



By Joe Girardo



## THE CRITICAL ROLE OF GACP COMPLIANCE

# Ensuring Full Traceability in Pharmaceutical-Grade Hemp Products

### INTRODUCTION

As the pharmaceutical industry increasingly incorporates hemp-derived products into drug development, the necessity for full traceability from seed to finished product has never been more critical. Unlike nutraceuticals and consumer hemp products, pharmaceutical-grade hemp Active Pharmaceutical Ingredients (APIs) must adhere to strict regulatory requirements to ensure safety, consistency, and efficacy.

At the foundation of these requirements is Good Agricultural and Collection Practices (GACP), a regulatory framework ensuring quality control in the cultivation and collection of medicinal plants. However, a large number of hemp cultivators do not hold GACP certification, creating significant risks for manufacturers, healthcare providers, and consumers.

### What Is Full Traceability and Why Does It Matter?

Full traceability refers to the ability to track a product through every stage of its lifecycle—from cultivation and harvesting to processing, manufacturing, and

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### THIS WHITE PAPER EXPLORES:

- The importance of GACP compliance for pharmaceutical-grade hemp
- The challenges associated with full traceability in hemp manufacturing
- The risks of sourcing from non-GACP-certified cultivators
- How Benuvia ensures regulatory compliance, safety, and quality in its hemp API sourcing





final distribution. In pharmaceutical manufacturing, traceability is not just a best practice—it is a regulatory mandate designed to:

- Prevent contamination from pesticides, heavy metals, and microbes
- Ensure product quality and consistency by standardizing cultivation and processing
- Protect consumers from mislabeled or unsafe products
- Enable manufacturers to investigate product defects or adverse reactions quickly.

### **Why This Matters for Hemp-Based Pharmaceuticals**

Hemp-derived pharmaceuticals must meet the same stringent standards as any other API used in drug manufacturing. This requires a documented, verifiable chain of custody for every raw material used in pharmaceutical production.

However, in the broader hemp industry, many cultivators do not adhere to standardized traceability requirements. Third-party testing alone is not enough—as numerous reports have shown mislabeling, contamination, and potency inconsistencies in hemp products across the U.S. ([FDA, 2023](#)).

A 2022 study by Johns Hopkins Medicine found significant evidence of inaccurate and misleading labeling of over-the-counter CBD products, with some containing undisclosed THC levels and others making unapproved therapeutic claims. ([hopkinsmedicine.org](#))

## **UNDERSTANDING GACP COMPLIANCE FOR HEMP**

### **What Is GACP and Why Is It Critical for Hemp?**

Good Agricultural and Collection Practices (GACP) is an internationally-recognized framework that ensures consistent quality, safety, and traceability in the cultivation and collection of medicinal plants, including hemp for pharmaceutical use. Unlike general hemp farming—which lacks stringent oversight—GACP establishes a structured, documented approach to managing agricultural risks and maintaining consistency in active pharmaceutical ingredients (APIs).

In the U.S., GACP certification is not a legal requirement for hemp cultivators, leading many to bypass these crucial standards in favor of cost-cutting measures. However, pharmaceutical companies operating under cGMP regulations require GACP-compliant raw materials to ensure their APIs meet regulatory expectations.

A 2020 article from Cannabis Science and Technology highlights how the lack of uniform GACP implementation in the hemp and cannabis industries has led to significant variability in quality and safety. The article emphasizes that





without strict agricultural oversight, hemp products often contain inconsistent cannabinoid profiles, residual pesticides, and microbial contamination, making GACP adherence essential for pharmaceutical applications ([Cannabis Science and Technology, 2020](#)).

**Key Requirements of GACP for Hemp Cultivation**

For a hemp grower to be GACP-compliant, they must adhere to the following:

- *Seed-to-Harvest Documentation* – Maintaining accurate, traceable records for all cultivation inputs, including seed genetics, soil treatments, fertilizers, and pest management strategies.
- *Controlled Growing Conditions* – Regulating factors such as soil quality, irrigation methods, and pesticide application to prevent contamination and ensure batch consistency.
- *Harvesting and Collection Protocols* – Implementing standardized harvesting techniques to minimize exposure to microbial contamination and degradation.
- *Post-Harvest Handling & Storage* – Following strict guidelines for drying, curing, and storing hemp biomass to preserve cannabinoid content and prevent mold, bacterial growth, or cross-contamination.
- *Personnel Training & Compliance* – Ensuring all farm personnel are trained in proper handling procedures, sanitation, and regulatory requirements to prevent unintentional contamination.
- *Independent Testing & Audits* – Conducting routine laboratory testing for potency, heavy metals, pesticides, and microbial contaminants under validated analytical methods.

