Case study

Clinical trials

Internal validation study: Ultra-low temperature labels

Objective

To identify and qualify a clinical label material and application method for vials intended for use in ultra-low temperature conditions down to –80°C, ensuring it can be applied, remain adhered, and stored reliably for clinical trials.

Background

Over 40% of newly approved drugs in 2024 were biologics, many of which require cold or ultra-cold storage [1]. If labels do not adhere to vials in ultra-cold environments, clinical trials can be compromised. An –80°C temperature condition is an extremely cold environment where adhesives struggle, resulting in a lack of qualified suppliers of labels in the market. Existing label material in –80°C conditions often failed, resulting in complaints by an existing client including lifting and detachment of labels.

Methodology

Multiple manufactured labels in (1) standard, (2) single-panel wrap-around, and (3) booklet wrap-around formats were tested. Critical equipment included an ultra-low temperature freezer, carbon dioxide meter, and a data logger with sensors that measured temperature and humidity levels of the room. Label application was performed over a tray filled with dry ice pellets, in a ThermoSafe™ polyethylene dry ice cart, and in a stainless-steel CryoCart with dry ice well trolley.

Results

New protocols were established for application of labels onto vials in temperatures conditions as low as –80°C. Selected materials were tested to qualify label adhesion and storage to ensure integrity and performance. Vials were previously stored without labels prior to application to ensure compatibility. Multiple label formats were tested, and the single-panel and booklet wrap-around formats met the standards for qualification.

Safety techniques are essential, and included adequate ventilation of the room and frequent breaks if CO_2 levels were elevated. Use of proper PPE for handling dry ice was enforced, and selection of appropriate gloves prevented contamination of the label adhesive, particularly from glove fibers.

All aspects of the study were performed in accordance with Thermo Fisher's procedures for process qualification, good documentation, and data integrity practices.

Outcome

Thermo Fisher Scientific completed a qualified selection of primary and secondary label sources. We are now ready to support our clients in implementing label application processes designed for ultra-cold conditions in their clinical trials.

Reference

1. www.eawlogistics.com/smart-ultra-cold-and-scalable-the-future-of-pharma-cold-storage/

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