COMPARATIVE ANALYSIS OF PRE- AND POST-OCCUPANCY HUMIDITY CONDITIONS IN A BLOOD BANK/CELL THERAPY LABORATORY

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Abstract/Executive Summary

This whitepaper presents a comprehensive comparative analysis of pre- and post-occupancy environmental conditions in a blood bank laboratory, with a specific focus on cell therapy manufacturing. The study was conducted to evaluate the effectiveness of the laboratory's environmental control systems in maintaining optimal conditions amidst operational activities and varying external weather conditions. Data were collected using 21 temperature and humidity sensors placed strategically throughout the laboratory, utilizing a Rees Mapping Kit and Rees Wireless Temperature and Humidity Probes.

Study Overview:

- **Objective:** To assess the capability of the laboratory's environmental control systems to maintain stable temperature and humidity conditions critical for cell therapy manufacturing before and after the laboratory became fully operational.
- **Methodology:** Environmental data were captured during two distinct phases: pre-occupancy (January 8-9, 2024) and post-occupancy (March 5-6, 2024). External weather conditions in San Antonio, TX, were recorded to correlate with the internal environmental data.
- **Data Collection:** Temperature and humidity sensors were positioned 2 feet from the floor, at mid-room height (approximately bench height), and 1 foot from the ceiling to ensure comprehensive coverage.

Introduction

Background on the Importance of Environmental Monitoring in Blood Bank and Cell Therapy Laboratories

Environmental monitoring is a critical aspect of quality control in blood bank laboratories, especially those involved in cell therapy manufacturing. Maintaining stable temperature and humidity conditions is essential to ensure the safety, efficacy, and quality of blood products and cell-based therapies. Fluctuations in environmental conditions can compromise the integrity of these sensitive products, leading to potential therapeutic failures and increased risks to patient safety.

Regulatory bodies such as the College of American Pathologists (CAP), the Food and Drug Administration (FDA), and the American Association of Blood Banks (AABB) have established stringent guidelines for environmental conditions in blood banks. Compliance with these regulations is mandatory to ensure that blood products are stored and processed under optimal conditions. Effective environmental monitoring systems help laboratories adhere to these standards, minimize risks, and maintain high levels of operational efficiency.

In cell therapy laboratories, where the manufacturing processes are particularly sensitive to environmental changes, robust monitoring systems are indispensable. These systems not only help in maintaining the required conditions but also provide real-time data and alerts that enable prompt corrective actions. This proactive approach is crucial in preventing deviations that could affect the quality of cell therapy products, ensuring that they remain viable and effective for patient treatments.

Purpose and Scope of the Study

The primary purpose of this study is to evaluate the effectiveness of the environmental control systems in a blood bank laboratory before and after it becomes fully operational. By comparing the pre-occupancy and post-occupancy environmental conditions, the study aims to assess how well the laboratory's climate control systems maintain stable temperature and humidity levels under varying operational activities and external weather conditions. In recent months some regulators have raised questions as to how laboratory management decides how many sensors are required to adequality monitor a given space for humidity. Currently, manufacturers of humidity sensors and providers of cEMS systems do not provide a recommendation based on cubic feet of space or other environmental variables.

Scope of the Study:

Objective: To provide a detailed analysis of the environmental conditions within a cell therapy laboratory at a blood bank for humidity by focusing on temperature and humidity variations before and after the laboratory becomes operational.

Methodology: The study utilized 21 temperature and humidity sensors placed strategically throughout the laboratory. Data were collected during two distinct phases: pre-occupancy (January 8-9, 2024) and post-occupancy (March 5-6, 2024). External weather conditions in San Antonio, TX, were also recorded to correlate with the internal environmental data.

Data Collection: Sensors were placed 2 feet from the floor, at mid-room height (approximately bench height), and 1 foot from the ceiling to ensure comprehensive coverage of the laboratory space. The Rees Mapping Kit and Rees Wireless Temperature and Humidity Probes were used for precise data collection.

