Case Study

Implementation of an ISO 6 Cleanroom for AdvoCare Pharmaceutical's Commercial Final Clean Production Facility

Executive Summary

AdvoCare Pharmaceutical, a leading provider of health and wellness products including nutritional supplements and performance enhancers, sought to enhance its manufacturing capabilities by constructing a state-of-the-art ISO 6 cleanroom facility. This Project focused on the "final clean" phase of production, where products undergo terminal processing, packaging, and quality assurance to ensure compliance with Good Manufacturing Practices (GMP) and minimize contamination risks. The new 30,000 square foot facility was designed to support high-volume commercial production while meeting stringent regulatory standards for pharmaceutical-grade supplements and strengthened AdvoCare's position in the competitive wellness market.

Company Background

Founded in 1993, AdvoCare Pharmaceutical specializes in developing and distributing a wide range of wellness products, including energy boosters, gut health supplements, immune support formulas, and sports performance aids. Headquartered in Richardson, Texas, the company operates as a family-owned entity with a strong emphasis on scientific research, high-quality ingredients, and ethical manufacturing. AdvoCare's products are formulated using pharmaceutical or USP-grade vitamins and minerals, with each batch rigorously tested for purity and potency. Manufacturing occurs in GMP-compliant facilities, where vendors are vetted for adherence to high ethical and regulatory standards. As demand for their products grew, particularly in the post-pandemic era emphasizing health and immunity, AdvoCare identified the need for an upgraded production environment to handle sensitive "ISO Clean" operations, such as powder blending, encapsulation, and sterile packaging, without compromising product integrity.

Project Challenges

AdvoCare faced several key challenges in expanding its production capabilities:

- ✓ Contamination Control: Existing facilities, while GMP-compliant, experienced occasional particulate contamination during final processing stages, leading to batch rejections and increased costs. The company needed an environment with ultra-low airborne particle levels to protect sensitive formulations.

- ✓ Regulatory Compliance: As a producer of supplements often scrutinized under pharmaceutical-like standards, AdvoCare required validation to ISO 14644-1:2015 Class 6, which limits particles ≥0.5 µm to 35,200 per cubic meter, alongside GMP guidelines for bioburden and microbial control.
- ✓ Scalability and Efficiency: The facility had to accommodate growing production volumes (targeting 500,000 units per month) while integrating seamless material and personnel flows to minimize downtime.
- ✓ Energy and Cost Management: Balancing high air change rates (typically 20-40 per hour in ISO 6 spaces) with sustainable operations to control utility costs without sacrificing air quality.
- ✓ Integration with Existing Operations: The new cleanroom needed to be modular for easy expansion and retrofitting into the company's Texas headquarters without disrupting ongoing production.

Solution

Design and Implementation

AdvoCare partnered with Arco Design Build and Checkmark to design, build and make ready a modular ISO 6 cleanroom tailored for ISO Operations. The Project adopted a turnkey approach, encompassing design, construction, and validation

- ✓ Air Handling and Filtration: Equipped with HEPA filters achieving 99.99% efficiency at 0.3 µm, the system provided 30 air changes per hour. Energy-efficient recirculation was achieved while positive pressure gradients ensured contaminants were directed away from critical areas.
- ✓ Construction Materials: Utilized flush-finish, non-shedding panels (e.g., Quadcore insulated UltraTech) compatible with GMP cleaning protocols. Floors were seamless epoxy for easy sanitation, and walls incorporated vision panels for monitoring without entry.
- ✓ Utilities and Integration: Included temperature-controlled cooling (68-72°F), humidity regulation (40-60% RH), compressed air terminals, and power outlets for equipment like high-speed encapsulators and automated packaging lines. The modular design allowed for future expansion to ISO 5 zones if needed.
- ✓ Monitoring and Controls: Real-time particle counters, environmental sensors, and Building Management System (BMS) integration for continuous validation. Alarms triggered for deviations in pressure, temperature, or particle counts.

Conclusion

The ISO 6 cleanroom Project exemplifies Checkmarks and AdvoCare Pharmaceutical's commitment to innovation and quality in the wellness industry. By addressing contamination risks and scaling operations efficiently, the facility positions the company for sustained growth. This case study highlights Checkmark’s role in the value of modular cleanroom solutions for pharmaceutical and supplement manufacturers, demonstrating how targeted investments in controlled environments can yield significant returns in compliance, efficiency, and market competitiveness.