**GACP VS. NON-GACP CULTIVATION**

ATTRIBUTE	GACP CULTIVATION	NON-GACP CULTIVATION
<b>Documentation</b>	✔ Strict Documentation & Traceability	✘ No to Minimal Documentation
<b>Contamination Risk</b>	✔ Controlled Pesticide Use & Testing	✘ High Contamination Risk
<b>Consistency</b>	✔ Validated Potency & Purity Testing	✘ Inconsistent Potency & Quality
<b>Regulatory Compliance</b>	✔ Regulatory Approval for Pharmaceutical Use	✘ Frequent Regulatory Rejection





### How GACP Enhances Pharmaceutical-Grade Hemp

Pharmaceutical-grade hemp APIs require absolute consistency in cannabinoid composition and freedom from contaminants. By adhering to GACP standards, cultivators can:

- Ensure uniform cannabinoid content across all harvested batches
- Reduce the risk of heavy metal, pesticide, and microbial contamination
- Improve regulatory acceptance for downstream processing in pharmaceutical applications
- Meet international pharmaceutical API sourcing requirements

### Why Most Hemp Cultivators Are Not GACP Certified

Despite these advantages, most U.S. hemp cultivators are not GACP certified due to lack of enforcement and cost barriers. The Cannabis Science and Technology article further explains that many hemp growers focus on maximizing yields rather than adhering to agricultural best practices, leading to significant inconsistencies in cannabinoid potency and product purity ([Cannabis Science and Technology, 2020](#)).

Additionally, the FDA's 2022 CBD Product Sampling Study revealed that many hemp-derived CBD products contain either excessive THC or significantly lower CBD levels than advertised, raising concerns about poor-quality control in non-GACP-compliant operations.





**RISK MATRIX FOR  
NON-GACP HEMP  
CULTIVATION**

**THE RISKS OF SOURCING FROM NON-GACP HEMP CULTIVATORS**

**How Non-GACP Hemp Puts Consumers and Businesses at Risk**

Hemp that is cultivated without adherence to GACP standards poses significant risks to both pharmaceutical manufacturers and consumers.

ATTRIBUTE	LIKELIHOOD	SEVERITY	DESCRIPTION
Mislabeling Risk	HIGH	HIGH	Incorrect CBD/THC content due to poor documentation.
Contamination Risk	HIGH	HIGH	Heavy metals, pesticides, and microbial contamination pose serious health hazards.
Consumer Safety Risk	MODERATE	HIGH	Unverified product purity can lead to adverse health effects.
Regulatory Risk	LOW	HIGH	Failure to meet FDA standards leads to product recalls or bans.
Inconsistent Potency	HIGH	MODERATE	Fluctuating cannabinoid levels affect product efficacy and consumer trust.
Legal Liability	MODERATE	HIGH	Non-compliance can result in lawsuits, regulatory fines, and reputational damage.

Without proper traceability and oversight, non-GACP hemp is more likely to contain:

- *Inconsistent Cannabinoid Content* – Variability in plant genetics, growing conditions, and processing methods leads to fluctuations in potency from batch to batch, making it impossible to ensure accurate dosing in pharmaceutical applications.
- *Pesticide and Heavy Metal Contamination* – Many hemp growers do not follow strict soil testing or pesticide application guidelines, leading to dangerous levels of contaminants that can pose serious health risks when consumed in medical treatments.
- *Microbial Contamination* – Improper harvesting and storage conditions promote the growth of bacteria, mold, and fungi, which can be hazardous to immunocompromised patients who rely on pharmaceutical-grade hemp APIs.
- *Regulatory Non-Compliance* – Without proper agricultural documentation, non-GACP hemp fails to meet pharmaceutical regulatory requirements, leading to product rejections, recalls, and legal liabilities.
- *Mislabeled or Misrepresented Products* – A study conducted by Johns Hopkins Medicine in 2022 found that a large percentage of CBD products sold online and in stores were inaccurately labeled, with some containing undisclosed THC levels, while others contained no CBD at all, demonstrating major failures in product consistency and safety ([Johns Hopkins Medicine, 2022](#))





### **FDA Crackdowns on Non-Compliant Hemp Products**

The FDA has repeatedly issued warnings to hemp product manufacturers for mislabeling, misleading health claims, and unsafe contaminants.

- A 2022 FDA enforcement action revealed that more than 25% of CBD products tested contained incorrect potency levels or failed safety testing for contaminants.
- The FDA issued multiple warning letters in 2023 to companies marketing hemp-derived products with unproven medical claims, stating that such violations pose a risk to consumers who may use these products instead of FDA-approved treatments ([FDA, 2023](#)).

