Article

Considerations of packaging and labelling a low-temperature sensitive product

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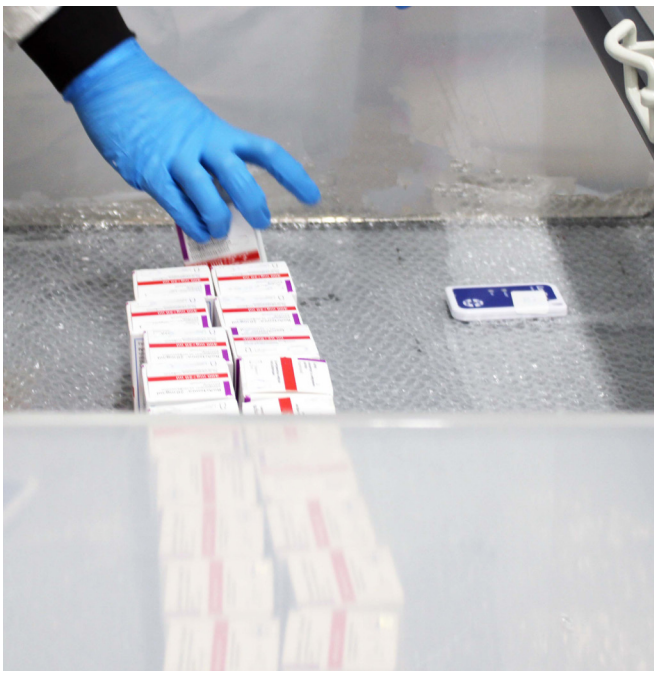
What is defined as a temperature-controlled product, and why is it so important?

A temperature-controlled product is a product that must be stored within a certain temperature range to ensure the product stays active for the purpose it serves. If the product falls below or rises above this temperature, the drug may not provide optimal performance or may become inactive and not work at all. These temperature ranges are determined through vigorous stability studies during the early phases of a clinical trial.

In this article, I will discuss the primary considerations with packaging and labelling cold chain products and what you need to look out for when choosing a vendor.



Packaging components

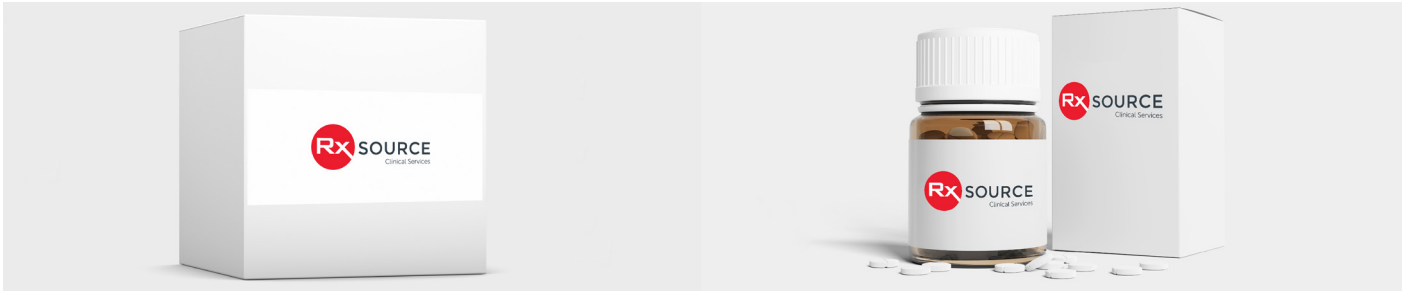
Firstly, let's look at the packaging components. When choosing the packaging for your product, you need to carefully consider how each packaging component will perform within the temperature range you need your product to stay within. When choosing label materials for cold temperature ranges, it is important to think about the adhesive you are using. Will the label remain stuck to the bottle/carton at those low temperatures, or will it fall off? It would be useful to carry out adhesive testing before deciding on a particular label; that way, you won't have the headache of re-labelling your product later down the line. Secondly, consider the ink that is being used to print the text on the label. When placed into cold temperatures, will it stay on or fade? With the ink, you also need to think about the possibility of condensation happening when the product is taken out of the fridge of freezer. Will the ink wipe off or smudge if it gets wet? Again, like with the adhesive, it is crucial to do ink testing to ensure your ink stays visible on your labels. The label material also needs some thought. Will it disintegrate when wet? I can't stress enough how important it is to test each component thoroughly before deciding what materials you will use for your packaging.

