Formulation Development and cGMP Clinical Batch Manufacturing with Vantage

Whether you are looking for a single, tailored manufacturing solution, or solutions throughout your product's clinical or commercial life-cycle, we can deliver.

Current Global Hemp Derived CBD Market:

- The Global CBD market was estimated at $12.8B USD in 2021, with North America making up $7.7B USD
- The market is expected to grow at a CAGR of 21.7% from 2022-2028, reaching $56.2B USD in 2028
- CBD is federally legal in the United States and Canada, as well as approximately 50 more countries around the world
- Oils, Tinctures, Capsules, Creams, and Roll-ons will dominate the CBD finished goods market in 2028

Source: Global Market Insights - Cannabidiol Report GMI4541 - Apr 2022

There are 900+ Cannabidiol (CBD) studies listed on clinicaltrials.gov

Current CBD Manufacturing Environment:

- The CBD industry is fragmented with many small and large producers and a wide range of quality available
- Few companies are seriously focused on providing access to pharmaceutical grade products and finished goods
- Production of, and access to, CBD products is highly controlled in international markets
- Product must be consistently manufactured to global cGMP standards to meet growing demand both for clinical studies and commercial supply

The Vantage AdVantage:

One partner the whole way

- With large-scale extraction facilities built and operated to WHO GMP, FDA 21 CFR 210/211, and ICH Q7 standards, Colorado-based Vantage Hemp delivers pharmaceutical-grade CBD Full Spectrum Oils, Distillates and Isolates that companies can trust
- Vantage's contract manufacturing services abide by stringent pharmaceutical-production standards
- In April 2022, Vantage further solidified its position as an industry leader by announcing its submission of a Drug Master File (DMF) for its hemp-derived cannabidiol (CBD) distillate to the US Food & Drug Administration (FDA)

VANTAGE HEMP

2337 115th Avenue, Greeley, CO 80634
General: 720-633-6082
Sales: 732-788-5353
vantagehemp.com

Vantage Hemp is North America's only WHO GMP, FDA 21 CFR 210/211, and ICH Q7 certified hemp processor. From raw crude to registered pharmaceutical APIs and manufactured finished goods, trust the science at Vantage Hemp.

Case Study Introduction – Growing with You

Vantage invests in world-class pharmaceutical manufacturing capabilities with a long-term view toward the CBD market. In developing novel drugs for novel indications, pharmaceutical companies and drug developers must have faith that their API provider and contract manufacturer can stay with them for the long haul. Free from the near-term pressures of today's capital markets, Vantage is a beacon of stability and scalability in the stormy seas of cannabinoid research. Vantage understands the requirements for clinical navigation from IND to commercial approvals for new treatments and new drug compounds. We understand manufacturing requirements and the need for scalable solutions including finish and fill.

We strive to be your trusted, long-term strategic partner

Like our client highlighted in this case study, some of our clients are small, privately-owned pharmaceutical companies. They have established clinical proof of concept and are looking to move into Phase 2a. Situated outside of the USA, their clinical development pipeline includes assets for cancer pain management using an innovative CBD/CBDA formulation.

Vantage Appears at iCDP 4.0

The International Cannabinoid-Derived Pharmaceuticals Summit (iCDP) is the world's largest conference devoted exclusively to the production of cannabinoid-derived pharmaceuticals for medical conditions using FDA/EMA approval pathways. In September 2021, Vantage COO, Deepank Utkhede addressed iCDP attendees on the application of pharmaceutical regulatory standards in the emerging global CBD market. This event announced Vantage's leadership position in Investigational New Drug development (IND) for hemp-derived CBD.

R&D, Clinical Trials, and Commercialization

Our client wished to form an early and lasting relationship with a pharmaceutical grade CBD producer that could grow with them throughout their product pipeline life-cycle. Our client required clinical product batches of CBD SoftGels in their proprietary formulation. The product was to be supplied and imported under their country's regulatory required Research and Development license for Cannabis.

Our client contacted us through a partner following iCDP 4.0 - where they saw Deepank's presentation.

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Vantage's FDA Drug Master Files (DMF)

Vantage confidentially provides the US Food and Drug Administration with all details on its facilities, processes, and the materials used in the manufacturing, processing, packaging, and storing of broad spectrum CBD Distillate API and CBD Isolate API as required for approval of drug ingredient applications.

"Our CBD Distillate and CDB Isolate Drug Master Files are a testament to Vantage's dedication to manufacturing the highest quality CBD API. Vantage exemplifies the breadth of knowledge, depth of collaboration, and attention to detail expected and required of an API producer."

- Deepank Utkhede, COO

The Vantage AdVantage

– One partner from R&D to commercialization

While the R&D and Clinical Trial phases of IND may not require significant volumes of API and finished goods, suppliers must provide consistently produced, registered inputs fit to survive the long journey to commercialization - which may take many years.

Our client required an API provider with the scope and capable scale to extend beyond Phase 2 clinical trial. Vantage's ability to deliver this enables the client to successfully partner across their own networks. This is a significant strategic play, and they really needed our help. They were happy to learn that Vantage could provide APIs, but even happier to learn of Vantage's ability to deliver a variety of finished goods.

The Results

Vantage provided this client with their API formulation, and finished and filled for a quantity of product that exceeded 200,000 softgels for each of their batch requirements. This includes further scope beyond their Phase 2a.

- Develop and manufacture cGMP phase 1/2 clinical supplies for the company's CBD product based upon the characteristics of the formulation and data gathered during the development cycle
- Produce the finished product as encapsulated in a softgel capsule
    - Conduct all necessary product tests, evaluations, screenings and validations
- Manufacture finished product to meet product demand (includes active clinical and placebo clinical batches

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Does your heart ache for a pharmaceutical grade CBD supplier?

In developing novel drugs for novel indications, global pharmaceutical companies and drug developers must have faith that their API provider can partner with them on the long journey to commercialization. Vantage Hemp's cGMP compliant manufacturing processes and facilities operate to ICH Q7, WHO GMP, and 21 CFR 210/211 standards. To avoid any heart aches, choose Vantage.

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