Document Purpose

This document is intended to:

1. Provide Adult Use Cannabis licensees and Registered Organizations with an understanding of the requirements to process cannabis in accordance with Good Manufacturing Practices (GMP),
2. Explain regulatory requirements for GMP audits, and
3. Summarize conditional exemptions that may be requested to the GMP audit requirement.

Section 123.6(a) of Title 9 NYCRR outlines the rules for Good Manufacturing Practices (GMP) for adult use cannabis processors, and Section 113.12 of Title 9 NYCRR for Registered Organizations, to promote quality and safety of the cannabis products they make.

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.
Adult Use Licensee	means a person or entity licensed by the Office.
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 Adult-Use cannabis processor facility or Registered Organization operations meet GMP requirements.
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).
Registered Organizations	are organizations registered under article 3 of the Cannabis Law that are responsible for manufacturing and dispensing medical cannabis in New York State.
Standard Operating Procedures (SOPs)	are established and prescribed methods that include documented step by step instructions for performing operational tasks or activities, designed to ensure quality and consistency, in accordance with the cannabis laws and regulations.
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 an Adult-Use cannabis processor's or Registered Organization's facility operation meets GMP standards. Upon successful completion of the audit, processors will be granted a certificate.
Other Common Terms	GMP FAQ

1. Processing Cannabis in Accordance with GMP Requirements

Good Manufacturing Practices (GMP) 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. Processing of Adult-Use and Medical cannabis products in accordance with GMP standards helps to safeguard cannabis products against potential hazards, promoting health and safety of consumers.

Pursuant to §123.6(a)(1) and §113.12(d)(2), all adult use cannabis products and medical use cannabis products respectively, must be processed in accordance with GMP standards, as applicable for the type of cannabis or cannabis product being processed. All licensees or registrants must maintain GMP standards in their processing facility operations for the duration of the license period (two-years). There are NO exceptions to the requirement to process cannabis in accordance with GMP requirements.

Please refer to 21 CFR Part 111 and Part 117 to review and understand the difference between each GMP standard. **A major difference between these GMP standards is that 21 CFR Part 111 addresses dietary supplements and 21 CFR Part 117 addresses human food.** According to **21 CFR 111.3**, a dietary supplement is defined as a product intended to supplement the diet that contains one or more of the following:

- A vitamin
- A mineral
- An herb or other botanical
- An amino acid
- A dietary substance for use by people to supplement the diet by increasing the total daily intake
- A concentrate, metabolite, constituent, extract, or combination of the above

According to **21 CFR 117.3**, human food is defined as food for humans and includes:

- Raw materials and ingredients
- Foods and ingredients
- Any combination of these components consumed by humans

The focus of CFR 117 is on the safety of human food through preventive controls, hazard analysis, and a comprehensive food safety plan.

For more information, please refer to GMP FAQs by clicking here: GMP FAQ

2. GMP Audit Requirements

A Third-Party GMP Audit or Certification helps to validate that New York State Licensed Adult-Use Cannabis Processors and Registered Organizations are demonstrating health, safety, and sanitation standards. Pursuant to Sections 123.6 and 113.12 of Title 9 regulations, Adult Use Cannabis licensees and Registered Organizations respectively, are authorized to conduct certain processing activities as determined by the Office, and shall establish compliance with GMP standards by submitting to the Office proof of a qualified third-party GMP audit, of the licensee's extraction and/or manufacturing processes as applicable, to the satisfaction of the

Office, within 1 year of commencing licensed operations. Third-party GMP audits or certifications must be conducted by an accredited, third-party certification body to the satisfaction of the Office.

All processors are required to submit to the Office proof of a qualified third-party GMP audit, unless the processing activity is limited to the activity included below and the licensee obtained prior written approval from the Office by completing the waiver process outlined in Section 3 of this document.

Adult Use Cannabis licensees and Registered Organizations who are required to provide proof of a qualified third-party GMP audit will also be required to submit an updated GMP audit or certification for each license renewal.

GMPs consist of 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:

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

3. GMP Audit Conditional Exemption Requests

Pursuant to §123.6(a)(2), a licensee who is authorized to conduct certain processing activities as determined by the Office shall establish compliance with GMP standards by submitting to the Office proof of a qualified third-party GMP audit, of the licensee's extraction and/or manufacturing processes as applicable, to the satisfaction of the Office, within one (1) year of commencing licensed operations. The Office shall determine which third-party GMP auditors are authorized and qualified.

Adult-Use Cannabis Type 3 processor licensees and **microbusiness licensees** may request a conditional exemption from submitting a full qualified third-party GMP audit, provided that their processing activities are limited to the following:

- Packaging, labeling, and branding of whole flower with no further grinding of cannabis on site.
- Packaging, labeling, and branding of non-infused pre-rolls provided that the flower is purchased pre-ground and no grinding of cannabis is conducted by the licensee.
- Packaging, labeling, and branding of kief that may be pressed into pucks using a punch press providing no grinding of cannabis is conducted by the licensee.
- Grinding of cannabis flower is not an activity that will be considered for GMP audit exemption due to employee protection concerns.

Licensees may request a conditional exemption here.

Note:
Conditional exemptions apply exclusively to the product types and activities listed above and are contingent upon the licensee's submission of a waiver request in accordance with the specified requirements, along with written approval from the Office. If licensees engage in any additional processing activities or handle different product types beyond those specified, they are no longer exempt and must undergo a GMP audit and certification, following the aforementioned procedures.

An approval to exempt a qualified third-party audit does not relieve the licensee's requirement to follow and execute the required GMP standards for the cannabis product type being processed.

How do I submit proof of my audit to the office?

Please submit proof of your third-party GMP Audit to compliance@ocm.ny.gov and include in the subject line: License number and GMP Audit Certificate

Who is qualified to conduct the audit?

Third-party GMP audits must be conducted by an accredited, third-party certification body. A list of GMP Auditors who have been authorized by the Office can be found here: https://cannabis.ny.gov/gmp-auditors. In order for the Office to accept a licensees' proof of GMP audit, the audit must be conducted by an Office authorized auditor. If the auditor is not listed as an authorized GMP auditor, please contact Compliance at compliance@ocm.ny.gov.