ULT Freezer external monitoring: LIMS, BMS, -80, etc.

External monitoring systems are one option of managing temperature alarms and door open alarms. They also collect critical temperature information required by many regulations. In some cases, the monitoring system will record a temperature every minute. The data must be presented in an easy to read and understand report for an auditing agency. External monitoring systems can come in many forms, including Laboratory Information Management System (LIMS), Building Management Systems (BMS) and Supervisory Control and Data Acquisition (SCADA).

Key takeaways/benefits/separating features

- Be sure to have a quality and business unit approved strategy document in place. This will demonstrate what you are trying to accomplish with your monitoring system.
- A procedure will govern how the monitoring system is qualified and released for use. It will also provide the details of how it will be used.
  - Qualification will include the IQ, OQ PQ and re-qualification details including any pass/fail criteria.
  - Details like temperature or door alarms, warnings and alarm delay settings must be addressed.
- **What are your alarm delay settings?**
  - A temperature alarm delay is the amount of time a freezer may exceed the hi/low temperature limit before an alarm is issued. A 30-minute alarm delay is common for a -20°C freezer with a +/- 5°C temperature limit.
  - A door alarm delay is much shorter. Usually 5 minutes is the most amount of time allowed to have the door open. There are no regulations that force a 5-minute alarm, but common sense is used here. If the door is open for 5 minutes, you will also experience a high temperature alarm.
- **Do you need an external alarm system?**
  - You will need an external alarm system if the freezer you own does not have one.
  - Utilize any built-in monitoring system if possible. Freezers with this option can simplify qualification and operation testing and will also allow you to utilize support already established.
  - Connectivity, a system of many internal sensors that collect data that will help to determine the health of your freezer, can be a critical asset to your business. Being notified days or even weeks of a situation that may cause possible sample stress is a critical tool in the asset managers bag of tools to prevent sample loss.
- **How will you be notified?**
  - There are a few options available including by phone, text message, email, on site flashing lights or strobes and audible
- **Reporting considerations**
  - How will you present the data in an audit? Report form or trending data
  - Will alarm reports automatically start and will alarms show up on a trend report?
  - Reports need to be simple. Be sure that you only need to enter a few fields to generate a report that is worthy of an auditor.
  - Be sure no data at any time can be changed or altered. This is a purchase deal breaker.
- **Security:**
  - The system should require a person to log in with a separate ID and password with no sharing.

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- **Training**
  - Ensure that there is a training plan in place.
  - Document the training and individual ID's.
  - Re-train when there are updates and provide refresher training every 2 years.
  - Be clear that everyone understands their responsibility of what to do in the case of an alarm. Who do you call, do you move samples, etc.
- **Back-up monitoring**
  - Most companies have some sort of back up monitoring. This can be a duplicate but totally separate system or even a chart recorder.
  - Having a gap in data or not having alarm information can critically impact your product study or test.

In review

External monitoring systems are a good way to keep your samples safe and can help to avoid costly loss of product. When a robust plan is in place and approved by quality, the chances of a failure that results in product loss is minimal.

It is critical that you will need to keep those that use any monitoring system engaged in sample safety. For instance, here's an example of how to properly use the monitoring system to your benefit:

1. Before retrieving a sample, check the monitoring system to be sure that the freezer door hasn't already been opened many times or for an extended time earlier and the temperature is already high. In this case you should wait until the freezer has recovered.
2. Once you establish that the temperature is within the alarm limits, you should have already looked at your inventory system to determine where the sample(s) are that you need. This will minimize the time the door will be open.
3. Make sure you have your cart or box ready to place the samples in.
4. Open the door, retrieve your samples, quickly check to see if there is a frost or ice issue and then close the door. This shouldn't take more than 10 to 15 seconds. Be sure the door is closed.
5. Check the monitoring system to be sure that the temperature recovers to within the alarm limits if the freezer went out of limits.
6. If there was frost or an ice issue, either notify your maintenance support team to set up time for a manual defrost or follow your in lab procedure on frost/ice removal.

By following those 6 simple steps, you will be sure that your sample will remain in a freezer that is in a qualified state of operation ensuring sample safety.

Find out more at **thermofisher.com/ult**

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