Another key packaging component you must consider is the carton or bottle in which you are packaging your product. Can it withstand the low temperatures? Will it withstand condensation from being taken in and out of the fridge/freezer? If it does get an element of water damage, can it withstand this without compromising the integrity of the product inside? Again, as with the previous components, pre-testing is key.

If you are outsourcing your packaging and labelling requirements, ensure your vendor is fully aware of your product needs. Sending stability data as early on in the process as possible will provide your vendor with adequate information to source suitable components for your product's packaging and labelling needs, thus, reducing any time added to your timeline through issues caused by inadequate components.

Packaging design

An element of time and thought will need to go into the actual design of your label and packaging itself, as we want to ensure the drug is handled correctly throughout its lifecycle. Have you ensured the storage temperature range is clearly marked on the label? Is it also clearly marked on the outer packaging? Have you made it easy for each person who handles the product to store? Is the packaging too bulky for domestic fridges and freezers? If so, is there something else that can be used? The thought process behind the design of the label and packaging is to ensure not only that the product gets to the end user in optimal condition, but that the end user, who is the patient, has the knowledge and capability of storing and using the product with ease.



Packaging and Labelling process

Health and safety play a major part in a cold chain product's packaging and labelling process. We can't have an operator locked in a freezer all day with zero time out. Therefore, you must allow for excursions, which will, in turn, make your packaging and labelling process longer. Something to consider here would be if your product does need to be packaged and labelled with a constant specific temperature range or if there is scope for your product to be taken out of the temperature-controlled zone for a certain amount of time. Can this be used to pack and label? Typically, excursion data is for the entire product life, so you may not want to use this time for packaging and labelling processes. That being said, there are other ways in which a cold chain product can be packaged and labelled without having an operator stand in a fridge or freezer, potentially reducing any downtime an operator needs. If you are outsourcing this operation, check to see if your preferred vendor has a cold plate for refrigerated temperatures or the capability of packing and labelling over dry ice. There are of course, limitations to this, for example, your product will need to be removed from the fridge or freezer it is stored in, therefore there will need to be allowable time within the stability data for this.

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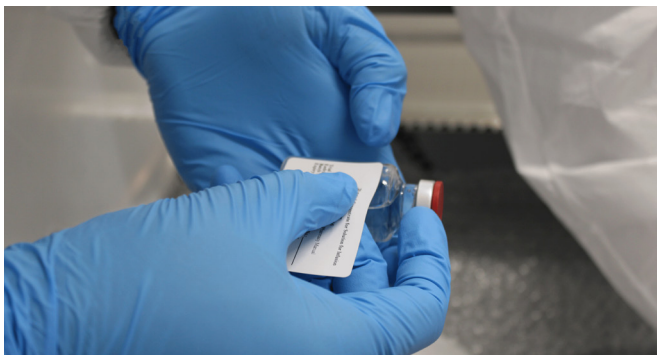

Other potential challenges

Even when carefully considering all of the above, there are other challenges you could face with your cold chain product. Who or what is tracking the temperature data of your product? Is this being done manually, or are you using a temperature monitoring system? Either way, any device used must be calibrated by you or your vendor's quality team. This is to ensure the accuracy of the data. If you or your vendor are manually tracking the data of these devices, you need to consider any human error, as this can happen. To reduce the chances of human error, ensure you or your vendor have robust SOPs (standard operating procedures) in place and that each operator/drug handler is aware of the temperature monitors, what they are for, and how to use them. It is essential to ensure all data off these monitors have been analysed after each process is complete to ensure no temperature excursions have taken place during any packaging or labelling process.

Final thoughts

After we go through all of the considerations outlined above, the product is finally handed to the patient, who then takes it home in their handbag or pocket. They then put it in their domestic unvalidated fridge, which could be a significant amount of time after receiving the product.
It's important to remember that we are responsible for the drug until it is given to the patient. If we do our part right and without any temperature excursions, it reduces the risk to the patient when the drug is in their care...regardless of how they treat it.

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