Designing Flexibility into GMP Storage Chambers

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INTRODUCTION:

When a small pharmaceutical company built a 5°C cold room, they never thought they'd fill it. Two short years later, the space was at capacity, and they found themselves needing to expand. They had no plan in place, and they weren't sure where to start.

This is a scenario we see time and again across the life sciences spectrum. The company might be a large biotech that outgrew their -20°C freezer or a CDMO that didn't plan for multiple temperature conditions. The type of company and the conditions are always different. Still, all these scenarios have a commonality--the company did not plan for growth or changes in their storage conditions. Nor did they realize the importance of creating flexible storage for current and future needs.

Factors to Consider in Creating a Flexible Chambers Storage Plan

These GMP storage problems seem simple enough to solve, but the reality is, there are so many factors to consider. When your life sciences company designs its facility, you want to consider every possible growth scenario. Then, you can create a flexible storage strategy based on budget, space, technology, and expertise.

The ideal situation is to design chambers that adapt to changing demands without needing heavy modifications or new construction. In some cases, it might just make sense to plan on outsourcing the storage of sensitive products, but without the proper planning and strategic framework, it's hard to know that.

When you are responsible for storing irreplaceable products and materials, there is no room for error. Any gaps in proper storage can lead to unthinkable ramifications. You risk losing years of research, critical materials, and life-saving medicines. In the end, the patients are the ones that have the most to lose. By creating a flexible storage plan, you are ensuring the safety of patients now and in the future. Below, we'll walk you through the various steps to take to create and execute such a plan, as well as our flexible storage examples.

Gathering Information and Building the Strategic Framework

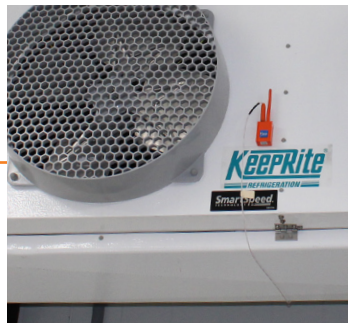
The first step is to involve all relevant stakeholders--even ones that don't utilize the storage chamber on a daily basis. The engineering team, the validation team, operations, and customers could all affect or be affected by the project. A wide variety of stakeholders will provide insights that can help prioritize needs and anticipate possibilities that you may not have thought of otherwise.

Since the goal is to build a storage chamber with versatility, adaptability, and flexibility, the next step is to identify the needs. The best way to do this is to start answering questions such as:

- What functions will the chamber have?
- What are the different temperatures and humidity settings?
- What is the chamber size and location?
- Do we need redundancies?
- How are we going to shelf it and install racking for maximum efficiency and effectiveness?
- What current and future products are we building this for?

In these initial steps, you gather enough information to lay the groundwork for the plan. You want to use your research to understand future conditions fully. This information will help you create a storage plan that allows you to adjust for new conditions and be prepared to change settings quickly.

Once you've done a thorough investigation and analysis of your needs, you've completed the first step of building the strategic framework.



Selecting an Optimal GMP Storage Chamber Design

Once you've created a strategic framework, you move into the tactical phase of the plan. At this juncture, you want to start thinking through every possible situation. A flexible chamber needs to be easily modified in the moment, which is why it's so important to walk through all the scenarios early on. Consider different manufacturers and back-up plans. Identify critical drivers for change and ask yourself what would cause us to require GMP storage conditions or space.

Change might come from new products or new test results. By thinking through these scenarios, you can identify practical designs options. You can also determine if you have the physical space to meet your current and future needs.

After you have identified all the options for chamber design, you can evaluate and select the most relevant ones. Then, you can execute an optimal strategy that is most appropriate and meets the project budget and timeline.

Throughout the strategic plan, you want to be planning with the end in mind. Consider calibration, validation, and a monitoring solution. The more you think ahead, the more flexibility you will have once the chamber is in use.

Essential Elements in GMP Storage Chambers

The chamber design will be influenced by space, budget, and temperature requirements. However, there are a few GMP storage elements that are essential.

- **Chamber Selection**: You always want to select the best-engineered/manufactured chambers and equipment to support the build-out. Be sure the manufacturing company offers a stellar service package because that's essential, as well.

