Cannabis Safety & Quality
cGMP Audit Requirements
September 2021
Version 1.0

CSQ
Cannabis Safety and Quality

Contents

Introduction

Liability

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Acknowledgments

CSQ wishes to acknowledge individuals in the cannabis industry who have contributed to the development of the CSQ cGMP Audit Requirements. CSQ would like to give special thanks to our Technical Advisory Committee (TAC) members and additional committees for all their hard work and dedication to improving the safety and quality of the cannabis industry.

Summary

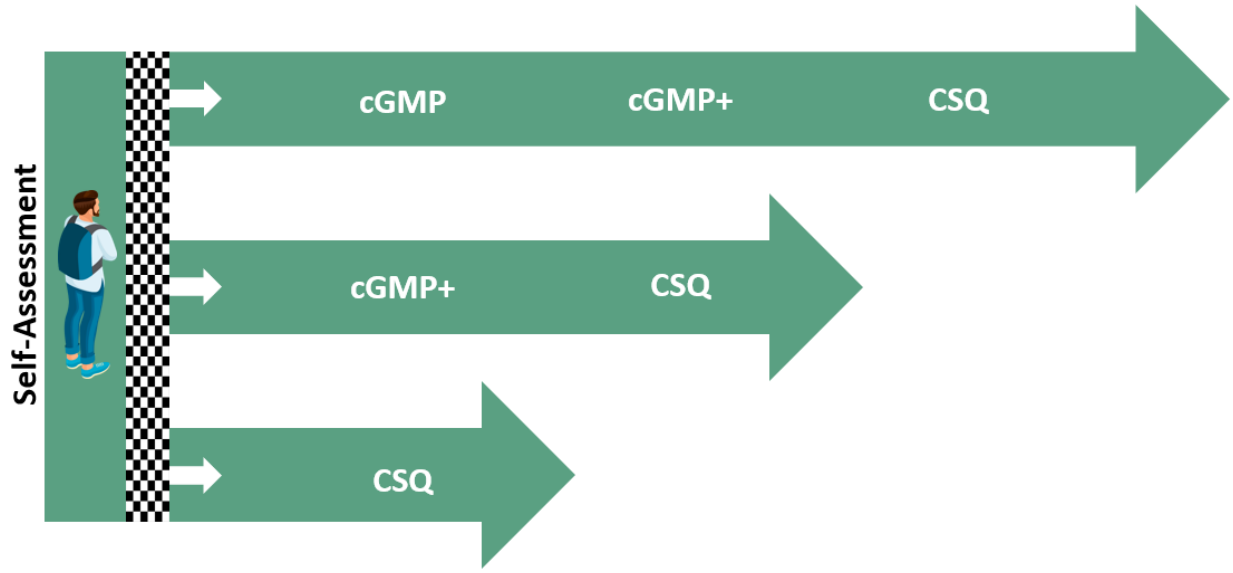
Cannabis Safety & Quality (CSQ) has developed a voluntary and independent third-party verification program to help cannabis manufacturers take a tiered approach to CSQ Certification. CSQ's cGMP Audit outlines the criteria expected for a modern cannabis manufacturing site to meet the basic safety requirements of retailers, applicable regulatory agencies, and the general public.

The CSQ cGMP Audit evaluates the competence of the site's cannabis safety management system, compliance to the cannabis safety management system's documented procedures, and the effectiveness of the cannabis safety management system's procedures to control and mitigate cannabis safety risks.

All facilities are required to meet local regulations for where the product is being manufactured and/or where the product is being sold.

Roadmap to CSQ Certification

The CSQ cGMP and cGMP+ audits set out how companies who have underdeveloped cannabis safety and quality management systems can meet the challenge of providing safe and quality products to consumers, while simultaneously working towards CSQ Certification. The cGMP and cGMP+ audits provide companies with an unaccredited entry point and a step-by-step approach designed to impower continuous improvement. The image below demonstrates some of the many routes a company might take to achieve CSQ Certification. Reach out to your Certification Body to help assess which path is right for your company.



Module 1: Cannabis Safety Management System

1.1 Management Commitment to Cannabis Safety

The site's senior management shall ensure adequate resources (e.g., people, equipment, training, etc.) are made available in a timely manner to implement, maintain, review, and improve cannabis safety.

