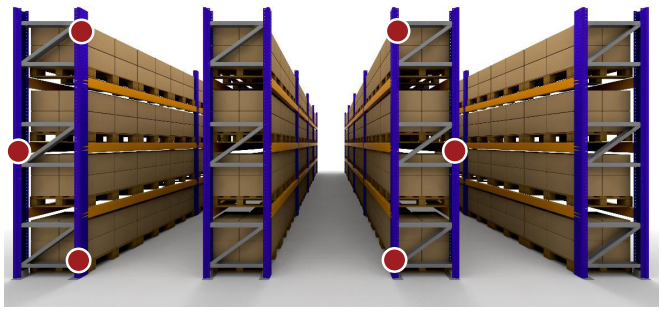


Figure 2: Example of Data Loggers' Location

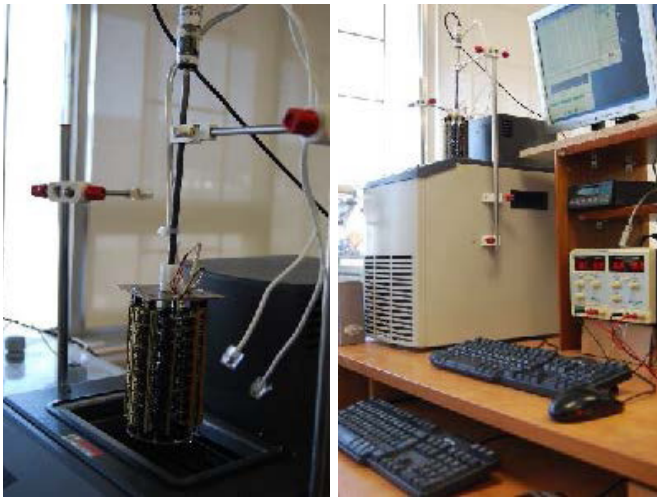


Figure 3: Post Calibration

REGULATIONS AND GUIDELINES AROUND THE WORLD

Canada	United States	Worldwide	Others
Health Canada • Guidelines for Temperature Control of Drug Products during Storage and Transportation (GUI-0069) • Food and Drug Regulation, Section C.02.015. **PIC/S** • Guide to Good Manufacturing Practice for Medicinal Products Annex.	**USP 36** • USP General Chapter <1079>_ Good Storage And Shipping Practices • USP General Chapter <1083>_ Good Distribution Practices-Supply Chain Integrity. **FDA** • CFR Part 820.150 Storage • CFR 21 Guidance for Industry Part 11, Electronic Records, Electronic Signatures Scope and Application.	**WHO** • Good Distribution Practices for Pharmaceutical Products TRS No.957.Annex 5 (2010) • Model requirements for the storage and transport of time and temperature sensitive pharmaceutical products TRS No.961, Annex 9 (2011). **PDA** • PDA Technical Report No. 64- Active Temperature Controlled Systems: Qualification Guidance. • Technical Report 58- Risk Management for Temperature Controlled Distribution. **ICH** • Guidance for Industry Q1A (R2) Stability Testing of New Drug Substances and Products.	**ISPE** • Good Practice Guide – Cold Chain Management (2011). **Irish Medicines Board** • Guide to Control and Monitoring of Storage and Transportation Temperature Conditions for Medical Products and Active Substances. **EMA (Europe)** • (2013/C 68/01) Good Distribution Practice of Medicinal Products for Human Use. **HPRA** • Guide to Control and Monitoring of Storage and Transportation Temperature Conditions for Medicinal Products and Active Substances.

CRYOPAK DIGITAL'S WINTER MAPPING SERVICE

Advanced Data Loggers

To address these winter challenges, Cryopak Digital has developed a specialized Winter Mapping Service. This service utilizes advanced data loggers capable of accurately monitoring both temperature and humidity levels within pharmaceutical storage and cold units. These data loggers are critical for mapping the environmental conditions, ensuring that any deviations from the required parameters are quickly identified and addressed.

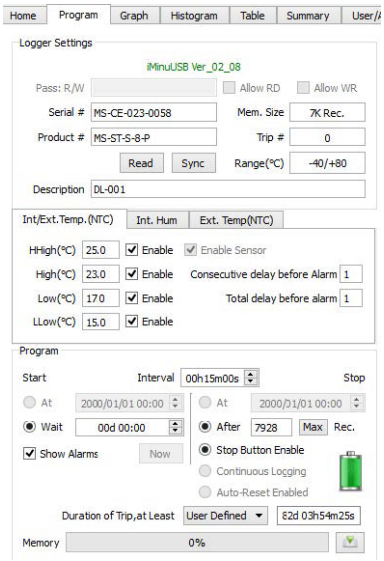


Figure 4: Programming Data Loggers

Importance of Accurate Monitoring

Accurate monitoring is essential for maintaining the integrity of pharmaceutical products. By continuously tracking the temperature and humidity levels, Cryopak Digital's service ensures that the storage conditions remain within the optimal range. Cryopak can provide customers with its iMini data loggers to perform the study. Using our CFR 21 part 11 compliant software, ConsolePlus, program each data logger according to the parameters specified in the protocol. This vigilance is crucial not only for the preservation of current stock but also for compliance with regulatory standards.

