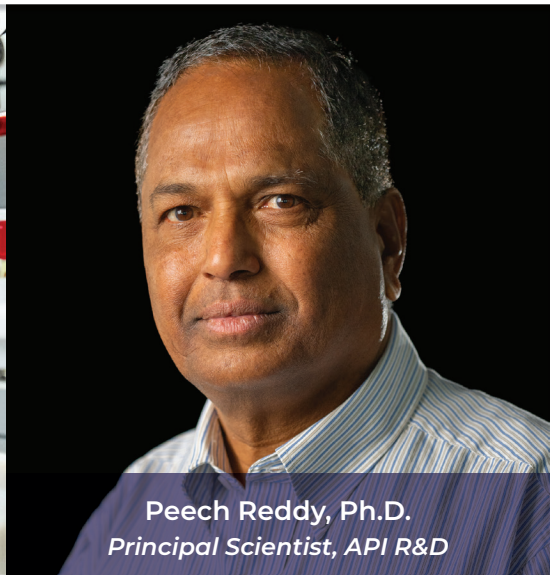
Benuvia
CONTROLLED SUBSTANCE SOLUTIONS

API CASE STUDY



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Providing A Reliable Supply of a Lisdexamfetamine Dimesylate

By Peech Reddy

Benuvia's Scalable Solutions for a Critical API Experiencing a Global Shortage.

OPPORTUNITY

A global shortage of lisdexamfetamine dimesylate (LisDex), used to treat ADHD and binge eating disorder, posed significant challenges for a client. Patent restrictions, tight timelines, and DEA quota limitations for phenylacetone compounded the difficulty. Developing a scalable, cost-effective process to produce metric ton quantities required innovative approaches to overcome regulatory and technical obstacles. The client needed a reliable partner to navigate these challenges, eliminate reliance on phenylacetone intermediates, and ensure a stable supply of high-quality API.

This urgent demand required rapid development of a compliant, efficient manufacturing solution tailored to meet global needs. These goals highlighted the need for rapid innovation and regulatory finesse.

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SOLUTION

Benuvia's team designed a synthetic route using non-controlled raw materials, avoiding phenylacetone isolation and associated DEA constraints. Within three months, the team developed a scalable process, addressing chemistry, raw material sourcing, and purification challenges. By eliminating chromatography and hazardous conditions, the method ensured high yields and regulatory compliance with GMP standards. A Quality-by-Design approach was used to optimize reproducibility and minimize risks of batch failures. The solution was engineered to produce LisDex at a metric ton capacity, meeting stringent regulatory and quality specifications for commercial and clinical use.

Actions included:

- Creating a synthetic route circumventing controlled intermediates.
- Developing scalable methods within an expedited timeline.
- Ensuring process compliance with DEA and GMP standards.

OUTCOME

Benuvia's innovative process enabled the cost-effective production of LisDex at multi-kilogram scales, addressing global shortages while meeting USP and ICH standards. The streamlined process ensured a stable supply chain, providing clients with high-quality API for both clinical and commercial applications. By responding rapidly to client needs, Benuvia reinforced its reputation as a leader in controlled substance manufacturing. The success of this solution highlighted Benuvia's ability to deliver scalable, compliant, and efficient processes, ensuring critical therapies remain accessible to those who need them most.

Achievements included:

- Reliable scalability addressing urgent global shortages.
- Reduced reliance on restricted raw materials.
- Delivery of compliant, high-purity APIs on a large scale.

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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