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REGULATORY CASE STUDY

From Hurdles to Milestones: Accelerated Global IND/CTA Approvals

By Esther Hendrickson

Leading a biotech start-up through a complex regulatory landscape

OPPORTUNITY

A start-up biotech company faced significant hurdles in obtaining Investigational New Drug (IND) and Clinical Trial Application approvals to launch first-in-human clinical trials globally. Navigating the complexities of diverse regulatory landscapes and meeting stringent compliance requirements created substantial obstacles for the biotech company.

These complex challenges were further complicated by routine regulatory tasks, including preparation for pre-IND, End-of-Phase 2, and Pre-BLA/NDA meetings; securing Orphan Drug Designation with pediatric rare disease vouchers; and drafting essential documents such as Initial Pediatric Study Plans (iPSPs) and Pediatric Investigation Plans (PIPs). The company was in dire need of expert guidance to streamline approval processes, reduce costs, and ensure timely market entry.

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SOLUTION

Benuvia's regulatory affairs team stepped in to provide comprehensive, tailored support that empowered the client to navigate complex regulatory pathways with confidence. Our approach included:

Regulatory Intelligence: Delivered up-to-date insights into regulatory changes and market trends, helping the company strategically position its product for competitive success.

Dossier Preparation: Assisted in crafting and submitting detailed regulatory dossiers aligned with global standards.

Compliance Support: Ensured all documentation met stringent guidelines, reducing the risk of rejections and delays.

Liaison with Authorities: Our team's deep expertise and established relationships with global regulatory agencies allowed us to facilitate direct, proactive communication. This ensured timely resolutions to agency queries and kept the project on track.

By integrating these services, Benuvia provided a seamless, end-to-end solution that kept the client in full control of their regulatory process.

OUTCOME

Thanks to Benuvia's expert support, the biotech company successfully obtained IND/CTA approvals in all target countries, achieving this milestone within their desired timeline. Key results included:

- Subject enrollment and clinical trials commenced on schedule.
- Approval timelines were reduced saving them time and money.
- Value in the eyes of investors was increased, and additional funding was secured.
- Improved compliance cut dossier prep time and greatly minimized rejections.

Benuvia's expertise enabled faster market entry and the ability for the client to focus on innovation and growth while staying ahead of the competition.

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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