Problem Statement

Maintaining optimal environmental conditions in cell therapy laboratories is a multifaceted challenge that is crucial for ensuring the safety, efficacy, and quality of cell-based therapies. Several factors contribute to the complexity of this task:

Stringent Regulatory Requirements:

Regulatory bodies such as the College of American Pathologists (CAP), the Food and Drug Administration (FDA), and the American Association of Blood Banks (AABB) mandate strict environmental conditions to safeguard the quality of blood products and cell therapies. Compliance with these regulations necessitates precise and continuous monitoring of temperature, humidity, and other environmental parameters.

Sensitivity of Cell Therapy Products:

Cell therapy products are highly sensitive to environmental fluctuations. Variations in temperature and humidity can adversely affect cell viability, potency, and functionality. Even minor deviations

from optimal conditions can lead to significant product degradation, rendering therapies ineffective or unsafe for patient use.

Operational Dynamics:

The operational activities within cell therapy laboratories, such as the use of equipment, movement of personnel, and handling of materials, can introduce variability in environmental conditions. These activities can cause transient temperature spikes, changes in humidity levels, and airflow disruptions, all of which must be managed to maintain a stable environment.

External Weather Conditions:

Laboratories are often affected by external weather conditions, which can fluctuate widely throughout the year. For instance, seasonal changes and extreme weather events can impact the internal environment of the laboratory, making it challenging to maintain consistent conditions. Effective climate control systems must be capable of compensating for these external influences to ensure internal stability.

Equipment and Infrastructure Limitations:

The performance and reliability of environmental control systems, such as HVAC units, sensors, and alarms, are critical to maintaining optimal conditions. Any malfunction or suboptimal performance of these systems can compromise the laboratory environment. Additionally, older infrastructure may not support advanced monitoring technologies, necessitating upgrades or replacements.

Data Management and Compliance:

Ensuring regulatory compliance involves meticulous documentation and data management. Laboratories must maintain detailed records of environmental conditions, calibration of monitoring equipment, and any corrective actions taken in response to deviations. This requirement adds to the operational burden and necessitates robust data management systems.

Methodology

Details of the Environmental Monitoring Setup

To accurately assess the environmental conditions within the blood bank laboratory, a comprehensive monitoring setup was employed. The study utilized Rees Mapping Services, which included Rees Wireless Temperature and Humidity Probes. These probes were strategically placed throughout the laboratory to ensure a thorough and representative collection of environmental data.

Rees Mapping Sensor Placement:

Sensor Distribution: 21 temperature and humidity sensors were deployed across the laboratory space. The sensors were placed at three different heights to capture vertical variations in environmental conditions:

- 2 feet from the floor: This height was chosen to monitor conditions at ground level, which can be affected by equipment and air circulation patterns.
- Mid-room height (approximately bench height): Sensors at this level captured the conditions most relevant to work surfaces and the handling of cell therapy products.
- 1 foot from the ceiling: These sensors provided data on the upper layer of the room, which is important for understanding the overall air distribution and stratification.

Sensor Placement Rationale: The placement of sensors at these specific heights ensures a comprehensive understanding of the temperature and humidity profiles within the laboratory. This setup helps identify any vertical gradients and ensures that the entire room is monitored effectively.

Data Collection Phases:
The study was conducted in two distinct phases to capture a comprehensive view of the laboratory's environmental conditions:

1. **Pre-Occupancy Phase:**

- Duration: January 8-9, 2024
- Objective: To establish baseline environmental conditions in the laboratory before it became fully operational. This phase provides a reference point for comparing post-occupancy data.
- External Weather Conditions: During this phase, external temperatures ranged from 1°C to 16°C. The weather was partly sunny with light rain and mist, providing a typical winter scenario in San Antonio, TX.
- Environmental Data Collected: Temperature and humidity levels were recorded continuously over the two-day period, capturing any natural fluctuations in the unoccupied laboratory.

2. **Post-Occupancy Phase:**

- Duration: March 5-6, 2024
- Objective: To evaluate the environmental conditions after the laboratory became fully operational. This phase assesses how the operational activities and equipment usage impact the laboratory environment.
- External Weather Conditions: During this phase, external temperatures ranged from 14°C to 33°C. The weather was partly sunny, representing a transition into warmer spring conditions.
- Environmental Data Collected: Similar to the pre-occupancy phase, temperature and humidity levels were recorded continuously. This data helps identify the impact of operational activities on the laboratory environment.