### **The Business Risk of Using Non-GACP Hemp in Pharmaceuticals**

For pharmaceutical manufacturers, sourcing non-GACP hemp creates enormous risks that go beyond consumer safety. These risks include:

- *Failed Quality Audits* – Regulatory agencies like the FDA and DEA require full traceability and adherence to cGMP. Non-GACP hemp fails to meet pharmaceutical traceability standards, leading to audit failures and potential loss of manufacturing licenses.
- *Market Rejections & Product Recalls* – Hemp-derived pharmaceutical products that fail to meet GACP standards risk denial of regulatory approvals, import/export bans, and expensive product recalls.
- *Legal Liability & Brand Damage* – Companies that use subpar hemp face class action lawsuits, consumer distrust, and reputational damage. Pharmaceutical companies must ensure they only work with GACP-certified hemp cultivators to mitigate these risks.

## **BENUVIA'S COMMITMENT TO FULL TRACEABILITY AND GACP COMPLIANCE**

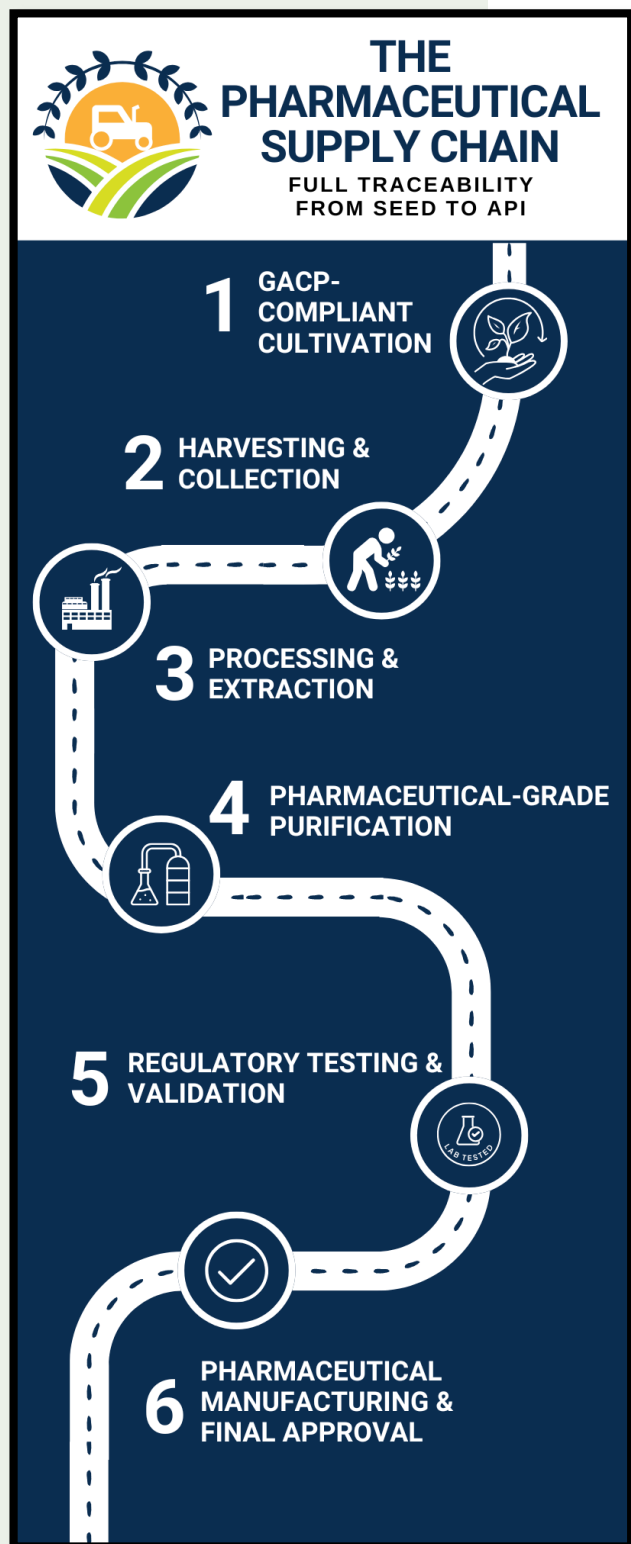
### **Why Full Traceability Matters for Pharmaceutical-Grade Hemp**

At Benuvia, we recognize that ensuring pharmaceutical-grade quality starts at the source. Unlike nutraceutical and consumer hemp products, which often lack rigorous oversight, our approach is rooted in full traceability and adherence to GACP standards.

