

THE MONITOR — October 2026

Built to share—Why future-forward flexible spaces engineered for compliance are winning.

1 • THE BRIEF:

Designing Cold Storage for Pharma, Food, and Biologics Under One Roof

A newly opened cold storage facility in Elizabeth, New Jersey, near the Port Newark–Elizabeth complex, made headlines for 9.85 million cubic feet of temperature-controlled space built to serve pharmaceutical, food, and seafood cold-chain uses.¹



For CER buyers, the real headline is the design question:

Can one controlled environment safely and compliantly support multiple regulated uses?

The answer is yes—but only through deliberate engineering. Four principles make it possible:

- **Segregate uses** - Dedicated zones, controlled access, and independent airflow paths reduce cross-contamination risks among pharmaceutical, food, and biologic products.
- **Design for the highest applicable standard** - Shared infrastructure should support the most stringent requirements for each zone rather than assuming one standard applies throughout.
- **Monitor continuously** - Temperature mapping, data logging, and redundant alarms strengthen control across pharmaceutical, food, biologic, and nutraceutical storage.
- **Plan for change** - Planning shell and utility capacity for future zone conversion or expansion can reduce the need for costly retrofits as the tenant mix changes. Although higher-grade controls may increase upfront costs, shared infrastructure and greater flexibility may lower lifecycle costs while supporting consistent quality standards.

This approach is especially relevant to nutraceutical companies, whose products may be regulated as foods or dietary supplements while customers still expect robust quality controls. Designing appropriate GMP-aligned controls in each zone can strengthen storage and stability practices without requiring entirely separate facilities.

[Footnote 1: [Refindustry](#), September 3, 2026.]

2 • ASK AN ENGINEER

"When is my cold room technically a CER and how does this affect my building project?"

Short answer: a cold room becomes a controlled environment room (CER) when holding a condition is part of the room's job, not just a comfort. If your process depends on the space staying at a setpoint within a defined tolerance, or on uniform conditions from corner to corner, and someone will ask you to prove it, you have a CER.

A foodservice walk-in only has to keep product cold. A stability room, an incubation room, or a process hold room has to keep it exactly right, everywhere, all the time.

Here is the catch: the agencies that regulate your project never use the word "CER." They classify a room by what it does, and that classification decides two things that shape your build.

1. **Which refrigerant you are allowed to use.** Under the EPA's HFC Technology Transitions rule, a walk-in serving a kitchen or cafeteria is "retail food refrigeration."

After the May 2026 reconsideration, remote condensing units and supermarket systems in that category can keep using familiar refrigerants such as R-448A and R-449A under an interim 1,400 GWP ceiling until 2032. Cold storage warehouses received a separate interim ceiling of 700 GWP over the same window.

A room tied to a pharmaceutical, biotech, or research process may instead be classified as industrial process refrigeration. The May 2026 change in that subsector is narrow: it moves certain semiconductor-manufacturing equipment and chillers with a charge of 100 pounds or less to January 1, 2030. It does not automatically place every process room on, or off, the 150/300 GWP schedule. Same box, same temperature, different rule, because of what happens inside it.

2. **How the room is permitted.** A walk-in is a listed appliance. A CER is usually an engineered system reviewed under ASHRAE 15 and the local mechanical code, and because people work inside it for hours at a time, the authority having jurisdiction will look at refrigerant charge, leak detection, and ventilation for an occupied space. That review is very manageable when it is planned from the start, and a headache when it surfaces after equipment has been ordered.

What this means for your project: tell your CER provider what the room is for, not just what temperature it holds. Storage of finished goods, a validated stability study, and a fermentation hold can all live in a 4 °C room and land in three different regulatory categories. Getting that classification on paper before the refrigeration package is specified is the single cheapest decision in the whole project.

Every new TriMark Scientific cold room and freezer room is built A2L-ready by default, so whichever category your room falls into, the refrigerant question is already answered. The classification conversation is one we are glad to have early.

Have a question for next month? Ask below or write to Scientific@trimarkusa.com.

3 · FROM THE FIELD: Fermentation rooms demonstrate the value of expertise

Las Positas's environmental rooms provide insight into the value of specialist knowledge and tailored solutions when requirements for safety, efficiency, and reliability are essential.

[Link: Read the full case study → [Las Positas](#)]

4 · MEET OUR TEAM

Rhett Affleck, TriMark Scientific General Manager – Controlled Environment Rooms

Rhett Affleck has served as general manager of TriMark's Controlled Environment Rooms division for the past 10 years. Before joining TriMark, he spent 20 years in senior R&D leadership roles at life science laboratory equipment companies, where he developed products for automated drug discovery and biobanking. A recognized industry expert, Rhett holds bachelor's degrees in chemical engineering and biophysics, a PhD in chemical engineering, and several patents.

Planning a controlled environment project, or have a question you'd like to share? Reply here or write to Scientific@trimarkusa.com. Most reader questions are answered in the next month's issue.

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