



MANUFACTURING CASE STUDY



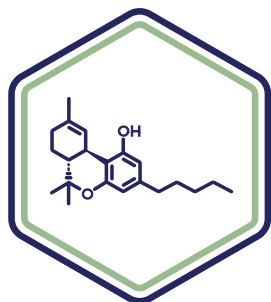
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Redefining Dronabinol Manufacturing for Consistency and Speed

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Benuvia's Solution to Scaling Synthetic Delta-9-THC.

OPPORTUNITY



Benuvia faced critical challenges in manufacturing dronabinol, a synthetic Delta-9-THC, to support FDA-regulated products like Syndros. Previous methods involved volatile chemicals, prolonged production times, and low yields, jeopardizing supply stability. Meeting stringent regulatory requirements, preventing oxidative impurities, and achieving consistent high purity were pressing concerns. Additionally, the client required a scalable, efficient process to address growing market demand while navigating complexities in controlled substance regulations.

The existing manufacturing delays and inefficiencies highlighted the need for a transformative approach that could ensure rapid, reliable, and compliant production of pharmaceutical-grade dronabinol. Overcoming these issues demanded innovative solutions tailored to efficiency and quality.





SOLUTION



Benuvia optimized the synthetic strategy to reduce process steps and eliminate the need for column chromatography. By avoiding aggressive reaction conditions and using a Quality by Design framework, the team ensured chemical stability and reproducibility. Stability studies validated that dronabinol could be stored in its neat form for extended periods without degradation, meeting FDA and ICH standards. The new method allowed for the production of GMP-compliant material in less than two weeks at a multi-kilogram scale. This innovative approach not only improved efficiency but also enhanced quality and ensured adherence to rigorous regulatory requirements for pharmaceutical-grade products.

Key initiatives included:

- Implementing an efficient synthetic pathway with fewer steps.
- Enhancing stability and storage conditions for long-term reliability.
- Adopting advanced purification techniques to improve yield and purity.

OUTCOME



Benuvia's advanced manufacturing process achieved >99% purity for dronabinol, meeting USP guidelines while significantly reducing production time and costs. The scalable, reproducible process ensured a stable supply chain, enabling consistent delivery to meet market demand. By addressing critical challenges, Benuvia positioned itself as a leader in synthetic Delta-9-THC production, supporting clinical trials, preclinical studies, and commercial applications. This transformative solution reinforced Benuvia's reputation for innovation, efficiency, and regulatory excellence in controlled substance manufacturing.

Results included:

- Cost reduction through optimized processes.
- Stabilized supply chains for uninterrupted market availability.
- Enhanced compliance with global regulatory standards.

ABOUT BENUVIA

Benuvia Operations, LLC is a global Contract Development and Manufacturing Organization (CDMO) that helps pharmaceutical, and biotech companies deliver life-changing therapies to patients in need. The company provides end-to-end development and manufacturing

services for Active Pharmaceutical Ingredients (APIs) and finished dosage products and has extensive experience with cannabinoids, psychedelics, and other controlled substances. Benuvia operates an 83,000 square foot, best-in-class manufacturing facility in Round Rock,

Texas that can produce Schedule I-V compounds, offering comprehensive solutions for companies throughout the entire drug development lifecycle—from API synthesis, clinical trial supply to commercial production.

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