Cannabinoid Hemp Processor Good Manufacturing Practices (GMP) Audit Guidance

Document Purpose

This document is intended to provide cannabinoid hemp processors with an understanding of the requirement to obtain a Good Manufacturing Practices (GMP) audit, why this requirement exists, what information will be necessary, and to provide information about the Third Party GMP Auditor Application Form at https://www.health.ny.gov/forms/doh-5764.pdf

Key Terms and Definitions

Accreditation Body	is an authoritative body that accredits certification bodies, in which they provide formal recognition of competence to perform third-party GMP audits or certification.
Cannabinoid Hemp Processor	means a person or entity licensed by the Department of Health to extract hemp extract and/or manufacture cannabinoid hemp products, whether in intermediate or final form, to be used for human consumption.
Cannabinoid Hemp Processor Certificate	is an official document, form or letter that cannabinoid hemp processors are granted by a certification body upon successful completion of a passing third-party GMP audit or certification.
Certification Body	is a business that employs specialists to conduct third-party GMP audits or certification. A certification body assesses, verifies, and attests in writing by issuing a certificate, that the cannabinoid hemp processor facility operations meet GMP requirements. Certification bodies are accredited (approved) by an accreditation body.
Good Manufacturing Practices (GMP, or cGMP for current Good Manufacturing Practices)	is a quality control system for ensuring that products are consistently produced and controlled in accordance with current federal regulations 21 CFR Parts 111 or 117 established by the Food and Drug Administration (FDA). The Department may accept auditing standards or other certifications that incorporate GMP requirements.
Third-Party GMP Audit or Certification	is a systematic independent and documented activity conducted by an accredited certification body, in which objective evidence is gathered and assessed to determine if a cannabinoid hemp processor's facility operation meets GMP standards. Upon successful completion of the audit, processors will be granted a certificate.
Standard operating procedures (SOPs)	are step-by-step instructions for performing operational tasks or activities, designed to increase performance, improve efficiency, and ensure quality.

Cannabinoid Hemp Processor Third Party GMP Overview

Cannabinoid Hemp Processors are required to follow GMP when extracting and/or manufacturing cannabinoid hemp products. All cannabinoid hemp products must be manufactured to the applicable product type (e.g. products marketed as food must be manufactured according to 21 CFR Part 117, while products marketed as dietary supplements must be manufactured according to 21 CFR part 111).

As part of the Cannabinoid Hemp Processor application process, applicants must provide evidence of GMP to the Department of Health (Department), by obtaining a Third-Party GMP Audit or Certification of their extracting and/or manufacturing facility operations. If evidence is not available at the time of application, the applicant must provide a detailed plan for obtaining a Third-Party GMP Audit or Certification within six months of receiving temporary license approval from the Department. Final licensure as a Cannabinoid Hemp Processor will not be issued without proof of a GMP audit. Such audits or certifications must be conducted by an accredited, third-party Certification Body to the satisfaction of the Department.

Pursuant to the regulations (https://health.ny.gov/regulations/hemp/) Cannabinoid Hemp Processors must maintain GMP standards and qualified third-party certification of their extraction and/or manufacturing facility operations for the duration of the license period (two-years). Cannabinoid Hemp Processors will be required to submit an updated GMP audit or certification for each license renewal.

Question: What is the purpose of the Third-Party GMP Audit or Certification?

Good Manufacturing Practices are quality control systems for ensuring that products are consistently produced and controlled according to current federal regulations established by the Food and Drug Administration. For the Cannabinoid Hemp Program, the most relevant GMPs are 21 CFR Part 117 which outlines requirements for food products and 21 CFR Part 111 which outlines requirements for dietary supplement products. Upholding GMP standards helps maintain consumer protections by ensuring that cannabinoid hemp products are produced in a manner that safeguards against potential hazards to the product. Requiring a Third-Party GMP Audit or Certification is a statement to consumers and the general public that New York State Cannabinoid Hemp Processors are committed to the highest level of health, safety, and sanitation standards. Benefits of following GMP standards include:

- Reduction in failed product testing;
- Improvement of product safety;
- Improvement of product quality and consistency;
- Elimination of potential risks and possible recalls;
- Advantages over competitors and other processors who are not following GMP standards; and
- Increased consumer confidence.

Question: What are the requirements for a Third-Party Audit or Certification?

GMPs can be broken into six major sections: (1) Management Commitment; (2) Risk Management; (3) Quality Management Systems; (4) Site & Facility Management; (5) Product Controls; and (6) Staff Training.

Typically, GMP audits must include the following technical requirements, which are explained in more detail on the Cannabinoid Hemp Third Party GMP Auditor Application Form at https://www.health.ny.gov/forms/doh-5764.pdf

- Complaint Management
- Regulatory Compliance
- Hazard Analysis Critical Control Point (HACCP)
- Document Control and Record-Keeping
- Hold and Release Controls
- Product Identification and Traceability
- Recall Program
- Corrective Actions and Preventative Actions
- Risk-based Preventative Controls
- Verification and Validation
- Crisis Management
- Packaging and Labeling Controls
- Supplier Controls
- Personnel Practices (cGMP/cGAP)
- Allergen Management
- Product Testing
- Environmental Monitoring
- Internal Audits
- Storage and Distribution Controls
- Equipment and Utensils
- Water Safety and Quality Management
- Air Safety and Quality Management
- Waste Management
- Pest Control
- Cleaning and Sanitation Controls/Operations
- Chemical Controls
- Employee Training

How to obtain a Third-Party GMP Audit or Certification

Step 1: Ensure your facility meets the basic FDA facility requirements before moving towards GMP requirements.

Step 2: Select a GMP accredited Certification Body. Keep in mind that although each Certification Body abides by FDA GMP requirements, each company may have their own additional requirements.

Step 3: Create SOPs and documentation per GMP guidelines. Documentation provides the route for auditors to assess the overall quality of operations within a company, the final product, and ensures traceability of all development, manufacturing, and testing activities.

Step 4: Implementation is a vital step; most Certification Bodies will make sure employees are following the SOPs and documents without deviation. Make sure all facility practices are finely tuned and are practiced habitually prior to the auditor visit.

Step 5: Pass the certifying audit and receive GMP certification. After creating plans, implementing plans, and completing employee training, you are ready for an audit by the selected certification body. In the event the auditor finds deficiencies, a corrective action plan may be required for a GMP certificate to be granted.

Department-Approved Accreditation Bodies

For a Third-Party GMP Audit or Certification to be accepted by the Department, Certification Bodies must be accredited and meet the requirements indicated on the Cannabinoid Hemp Third-Party GMP Auditor Application Form at https://www.health.ny.gov/forms/doh-5764.pdf. Please note, that many certification programs or standards incorporate GMP requirements into their certifications.

Certification Bodies are accredited (approved) by an Accreditation Body, to ensure their internal procedures and audit processes follow strict guidelines for different audit standards. Accreditation Bodies accepted by the Department include but are not limited to*:

- **International Standards Organization (ISO)**
- **American National Standards Institute (ANSI)**
- **ANSI-ASQ National Accreditation Board (ANAB)**

*To propose an alternate Accreditation Body please e-mail: hemp@health.ny.gov

Department-Approved GMP Certification Bodies

Certification Bodies accepted by the Department may be found on our webpage: www.health.ny.gov/hemp

To propose an alternate Certification Body please e-mail a completed Cannabinoid Hemp Third-Party GMP Auditor Application Form to: hemp@health.ny.gov

Program Contact Information

For more information about the NYS Department of Health Cannabinoid Hemp Program please visit:

https://www.health.ny.gov/regulations/hemp/

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