Adaptive Sterile Modular ISO Class 7 Biomedical Manufacturing Cleanroom

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Mechanical Engineering

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Abstract

Motivated by a shared commitment to enhancing human healthcare, our project aligns with the mission of Aneuvas Technologies by developing a sterile environment for medical device manufacturing. We aim to address the challenge of constructing a cleanroom that complies with FDA's ISO Class 7 standards while repurposing the existing cleanroom space into a gowning room. Our approach involves the construction of a 12x16 foot cleanroom featuring clear rigid polycarbonate walls, four Fan Filter Units (FFUs), and reinforced with Aluminum beams to meet the stringent ISO Class 7 requirements. The anticipated results include the successful qualification of the cleanroom, facilitating its utilization by Aneuvas Technologies for the development and testing of medical devices for stroke treatments. Our solution's implications extend to ensuring compliance with FDA standards and client requirements, providing a controlled environment essential for high-quality medical devices. The major engineering requirements, such as modularity and strict particle count control, have been locked in to guarantee the adaptability and cleanliness necessary for the cleanroom's functionality and adherence to regulatory standards.

Project Requirements

Customer Requirements:

- Modular
- Transportable
- Spacious
- Safe
- ISO Class 7 Requirements

Engineering Requirements

Table 1: Engineering Requirements & Targets

Requirement	Target
ER1: Spacious	216 ft^2
ER2: Particle Count	$0\mu g$ > 0.5 μm
ER3: Airflow	> 90 ft/min, > 60 air changes per hour
ER4: Ceiling Coverage	> 15%
ER5: Reynold's Number	$< 1 * 10^7$
ER6: Deflection	~ 0in

Design Iterations

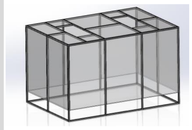
Figure 1: Iteration 1: 12'x8' Cleanroom


Figure 2: Iteration 2: 12'x16' Cleanroom

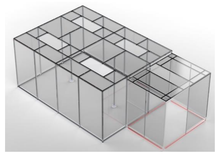
Figure 3: Iteration 3: 12'x8' Cleanroom with Support Beams and Gowning Room

Materials & Fabrication

Materials:

- 1.5" Aluminum Square Tubing
- 1.5" Steel Square Tubing
- 1/16" Polycarbonate Sheets
- Nylon Composite Connectors
- ¼-20" Bolts and Nuts
- 1/8" Vinyl Sheets

Fabrication Methods:


Figure 4: Vertical Mill


Figure 5: Drill Press

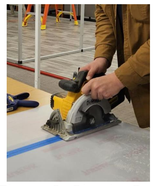
Figure 6: Circular Saw


Figure 7: Hand Drill

Methods

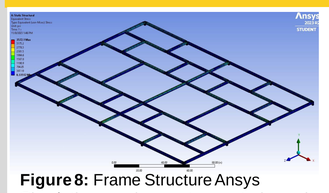
Figure 8: Frame Structure Ansys Simulation: maximum stress, strain, and deflection of ceiling beams from FFU weight

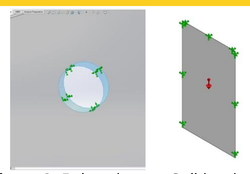
Figure 9: Polycarbonate Solidworks Simulation: hanging force on bolts, weight of sheets on frame

Table 2: Material Properties Table

Sub-System	Yield Strength (MPa)	Max Stress (MPa)	Factor of Safety
Bolts	758	0.034	22294.7
Aluminum	61.53	24.61	2.5
Polycarbonate	60	0.485	123.7

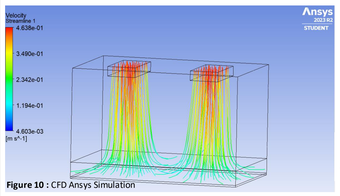
Figure 10 : CFD Ansys Simulation

CFD Ansys Simulation: FFU placement and speed, polycarbonate wall gap

$$Ceiling\ Coverage = \frac{Area\ FFUs}{Area\ Cleanroom\ Ceiling}$$

$$Air\ changes = \frac{Average\ Velocity * \frac{60min}{hour} * \#FFUs}{Cleanroom\ Volume}$$

$$Reynold's\ number = \frac{\rho V L}{\mu}$$

Testing

Experiment 1: Deflection

Goal: Determine where support beams are needed

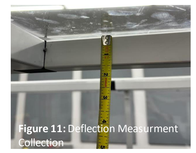
Figure 11: Deflection Measurment Collection

Experiment 2: Particle Count

Goal: Measure number of particles in the air


Figure 12: Particle Counting Data Collection

Experiment 3: Airflow

Goal: Measure Air velocity under each FFU

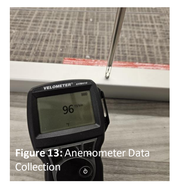
Figure 13: Anemometer Data Collection

Experiment 4: Area

Goal: Measure cleanroom area and percentage ceiling coverage


Figure 14: Measuring Cleanroom Area

Results


Figure 15: Final Build

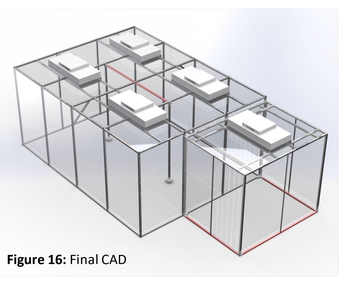
Figure 16: Final CAD

The 12'x18' cleanroom with gowning room passed all necessary testing specifications to be qualified as an ISO Class 7 cleanroom for medical device manufacturing.

Table 3: Final Cleanroom Specs

Final Cleanroom Specifications	
Deflection	0 in
Particle Count	$0\mu g$ > 0.5 μm
Airflow	100.6 ft/min, 81.6 air changes per hour
Reynold's Number	$1.00 * 10^5$
Area	185.4 ft^2
Ceiling Coverage	15.7%
Modularity	Assembly – 7.25hrs, Disassembly – 10.75 hrs

Conclusion

The goal of this project was to build a modular, sterile cleanroom to be used for medical device manufacturing. The team created a 12'x18' cleanroom with FFUs and polycarbonate walls to maintain ISO Class 7 requirements. The sturdy aluminum frame and support beams provided the necessary structural support for cleanroom longevity. The converted steel cleanroom with polycarbonate and vinyl sheets helped maintain sterile entrance into the cleanroom. The designed cleanroom met all ISO Class 7 requirements to be qualified for medical manufacturing. Due to the cleanroom's modular nature, future size and shape modifications could be made to the manufacturing area.to align with changing needs.

References

- [1] "ISO 7 cleanroom," ISO Class 7 Cleanrooms | Cleanroom ISO 7 Specifications, (accessed Sep. 14, 2023).
- [2] J. W. Mitchell, R. W. Fox, and A. T. McDonald, Fox and McDonald's Introduction to Fluid Mechanics. Hoboken, NJ: Wiley, 2020.
- [3] Terra Universal: Critical Environment Solutions Inc, "FS209E and ISO Cleanroom Standards," Terra Universal INC, Fullerton, 2012.
- [4] W. Callister, Materials Science and Engineering. John Wiley & Sons, 2018.
- [5] ePlastics, "1/16" X 48" X 96" CLEAR POLYCARBONATE SHEET," [Online]. Available: https://www.eplastics.com/LEXAN-CLR-0-060AM48X96
- [6] "WhisperFlow® fan filter units," Cleanroom Fan Filter Units, https://www.terrauniversal.com/whisperflow-fan-filter-units.html (accessed Oct. 7, 2023).
- [7] 80/20, "Ready Tube," [Online]. Available: https://8020.net/9700.html.

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