NEW YORK STATE | Office of Cannabis Management

Cannabinoid Hemp Program

Cannabinoid Hemp Third Party GMP Auditor Application Form

Document Purpose

Current NYS Office of Cannabis Management (Office) regulations require Cannabinoid Hemp Processors acquire a third-party GMP audit of their extraction and/or manufacturing facilities. Processors must manufacture cannabinoid hemp products in accordance with applicable Good Manufacturing Practices (GMP) standards (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). Such audits must be performed to the satisfaction of the Office by a qualified, independent third-party Certification Body. Third-Party Auditors who want to be listed on the Office's approved list of GMP auditors should fill out this form.

General Instructions for the Application Form

This form, along with the following application materials, must be submitted in order for the Office to accept the GMP Audit:

- Evidence for each Applicable Question
- Copy of GMP Audit Checklist(s)
- Copy of GMP Audit Template or Scheme

When completing your application form, please follow the instructions listed below:

- Please complete ALL items on the form unless otherwise instructed. Failure to complete all required fields will result in your application form being returned.
- The signature field must be completed, and the signature must be an original signature. Initials or rubber-stamped signatures will not be accepted.
- Type or legibly print in black or blue ink. Do not use red ink, nor white-out. All attachments will be scanned so they must be legible and on standard 8.5 x 11 paper in good condition.
- Keep a copy of all documents submitted.

If you have any questions or concerns, please contact the NYS Cannabinoid Hemp Program by calling 866-NYS-HEMP (866-697-4367) or e-mail: hemp@ocm.ny.gov

Required Application Materials

- Evidence for each Applicable Question
- Copy of GMP Audit Checklist(s)
- Copy of GMP Audit Template or Scheme

Submission Instructions

Please submit the completed Cannabinoid Hemp Third-Party GMP Auditor Application Form and all supporting documentation via non-secure e-mail attachment to hemp@ocm.ny.gov with the subject line: "Cannabinoid Hemp Third-Party GMP Auditor Application Form."

SECTION I: Contact Information

Third-Party GMP Certification Auditor General Information

Company Name: _____

Doing Business As (DBA) Name (if applicable): _____

Business Street Address (PO Box not acceptable): _____

City: _____ State: _____ ZIP Code: _____ Country: _____

Company Website: _____ Phone Number: _____

Main Contact Person

Full Name: _____ Title: _____

E-mail Address: _____ Phone Number: _____

SECTION II: Third Party - GMP Certification Auditor Operation

Organization Overview

1. What product type(s) do you offer GMP certification for? Please check all that apply.

- ☐ Food or Beverage
- ☐ Dietary Supplement (Tincture/Oil, Pill/Capsule, Chewable/ Tablet)
- ☐ Topical (Balm, Lotion, Salve)
- ☐ Cannabinoid Hemp-Specific (e.g. Flower, Oil for Vaporization)
- ☐ Other, please specify:

2. What is the name of the certification standard(s)/scheme being used? Please list all that apply and attach a copy of the standard(s)/scheme.

3. What organization(s) are you accredited by? Please attach a copy or proof of accreditation or relevant documentation indicating you are qualified to conduct the audit. Common accreditation bodies include, International Standards Organization (ISO), American National Standards Institute (ANSI), and ANSI-ASQ National Accreditation Board (ANAB).

4. What state(s) do you currently certify processors in?

5. How will you conduct certification? Please check all that apply.

- ☐ In-Person
- ☐ Remote
- ☐ Hybrid

SECTION III: Third-Party GMP Certification Auditor Requirements

Requirements – Please attach a copy of the GMP Audit Checklist(s).
Please reference the section in the audit checklist where the following requirements are met.
If a requirement does not apply to your audit, please check off 'N/A' and explain.

Audit requirements include a provision for:	Requirement met:	N/A
1. the management of complaints and trending complaint data.	☐	☐
2. meeting state and local requirements.	☐	☐
3. a Hazard Analysis Critical Control Point (HACCP) system based on the 12 steps of the Codex Alimentarius.	☐	☐
4. document controls and record keeping.	☐	☐
5. holding and releasing products out of specification and products waiting on finished product testing.	☐	☐
6. identifying and tracing raw materials, works in progress (WIP), and finished products throughout the entire process.	☐	☐
7. a recall program that requires at least annual testing of the program.	☐	☐
8. implementing and tracking corrective actions and preventative actions.	☐	☐
9. implementing and tracking risk-based preventative controls.	☐	☐
10. validation and verification activities.	☐	☐
11. crisis management planning.	☐	☐
12. ensuring packaging and labeling requirements are met and do not pose a risk to consumers.	☐	☐
13. controlling and approving all suppliers of raw materials.	☐	☐
14. ensuring personnel are following cGMPs and/or cGAPs.	☐	☐
15. allergen management.	☐	☐
16. finished product testing through ISO/IEC 17025 accredited labs or labs approved to test Cannabinoid Hemp in NYS.	☐	☐
17. environmental monitoring and identifying indicator organisms specific to the facility's processes.	☐	☐
18. conducting, at minimum, one internal audit annually.	☐	☐
19. storage and distribution controls.	☐	☐
20. equipment and utensil controls.	☐	☐

SECTION III continued

Audit requirements include a provision for:	Requirement met:	N/A
21. managing the safe supply of any water used onsite. At a minimum, the requirements should consist of annual testing of the facility's water supply and the use of potable water.	☐	☐
22. managing the safety and quality of the air in processing environments.	☐	☐
23. waste disposal, including requirements for both cannabis waste and regular waste.	☐	☐
24. controlling pests.	☐	☐
25. cleaning and sanitation controls.	☐	☐
26. the control of all chemicals used onsite.	☐	☐
27. training of all employees involved with the safety and quality of cannabis products.	☐	☐

SECTION IV: Signature and Affirmation

By signing this application form to be qualified as a third-party GMP Certification Auditor in the New York State Cannabinoid Hemp Program, the Applicant understands and agrees to the following:

- The Office may request additional or follow-up information relating to answers or attachments provided in this application.
- The information contained in this application is true and accurate. The Office, in its discretion, may reject or deny an application if it determines that information contained therein is false, inaccurate or contains an omission of a material fact. False statements made herein are punishable as a class A misdemeanor pursuant to § 210.45 of the Penal Law.
- The applicant has read and understands the requirements for Cannabinoid Hemp Processors set forth in the current regulations governing the New York State Cannabinoid Hemp Program.
- The applicant will audit processors according to Good Manufacturing Practices standards as outlined in Parts 101, 111 and 117 of Title 21 Code of Federal Regulations, depending on the processor's final product.
- The applicant will maintain all records for at least five years from the date of the transaction and make such records available, upon request, to the Office, the Office's authorized representative, or to state or local law enforcement of the competent jurisdiction.

☐ **I hereby certify that the information provided in this form, is truthful and accurate to the best of my knowledge. I understand that any material omissions, material errors, false statements, misrepresentations, or failure to provide any requested information may result in action as may be allowed by law.**

Signature _____ Date (MM/DD/YYYY) _____

Print Name _____ Title _____