We believe that GACP compliance is not optional for pharmaceutical applications—it is the foundation of patient safety, regulatory compliance, and product consistency. Every step of our hemp sourcing, processing, and API manufacturing follows a meticulously documented chain of custody to ensure:

- Hemp biomass meets strict GACP cultivation standards
- All raw materials are traceable from seed to finished product
- Quality control measures prevent contamination or variability
- Regulatory expectations for pharmaceutical-grade APIs are exceeded





According to the U.S. Pharmacopeia (USP) Cannabis Monograph, strict traceability and GACP compliance are critical for ensuring pharmaceutical cannabinoids meet safety and efficacy requirements ([USP, 2023](#)).

### How Benuvia Ensures Compliance and Safety

At Benuvia, we have established a comprehensive supply chain that guarantees the highest standards of quality and safety:

- *GACP-Compliant Supplier Qualification* – We rigorously vet and audit all hemp cultivators to ensure full adherence to GACP guidelines before integrating them into our supply chain.
- *Seed-to-Finished-Product Traceability* – Every batch of hemp-derived API is fully documented, including seed genetics, cultivation conditions, processing records, and lab test results.
- *FDA & DEA Oversight* – As a cGMP-compliant pharmaceutical API manufacturer, Benuvia operates under FDA and DEA regulatory oversight, ensuring all manufacturing and testing procedures meet the highest industry standards.
- *Validated Analytical Testing Methods* – Unlike many third-party labs that lack standardized testing protocols, we use validated methods for potency, purity, heavy metals, pesticides, residual solvents, and microbial contaminants.

A 2023 study published in the Journal of the American Medical Association (JAMA) found that 75% of hemp-derived products purchased online had inaccurate potency labeling, reinforcing the urgent need for pharmaceutical-grade quality control ([JAMA, 2023](#)).

### How Benuvia Sets the Standard in Hemp API Manufacturing

By adhering to GACP and cGMP standards, Benuvia delivers APIs that are:

- Pharmaceutical-grade and fully compliant with regulatory expectations
- Backed by robust quality control and full traceability
- Safe, effective, and consistent in potency and purity

Our commitment to GACP compliance, full traceability, and regulatory excellence ensures that Benuvia's hemp-derived APIs set the gold standard for pharmaceutical applications.





### Benuvia's Commitment to Raising Industry Standards

At Benuvia, we are committed to:

- Educating the industry on the importance of GACP compliance
- Ensuring pharmaceutical-grade safety and efficacy in all hemp APIs
- Providing full traceability from seed to finished product
- Leading the way in regulatory compliance and quality assurance

**Disclaimer:** This white paper is for informational purposes only and is not intended as medical advice. Always consult with a qualified healthcare professional before using any CBD or hemp-derived products.

### CONCLUSION: WHY GACP COMPLIANCE IS ESSENTIAL FOR PHARMACEUTICAL-GRADE HEMP KEY TAKEAWAYS

The hemp industry is at a crossroads—with pharmaceutical manufacturers demanding higher quality and greater traceability, while many cultivators continue to operate without GACP compliance. As this white paper has shown:

- GACP is critical for ensuring safe, consistent, and pharmaceutical-grade hemp products
- Many hemp cultivators do not follow GACP standards, leading to inconsistent potency, contamination risks, and regulatory concerns
- Consumers are often misled by inaccurate product labeling and unverified third-party testing
- Regulators are increasing scrutiny on hemp-derived products that fail to meet quality and safety expectations
- Benuvia sets the industry standard by adhering to full traceability, GACP compliance, and cGMP manufacturing

#### The Future of Hemp in Pharmaceuticals

As regulatory bodies such as the FDA, USP, and DEA continue to refine quality expectations for pharmaceutical hemp-derived APIs, companies that fail to comply with GACP and full traceability requirements will struggle to remain competitive.

The U.S. Hemp Authority's 2023 Industry Report predicts that pharmaceutical demand for hemp APIs will significantly outpace demand for consumer CBD products, but only GACP-compliant suppliers will be eligible for pharmaceutical partnerships ([U.S. Hemp Authority, 2023](#)).

#### Final Thought: Why Traceability Matters

Pharmaceutical manufacturers cannot afford to take risks when it comes to sourcing hemp-derived APIs. GACP compliance is not a marketing term—it is the foundation of pharmaceutical safety, regulatory approval, and patient trust.

Benuvia is proud to be at the forefront of this movement, ensuring that every hemp-derived API we produce meets the highest pharmaceutical standards in the world.

### 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 Process Development, clinical trial supply to commercial production.

Visit us at [www.benuvia.com](http://www.benuvia.com)

