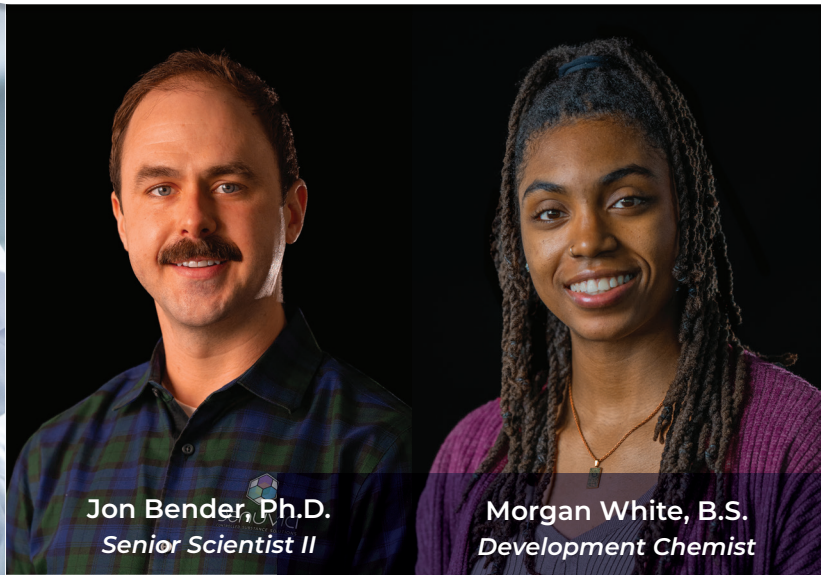
Benuvia
CONTROLLED SUBSTANCE SOLUTIONS

MANUFACTURING CASE STUDY

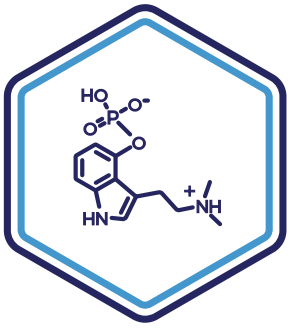


Delivering Scalable Manufacturing with Increased Stability and Reduced Costs

By Jon Bender, Ph.D. & Morgan White, B.S.

How Benuvia Revolutionized Psilocin and Psilocybin Production

OPPORTUNITY



The rising demand for psilocin and psilocybin in therapeutic applications posed a unique set of challenges for a client. They required a cost-effective, scalable manufacturing process that could achieve >99% purity in compliance with ICH Q3 guidelines while ensuring long-term stability for clinical studies. Additionally, the solution had to be adaptable for commercial-scale production while navigating complex U.S. and international regulatory frameworks for controlled substances.

Meeting these stringent requirements while reducing costs and maintaining sustainability proved to be a significant challenge. The client also needed a process capable of addressing the global demand for these emerging therapies, requiring precise solutions to optimize production efficiency and meet regulatory expectations. Achieving these goals required innovation in process design and comprehensive quality management.

Benuvia
CONTROLLED SUBSTANCE SOLUTIONS

MANUFACTURING CASE STUDY

SOLUTION

Benuvia applied its deep expertise in controlled substances and synthetic process development to design a comprehensive solution. By streamlining intermediates and reducing process steps, Benuvia created an efficient, high-quality synthetic pathway. Advanced HPLC and gas chromatography monitoring ensured exceptional purity and batch consistency. Quality by Design principles underpinned the development, guaranteeing process robustness and minimizing risks. Innovations in shelf-life stability included polymorph management and specialized packaging solutions. The process seamlessly transitioned from R&D to full-scale production, maintaining compliance with FDA, DEA, and ICH standards while meeting the client's needs for scalability and cost-efficiency.

Key actions included:

- Designing a synthetic process with fewer steps for efficiency.
- Implementing advanced monitoring for quality assurance.
- Developing adaptable methods for commercial-scale transitions.

OUTCOME

Benuvia delivered a groundbreaking manufacturing process capable of producing up to 10 kg of psilocin and 5 kg of psilocybin monthly, supporting both clinical and commercial needs. The cGMP-compliant process ensured full regulatory adherence and reduced production costs, making these therapies more accessible. The versatile synthetic pathway allowed for the production of other tryptamines, showcasing flexibility for diverse therapeutic applications.Benuvia's innovative approach solidified its position as a leader in controlled substances, driving advancements in mental health treatments while maintaining unparalleled quality and compliance standards.

Achievements included:

- High scalability with consistent quality across large batches.
- Reduced production costs for broader accessibility.
- Enhanced global market readiness through regulatory excellence.

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.

Visit us at **www.benuvia.com**