

How To Guide for Kentucky Cannabis Business GMP Requirements

This quick reference guide provides a summary of the good manufacturing requirements established by the following:

Applicable regulations

- ▶ Current Good Manufacturing Practices (**CGMPs**) 21 CFR 117 subparts A, B, C, F, and G.
- ▶ **902 KAR 45:160: Sections 4, 5, 6, 7, 8, 9, 10, 11, and 14.**
- ▶ **915 KAR 1:040: Section 1(1)(a) and (b), Section 2(1), (2), (4), and (6) through (21), and Section 3.**

Contact the Kentucky Drug and Supplement Branch to set up an opening inspection: drug.supplement@ky.gov

Building and fixtures requirements

Processing facilities must meet the following requirements:

- ▶ Be connected to a municipal water source or have a water supply approved by the Kentucky Division of Water.
- ▶ Be connected to a municipal sewer or an approved onsite septic system.
- ▶ Be constructed of smooth, non-absorbent, and easily cleanable materials designed to be insect/rodent-proof.
- ▶ Plumbing plans must be approved by the Kentucky Division of Plumbing with fixture requirements (at minimum) including:
 - ✓ A hand wash sink in the preparation area, utensil wash area, and in each restroom;
 - ✓ A three-compartment sink with drain-boards for washing utensils;
 - ✓ A utility/mop sink; and
 - ✓ Restroom facilities

All new or renovated facilities must submit plumbing plans for review through the area's Local Health Department.

Find your Local Health Department using the [Local Health Department Listing](#) available through the Cabinet for Health and Family Services website at <https://chfs.ky.gov>.

Training requirements

Training is required for all employees working in the cannabis processing and manufacturing facilities.

The following applies to all stages, from processing to packaging:

- ▶ Management is required to ensure that all employees who manufacture, process, pack, or hold cannabis are qualified to perform their assigned duties.
- ▶ Employees must receive training in the principles of hygiene and product safety, including the importance of employee health and hygiene as appropriate to the cannabinoid products, the facility, and the individual's assigned duties.
- ▶ Records documenting training for each employee must be maintained

Hazard analysis and preventative controls

A processing facility must conduct a hazard analysis in accordance with 902 KAR 45:160 Section 2(1)(u) to identify and evaluate, based on experience, illness data, scientific reports, and other information known, or reasonably foreseeable hazards associated with each type of cannabinoid product produced by extraction, conversion, catalyzation, distillation, hydrogenation, or other refinement processes, and must include:

- ▶ Processing reagents or catalysis;
- ▶ Processing by-products or compounds; and
- ▶ Tentatively identified compounds

The hazard analysis must include an evaluation of the hazards identified to assess the severity of illness or injury from the hazard and the probability that the hazard will occur in the absence of preventative controls. A processing facility must identify and implement preventative controls to provide assurances that any hazards requiring a preventative control will be significantly minimized or prevented, and the cannabinoid product not adulterated.

To set up a required hazard evaluation conducted by the Kentucky State Fire Marshal, contact Michael.Burke@ky.gov.

PCQI requirements

Processing facilities must have at least one (1) credentialed **Preventative Control Qualified Individual (PCQI)**. PCQI training qualifies individuals to oversee and prepare product safety plans, validate preventative controls, and comply with GMP requirements.

The **Federal Food and Drug Administration (FDA)** has established the requirements for a PCQI and provides a list of [FAQs regarding the Food Safety Modernization Act \(FSMA\)](#) on its website at <https://fda.gov>.

The **Food Safety Preventative Controls Alliance (FSPCA)** provides [training and resources for PCQIs](#) on its website at <https://fspca.net>.

Resources

- ▶ For more information about the requirements for cannabis businesses, please visit the "Businesses" page on the Office of Medical Cannabis website at: <https://kymedcan.ky.gov/>.