Mayne Pharma, Metrics Contract Services, designate their new stability storage facility a Center of Excellence.

Mayne Pharma and its contract pharmaceutical development and manufacturing organization, Metrics Contract Services, have designated their new stability storage facility a “Center of Excellence.”

The $3.5-million standalone facility located in Greenville, N.C., earned the classification by integrating best-in-class operational standards and equipment during construction, said John Ross, president of Mayne Pharma USA.

A view of the aisle of the 40°C/75% RH walk-in chamber.

The Stability Center of Excellence, which is 17,000 square feet in size, triples the company’s previous stability storage capacity. The center is fully validated and operational.

When designing the new facility, company officials incorporated cutting-edge standards at every level, ranging from walk-in chambers to back-up generators.

“The result is a world-class facility that will allow Mayne Pharma and Metrics Contract Services to readily meet the needs of our clients’ stability storage projects today and well into the future,” Ross said.

Features that establish the stability storage facility as best in class include:

- 100-percent back-up power generation providing 1,200 kilowatts of electricity, fueled by an uninterrupted supply of natural gas.
- Integrated system redundancies for HVAC, chillers and humidifiers.
- 100-percent seamless and sealed construction inside and outside units.
- Specialty climatic mapping and tolerances that include each International Conference on Harmonisation (ICH) stability zone for temperature and humidity.
- Sufficient square footage to double the number of chambers initially installed, providing room to grow for years.

The Metro Top-Track, High-Density Storage System is a versatile storage system that allows maximum use of floor space. (Inside of the 30°C/65% RH walk-in chamber looking at the Metro Top-Track, High-Density Storage System.)

Included in the facility are three stability chambers with available shelving capacity of 900 square feet each; one chamber with available shelving capacity of 1,530 square feet; and one chamber with available shelving capacity of 6,444 square feet.

Stability testing is a critical part of the drug approval process. Testing determines how a particular drug product, including packaging, reacts over time under the influence of temperature, humidity and light. The process determines whether any physical, chemical or microbiological changes affect the efficacy and integrity of the final product, thus ensuring that it is safe and effective, regardless of where it will be supplied. Stability testing also establishes the shelf life and recommended storage conditions of a finished pharmaceutical product.

For the purpose of stability testing, the ICH divides the world into four climatic zones based on a combination of temperature and relative humidity. The climatic zones are replicated in long-term stability studies to simulate conditions a drug product could be subjected to worldwide. Mayne Pharma has significant capacity to support studies for all major ICH climate zones and reach-in chambers to support specialized conditions.

Mayne Pharma investigated a number of stability storage room and chamber manufacturers before choosing to partner with Weiss Technik North America, a Schunk company. Weiss Technik has supplied high-quality, GMP-compatible and FDA-compliant stability testing solutions to leading pharmaceutical companies in Europe and Asia for years. Relying on proprietary environmental simulation technology, Weiss Technik stability storage systems are customized for specific users and employ energy efficiency standards that top competing systems by as much as 50 percent.

Weiss Technik is accredited with ISO 9001:2008, and its stability storage systems meet ICH Guidelines Q1A for Stability Testing and Q1B for Photostability Testing. They also comply with guidelines established by the U.S. Food and Drug Administration, the World Health Organization and the European Medicines Agency's Committee for Proprietary Medicinal Products.

A view of the 30°C/75% RH walk-in chamber.

In addition to installing state-of-the-art rooms and chambers, Mayne Pharma carefully designed the facility to ensure robust primary and auxiliary infrastructure.

The facility is served by back-up generation capable of producing and delivering 1,200 kilowatts of electricity throughout the entire site. The system has a dedicated and uninterrupted natural gas supply similar to that in use at the academic medical center

down the road. System redundancies have been implemented for chillers, HVAC and humidifiers.

“If we were to lose any aspect of our system, we would be operational right away,” Ross said. “We have invested more than most companies in stability storage to ensure the continuous integrity of our clients’ products.”

The need for the Stability Center of Excellence was driven by growth across all of Mayne Pharma’s businesses, including Metrics Contract Services. With the addition of commercial manufacturing to its portfolio, Metrics has seen an increase in late-phase and registration-batch stability programs, which support various international markets. The company’s expanding client base also required additional stability storage capacity.

The Stability Center of Excellence is part of planned expansions at the Mayne Pharma site in Greenville, N.C. Mayne Pharma is investing $80 million to repurpose existing capacity and to add new facilities and equipment — doubling pre-commercial analytical labs and clinical manufacturing capacity for Metrics. The 126,000-square-foot facility now under construction expands commercial-scale manufacturing capability to include multi-particulate layering and bead-coating fluid bed technology, as well as significantly increased capacity for manufacturing highly potent products.

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KEEP ACCESS CLEAR
AT ALL TIMES

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ON / OFF
POWER
manual
user:
admin
Temperature
30.1 °C
30.0 °C
Humidity
65 %
65 %
Options
Operation
ProgEdit.
Settings