

ULT Freezer sample management

Sample safety is without a doubt the single most important thing to consider when purchasing a freezer. That's why it's critical to develop and follow a sample management plan.

Key takeaways/benefits/separating features

- An approved sample handling procedure is critical not only to effectively manage the safety of your sample regarding physical and temperature requirements but will detail the path of the sample from acceptance, through storage to delivery to the lab or other customer. The procedure should come after the strategy document and should list all the regulations and guidance documents that will be followed including the revision number and where they can be found.
- **Sample considerations for storage**
 - Is the sample considered a “controlled substance” by the DEA or a “high profile” product by the customer? A “high profile” product might not be a product regulated by the DEA but may be a product that could be used for “off label” treatments.
 - Requirements for sample labeling include making sure all the necessary information is easily readable and can identify the sample. This could include batch number, material ID, storage condition and safety information.
 - Receipt of samples should be logged in a sample management system. Include date, batch#, quantity, material ID, condition of the sample and interim storage location, as well as the receiver's name.
 - Properly log temperature monitoring records that were collected during shipment.
 - How will they be stored? Upright? Inverted? Enclosed for darkness?
 - Which condition will they be stored? -20°C, -80° etc.
- Will the sample be at room temperature when received? If not, a “flash freezer” may be an option rather than risk other samples in the freezer by adding warm samples that could keep the temperature higher for a longer period of time.
- Be sure you have an accurate sample count and it's properly documented.
- How often will you take inventory and how will you resolve any discrepancies?
- **Sample storage space consideration**
 - Will all samples be stored in the same unit or are there enough samples to warrant several freezers? Are you willing to put “all of your eggs in one basket” or would the importance of the samples be enough to justify splitting them up and store them in completely different storage units? Splitting up samples in to at least 2 different freezers is a common practice in the pharmaceutical industry.
 - Have you planned for back up storage in preparation of preplanned scheduled maintenance including an annual defrost of the freezer or possible unplanned event like a power failure?
 - Be sure that the sample containers that you will be using will fit in the freezer in a manner that they can be retrieved without extended door open times. The longer the door is open greatly affects how fast a freezer can recover to your desired temperature. Also how many times the door is opened and how soon it's opened after a previous sample retrieval greatly affects the temperature recovery as well.

- **Sample retrieval**

- Be sure to have a process for sample retrieval including adjusting the inventory count.
- Do they need to be packaged in special containers to maintain temperature and do the packages need to be monitored?
- Do you need a temporary storage area or unit before they are permanently stored?

- **Adjusting pre-scheduled sample retrieval dates**

- Why was it retrieved off schedule? Sometimes this happens when a weekend is coming up or maybe a holiday.
- Where will it be documented? Many use programs like “Trackwise” to capture any deviation from normal operation. Being able to retrieve this information quickly will pay off in dividends in an audit.
- Is it a deviation? Did retrieving the samples early or late affect the integrity of the sample? Be sure you can “prove” that it did not. If you can’t prove it and properly document that the sample is OK, then the test results of the sample could be viewed as a failure.
- Who approves? Be sure your quality unit and business leaders are involved.

- **Training**

- Do you have a sample management training program? This is the easiest way to ensure that your samples are in the required temperature for the longest period of time.
- Do you have personnel assigned to review temperature trends to be sure that everything is okay, no alarms were missed and that the freezer is showing no signs of failure? You can actually see on a temperature trend at least a month in advance that a freezer will need to be defrosted.

- Be sure to include a quick physical inspection of the door seals and amount of frost accumulated in the freezer. You may need to defrost sooner than the pre-scheduled defrost PM.

In review

It is of critical importance to properly train anyone who will be using the freezer. There is a misconception that when you say “freezer”, it’s just a freezer. In most cases, the application of a freezer is just as important as any other instrument in the lab. It will at some point contain a sample and will produce data that will most certainly be needed to successfully pass an audit. Asset managers everywhere understand that a freezer in a lab must be managed to the same standards as an NMR or HPLC.

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