Data Collection Method:

- Continuous Monitoring: Both temperature and humidity were monitored continuously using the Rees Wireless Probes. Data was logged at regular intervals to provide a detailed time series of environmental conditions.
- Calibration and Validation: All sensors were calibrated before deployment to ensure accuracy. Validation of sensor placement and data integrity was performed to maintain the reliability of the collected data.

Data and Analysis

Presentation of Temperature and Humidity Data Collected

The environmental data collected during the pre-occupancy and post-occupancy phases provides a comprehensive view of the temperature and humidity conditions within the blood bank laboratory. The data was recorded continuously over two-day periods in both phases, allowing for detailed analysis of the environmental stability and the impact of operational activities.

Temperature Data:

- **Pre-Occupancy Phase (January 8-9, 2024):**
    - **Range:** 18.07°C (Low) to 27.3°C (High)
    - **Average Temperature:** 21.02°C
    - **External Temperatures:** Ranged from 1°C to 16°C
- **Post-Occupancy Phase (March 5-6, 2024):**
    - **Range:** 18.11°C (Low) to 25.80°C (High)
    - **Average Temperature:** 21.10°C
    - **External Temperatures:** Ranged from 14°C to 33°C

Humidity Data:

- **Pre-Occupancy Phase (January 8-9, 2024):**
    - **Range:** 32.86% (Low) to 54.61% (High)
    - **Average Humidity:** 45.57%
- **Post-Occupancy Phase (March 5-6, 2024):**
    - **Range:** 34.45% (Low) to 63.55% (High)
    - **Average Humidity:** 44.16%

Analysis of Variations and Their Correlation with External Weather Conditions

Temperature Analysis:

- **Pre-Occupancy:**
    - During the pre-occupancy phase, the laboratory maintained a stable average temperature of 21.02°C, despite the external temperatures ranging from 2°C to 16°C
    - The temperature variation within the laboratory was between 18.07°C and 27.3°C, indicating the effectiveness of the environmental control systems in maintaining stable conditions in an unoccupied state.
- **Post-Occupancy:**
    - In the post-occupancy phase, the average temperature slightly increased to 21.10°C. The temperature range narrowed to 18.11°C to 25.80°C, reflecting reduced variability compared to the pre-occupancy phase.
    - The laboratory managed to maintain a stable temperature despite higher external temperatures (14°C to 33°C, demonstrating the robustness of the climate control systems under operational conditions.
    - **Correlation with External Weather:** The data suggests that the internal temperature control systems effectively mitigated the influence of external weather conditions. The slight increase in average temperature and reduced variability post-occupancy indicate that operational activities had a stabilizing effect on the internal temperature.

Humidity Analysis:

- **Pre-Occupancy:**
    - Humidity levels during the pre-occupancy phase ranged from 32.86% to 54.61%, with an average of 45.57%. The external weather conditions, which included light rain and mist, contributed to the moderate humidity levels.
    - The relatively stable humidity range suggests that the environmental control systems were effectively managing humidity in an unoccupied laboratory.
- **Post-Occupancy:**
    - In the post-occupancy phase, humidity levels showed greater variability, ranging from 34.45% to 63.55%. The average humidity slightly decreased to 44.16%.
    - The increase in humidity variability can be attributed to operational activities, such as the use of equipment and the presence of personnel, which can introduce additional moisture into the environment.
    - **Correlation with External Weather:** The external temperatures during the post-occupancy phase were significantly higher, ranging from 14°C to 33°C. This increase in external temperature likely contributed to the higher humidity levels observed inside the laboratory. Despite this, the environmental control systems managed to keep the average humidity close to the pre-occupancy levels, indicating effective humidity regulation.

