What is GMP?

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.

Who is Required to Follow GMP?

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).

Are There Exceptions to Following GMP?

There are NO exceptions to the requirement to process cannabis in accordance with GMP requirements.

Who is Required to have a GMP Audit?

Adult Use Cannabis licensees and Registered Organizations authorized to conduct certain processing activities as determined by the Office shall establish compliance with GMP standards by submitting proof of a qualified third-party GMP audit within 1 year of commencing licensed operations.

Who Can Conduct a GMP 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 licensee's 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

Why Must I have a GMP Audit?

A Third-Party GMP audit or certification helps validate that New York State Licensed Adult-Use Cannabis Processors and Registered Organizations are demonstrating practices that uphold of health, safety, and sanitation standards.

Are There Any Exceptions to the GMP Audit Requirement?

Adult-Use Cannabis Type 3 processor licensees and microbusiness licensees may request a conditional exemption under certain conditions, such as limited processing activities related to packaging, labeling, and branding of specified products. Conditional exemptions apply exclusively to the listed product types and activities below and are contingent upon submission of a conditional exemption request and written approval from the Office.

To request a conditional exemption from a full qualified third-party GMP audit, processing activities must be limited to the following:

- Packaging, labeling, and branding of whole flower with no further grinding on site.
- Packaging, labeling, and branding of non-infused pre-rolls provided that the flower is purchased pre-ground, and no grinding 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 an exemption by filling out the waiver request form by clicking here.

How Do I Know Which GMP Standard I must Follow When Processing?

The determination between Part 111 and Part 117 GMP standards is primarily based on the intended use of the cannabis product. Part 111 specifically addresses the manufacturing, packaging, labeling, and holding operations of dietary supplements; while Part 117 emphasizes current Good Manufacturing Practices (cGMP) for human food and a wide range of food products consumed by humans.

When deciding which standard applies to your cannabis products, consider their intended use. If the products are designed to supplement the diet, such as capsules, tinctures, or similar ingestible forms, they would align with the standards outlined in Part 111.

How do I submit proof of my third-party GMP audit for Office approval?

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

If I received a GMP audit last year will that cover my submission or does the audit need to be conducted in the period of licensure?

If you received a GMP audit last year, and it was within the required timeframe (i.e., within one year of commencing operations or within one year of the previous license renewal), then it should still be valid for your current submission,

However, if you are approaching or have reached the end of your two-year licensure period, another audit will be required within one year of your license renewal.

Who do I contact with questions regarding GMP requirements of the Office?

Please email compliance@ocm.ny.gov with any questions you may have.