Benuvia
CONTROLLED SUBSTANCE SOLUTIONS

API CASE STUDY

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Pioneering Scalable Production of 5-MeO-DMT to Meet Demand

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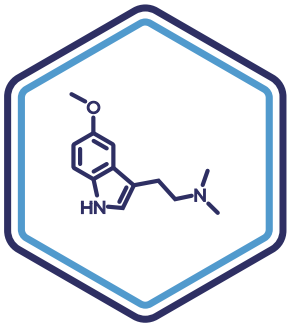
Benuvia Innovation Ensures Critical Psychedelic Therapies Can Thrive.

OPPORTUNITY



The increasing interest in 5-MeO-DMT for treating depression, PTSD, and addiction required a robust, scalable manufacturing process. Challenges included achieving >99.9% purity and high yields while complying with DEA and FDA regulations for Schedule I substances. Existing methods were either overly simplistic or involved extensive purification steps, making them unsuitable for clinical-grade production. The client needed a partner capable of navigating regulatory complexities and delivering a process that adhered to ICH Q3 guidelines, ensured consistent quality, and supported clinical research.

The demand for a reliable supply of high-purity 5-MeO-DMT highlighted the need for innovative solutions to meet stringent safety and efficacy standards. Addressing these complexities was essential for supporting transformative therapeutic research.

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SOLUTION

Benuvia designed a multi-step synthetic process aligned with ICH Q11 guidelines, achieving exceptional purity and yield without column chromatography. Using a Quality-by-Design approach, the team ensured high reproducibility and minimized batch failures. Advanced purification techniques streamlined the process, while efficient storage conditions maintained API integrity. Regulatory compliance was achieved through meticulous adherence to GMP standards and the acquisition of necessary DEA licenses. This end-to-end solution enabled seamless manufacturing operations for 5-MeO-DMT, providing clients with the confidence needed for clinical and preclinical research applications.

Actions taken included:

- Developing a multi-step process for optimal results.
- Utilizing advanced purification methods for high-yield production.
- Ensuring full regulatory compliance for Schedule I substances.

OUTCOME

Benuvia delivered a GMP-compliant process capable of producing multikilogram quantities of 5-MeO-DMT with >99.9% purity. The innovative approach supported FDA-regulated clinical trials and preclinical studies, ensuring stability and safety to meet the highest standards. By overcoming regulatory and technical hurdles, Benuvia positioned itself as a trusted leader in psychedelic API production. The solution enabled transformative research in mental health and addiction therapies, showcasing Benuvia's ability to deliver scalable, high-quality manufacturing solutions for emerging therapeutic needs.

Key achievements included:

- Reliable production scalability supporting global research demands.
- Consistent purity and stability across all production batches.
- Reinforced leadership in the production of psychedelic APIs.

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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