Comparative Insights:

- The laboratory maintained stable average temperatures despite the transition from an unoccupied to an operational state and significant external temperature fluctuations. This stability demonstrates the effectiveness of the laboratory's climate control systems.
- While there was greater variability in humidity levels post-occupancy, the average humidity remained within a similar range to the pre-occupancy phase. This suggests that the environmental control systems are capable of managing the additional moisture introduced by operational activities in this building.
- The correlation between internal environmental conditions and external weather highlights the importance of robust climate control systems that can adapt to external influences and maintain stable conditions critical for cell therapy manufacturing.
- Building design can directly impact the ambient humidity of a building through passive means. This study does not directly consider building design and the impact of that design on humidity and its management.

Results

Key Findings from the Temperature and Humidity Analysis

Temperature Analysis:

- **Pre-Occupancy:**
    - **Range:** 18.07°C to 27.3°C
    - **Average Temperature:** 21.02°C
    - **External Temperatures:** 2˚C to 16C˚C
- **Post-Occupancy:**
    - **Range:** 18.11°C to 25.80°C
    - **Average Temperature:** 21.10°C
    - **External Temperatures:** 14°C to 33°C

Humidity Analysis:

- **Pre-Occupancy:**
    - **Range:** 32.86% to 54.61%
    - **Average Humidity:** 45.57%
- **Post-Occupancy:**
    - **Range:** 34.45% to 63.55%

- **Average Humidity:** 44.16%

Comparative Insights Pre- and Post-Occupancy:

Temperature:

- The laboratory maintained stable average temperatures despite operational activities and external weather changes.
- A slight increase in average temperature from 21.02°C to 21.10°C was observed, along with a reduction in temperature variability, indicating effective temperature control systems.

Humidity:

- Post-occupancy, the laboratory experienced greater humidity variability, with the range increasing from 32.86%-54.61% to 34.45%-63.55%.
- Despite this variability, the average humidity remained relatively stable, decreasing only slightly from 45.57% to 44.16%.

Discussion

Interpretation of the Stability of Environmental Conditions:

- The consistent average temperature and slight decrease in humidity variability post-occupancy highlight the effectiveness of the laboratory's climate control systems.
- The control systems managed to maintain stable conditions despite the increased operational activities and significant external temperature fluctuations.

Insights on the Effectiveness of the Laboratory's Control Systems:

- The laboratory's environmental control systems successfully mitigated the impact of operational dynamics and external weather conditions, maintaining stable internal conditions essential for cell therapy processes.
- The reduced temperature variability post-occupancy suggests that the operational activities contributed to a more consistent temperature environment.

Conclusion

Summary of Findings:

- The study demonstrated that the laboratory maintained stable temperature and humidity conditions both pre- and post-occupancy.
- Despite increased external temperatures and operational activities, the laboratory's climate control systems were effective in ensuring consistent environmental conditions.

Importance of Maintaining Controlled Conditions for Cell Therapy Processes:

- Stable environmental conditions are critical for maintaining the viability, potency, and safety of cell therapy products.
- Effective environmental control systems are essential to comply with regulatory requirements and ensure the quality of cell therapy products.

Recommendations

Continuous Monitoring and Adjustment of Environmental Controls:

- Regular monitoring and periodic adjustments of the environmental control systems are recommended to address any variations in temperature and humidity.
- Implementing advanced monitoring technologies can provide real-time data and alerts, allowing for prompt corrective actions.

Further Studies on the Impact of Specific Operations on Environmental Conditions:

- Conducting detailed studies on the impact of specific laboratory operations, such as equipment usage and personnel movement, on environmental conditions can help refine control strategies.
- Understanding these impacts can lead to better planning and management of laboratory activities to maintain optimal conditions.

Vigilance to External Weather Conditions:

- Laboratories should remain vigilant to external weather conditions and incorporate adaptive measures into their environmental management practices.
- This includes adjusting climate control settings in response to seasonal changes and extreme weather events to ensure consistent internal conditions.

Summary:

- The study underscores the importance of robust environmental control systems in maintaining optimal conditions for cell therapy manufacturing.
- By addressing the identified challenges and implementing the recommended measures, laboratories can enhance their operational efficiency, comply with regulatory standards, and ensure the quality and safety of cell therapy products.