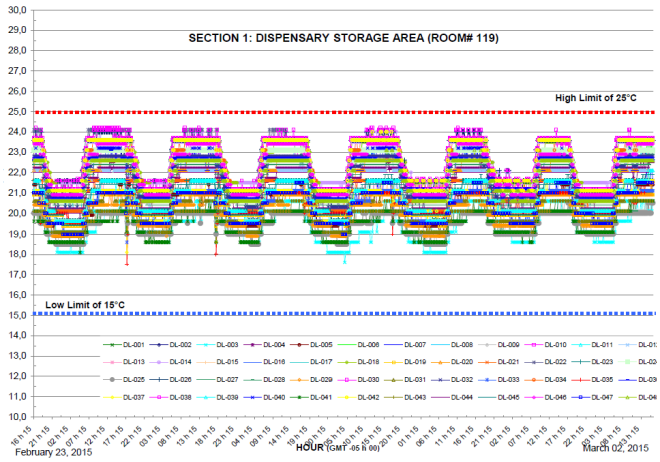


Figure 5: Data Compilation 7-day Temperature Graph

Tailored Solutions for Businesses

Recognizing that each business has unique needs, Cryopak Digital's specialists are dedicated to tailoring solutions that best fit the specific requirements of each facility. By understanding the particular challenges and needs of a business, Cryopak can offer customized strategies to effectively manage the winter challenges in temperature-controlled environments.

CONCLUSION

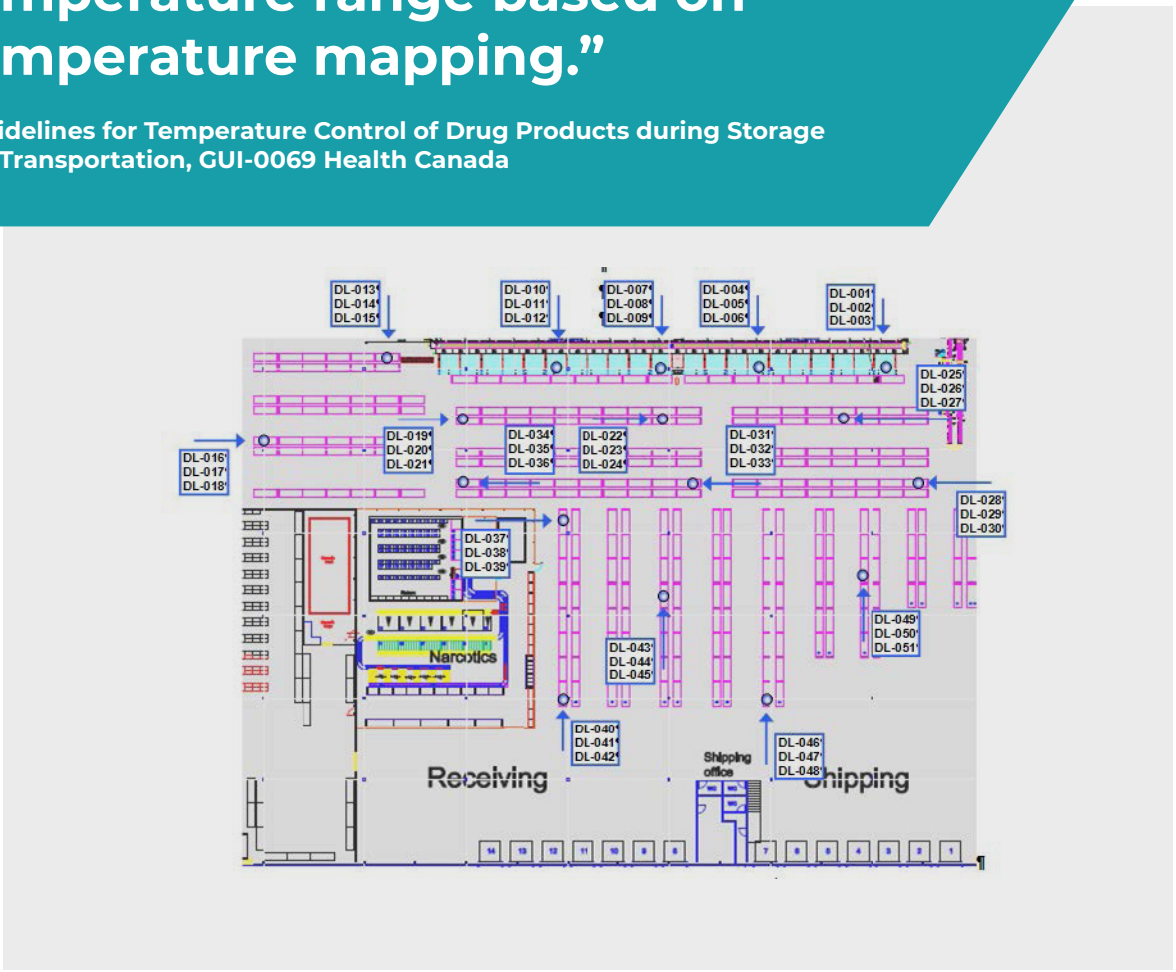
Winter poses significant challenges for the pharmaceutical industry, particularly in maintaining the integrity of products in cold environments. Cryopak's Winter Mapping Service offers a robust

solution to these challenges, utilizing advanced technology to ensure accurate monitoring and control of environmental conditions. By adapting to the specific needs of each business, Cryopak not only guarantees the stability of pharmaceutical products but also supports compliance with industry standards.

For more information or to discuss a tailored solution for your business, visit Cryopak's contact page.

"Monitoring of storage facilities is conducted at points representing the worst case scenarios of the temperature range based on temperature mapping."

– Guidelines for Temperature Control of Drug Products during Storage and Transportation, GUI-0069 Health Canada



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