- **Redundancies**: Multiple equipment redundancies are crucial in protecting critical assets against mechanical, electrical, or power failures. A single generator will protect your products during a power failure, and a redundant secondary generator extends your coverage. An additional complete redundant refrigeration system assures that a second system will provide continuous coverage if the primary system fails. You want to install an independent LN2 refrigeration system with dual bulk LN2 supply tanks for a third level of support. This tertiary support mitigates risk in freezers and ultra-cold chambers.

- **A monitoring system**: A continuous monitoring system with alarms, notifications, and reporting alerts you when excursions occur. The monitoring system provides peace of mind and a GMP record that your chamber requirements have been met.

Another point of note in chamber design is that walk-in chambers will give a maximum amount of storage volume without the extensive equipment of reach-in chambers. Walk-in chambers require far less energy to run. The validation and maintenance costs are cheaper, as well. So, the future savings balances out the upfront installation costs.

Examples of Flexible GMP Storage Chamber Design

You should now have a good sense of the required steps to design and execute a flexible chamber. To further illustrate this framework, below are a few of our examples of chambers that have flexibility incorporated into the design.

Flexible ambient chambers can be designed to accommodate a range of setpoints, eliminating the need to build multiple chambers if several specific ranges are required over time. For example, our 15,000 SQ FT ambient room is run at 20°C to 25°C because it overlaps and encompasses all these ranges:

- 15°C to 30°C (USP)
- 15°C to 25°C
- 20°C to 30°C (medical device)

This ambient warehouse has a Hussmann Variable Refrigerant Control System. This independent sophisticated system is self-tuning, creating efficiencies. It balances the room air conditions, gaining in precision and accuracy over time. The multiple refrigerant systems create redundancies allowing for flexibility.

The insulation in our 2°C to 8°C refrigerated warehouse was overdesigned and has four times more than normal. When the warehouse was validated, the additional insulation offered a buffer of 11 hours before it went out of specification, allowing for more response and repair time. Similarly, we have installed quadruple compressors with our normal rotation. This means two compressors perform 12 hours on and 12 hours off for 3 months at a time, and then the system switches to the redundant set. These redundancies give our equipment a rest and allow time for repairs.

To mitigate concerns of mold and moisture in the refrigerated warehouse we have installed a gas fire desiccant dryer with an electric desiccant dryer back-up. These alternate energy sources and systems create ultimate redundancies.

A well-designed versatile ambient/cooling room could operate at:

- 15°C to 30°C
- 15°C to 25°C
- 8°C to 15°C
- 2°C to 8°C
- 20°C to 30°C

The only way to accommodate the multiple ranges is to specify a quality, high-end precise chamber. The benefits of validating for multiple ranges allows flexibility to move product as your business needs change and grow.

A -20°C walk-in freezer generally cycles from -10°C to -30°C, oscillating over a 20-degree window. Our freezer is set at -22.5°C, operating more tightly at -20°C to -25°C.
We also have a dry air positive pressure system continuously pumped into the freezer. The system eliminates the need for electric defrost. In poor performing chambers defrost inserts heat to the cold chamber, exacerbating the temperature control in the freezer.

A well-designed -75°C ultra-cold freezer could hold product that is designed to be stored at:

- -60°C to -80°C (biologics)
- -70°C to -90°C (pharmaceuticals)

We uniquely designed our freezer -70°C to -80°C to accommodate both ranges. With a tightly-controlled high precision freezer we allow for current and future flexibility.

These are just a few examples of our many GMP storage chambers and how we've designed them with more flexibility. As GMP storage experts, we recognize that biopharma storage needs constantly shift, but we can keep up with the changes with ample preparation.

Conclusion

We're able to accommodate a variety of customers and their varying storage needs because we have built flexibility into our chambers. However, being flexible does take a lot of up-front work, and it's not possible for every company. We encourage companies to look at the whole picture when designing a biopharma storage chamber. Consider if your footprint is big enough for an on-site chamber and decide if it makes financial sense. For many companies, outsourcing storage is more economical and efficient.

When designing a flexible GMP storage chamber, you want to plan it out, test it, and then test it again before you begin storing. When you design it right the first time, you can avoid costly mistakes. In the life sciences industry, mistakes can ruin a lifetime of research or prohibit patients from receiving life-saving medicine. When you take the time to design a flexible storage chamber, you are ensuring a better quality of life for patients.