1.2 Regulatory Compliance

The site shall ensure that all products comply with all regulatory requirements for which the product is being manufactured and supplied. Examples include, but are not limited to, compliance with the following:

a) Cannabinoids Potency
b) Terpenes
c) Microbials
d) Pesticides
e) Residual Solvents
f) Heavy Metals
g) Food Safety requirements
h) Allergens
i) Shelf-life studies
j) Packaging requirements
k) Labeling requirements
l) Seed-to-Sale Traceability
m) Interstate or international trade regulations

1.3 Complaint Management

The site shall have documented procedures and practices in place for the investigation and resolution of complaints. The established procedures and practices shall:

a) Identify who is responsible for investigating, communicating, and resolving the complaint.
b) Describe the process for implementing corrective actions resulting from a complaint to ensure the issue does not reoccur.

1.4 Document Control and Record-Keeping

The site shall have documented procedures and practices to manage documents and records that are part of the cannabis safety management system. The established procedures and practices shall:

a) Describe the method for the identification of the most current document version.
b) Include a process to securely maintain legible records for a period of time that meets regulatory requirements.
c) Ensure records are only written in ink, not pencil.
d) Ensure white-out is not used on any records.

1.5 Training

The site shall have a documented training program and practices to ensure that all personnel, including temporary employees and contractors, are adequately trained upon initial hiring. The established training program and practices shall:

a) Ensure at a minimum all personnel receive appropriate training on current Good Manufacturing Practices (cGMPs), HACCP, Security/Food Defense, Allergen Management, and any specialized training required to complete job duties (e.g., CCP Monitoring) by a qualified individual.
b) Include a training matrix indicating what each employee has been trained on and the most recent date of training.
c) Include a provision for refresher training at appropriate intervals (at a minimum annually).
d) Ensure trainers are qualified, through experience or certification, to provide training on the subject matter.
e) Ensure training is available in a language understood by all staff.

Module 2: Current Good Manufacturing Practices (cGMP)

2.1 Processing Controls

2.1.1 Process Flow, Segregation and Cross-Contamination Prevention

The site shall have established practices to ensure the process flow and employee practices promote segregation and prevent cross-contamination.

2.1.2 Personnel Processing Practices

The site shall have established practices to ensure that all personnel handle raw materials, Work-in-Progress (WIP), finished products, and packaging materials as to not pose risk to product safety.

2.1.3 Raw Materials

The site shall have established practices that ensure all raw materials, including packaging materials, comply with regulatory requirements for where the product is manufactured and/or sold.

2.1.4 Labeling

The site shall have established practices for finished product labeling that ensures products are labeled according to regulatory requirements for where the product is manufactured and/or sold. The established practices shall ensure labels are affixed to the correct product and finished products are not mislabeled.

2.1.5 Allergen Management

The site shall have documented procedures and practices that effectively control allergens. The established procedures and practices shall:

a) Ensure allergen labeling meets legal requirements applicable in the country and/or region for sale.
b) Describe how allergens are identified and handled onsite.
c) Describe the methods for the identification, handling, cleaning, changeover, and storage of allergens to prevent cross-contamination.
d) Include verification of the correct labeling of allergenic finished products.
e) Ensure that facilities (even those that do not produce allergenic products) address how the site prevents unintended allergens from entering the manufacturing process from suppliers, employees, and visitors.

2.1.6 Environmental Monitoring

The site shall have documented procedures and practices for environmental monitoring. The established procedures and practices shall:

a) Identify who is responsible for the environmental monitoring program.
b) Define the methods, frequency, indicator organisms, and limits that are used for sampling.
c) Include the trending of environmental monitoring records.

2.2 Non-Conforming Goods

2.2.1 Hold and Release

The site shall have documented procedures and practices for holding and releasing non-conforming raw materials, Work-in-Progress (WIP), finished products (including returned products), and packaging materials. The established procedures and practices shall:

a) Ensure that non-conforming goods are clearly identifiable and not comingled with products not on hold.
b) Ensure that non-conforming goods are quarantined and stored to prevent accidental release.
c) Include a process for the decision-making by qualified and authorized personnel on the continued use or disposal of the non-conforming goods.

2.2.2 Rework

The site shall have documented procedures and practices for the rework of raw materials, Work-in-Progress (WIP), and packaging materials. The established procedures and practices shall:

a) Ensure reworked goods are clearly identifiable and dated for traceability.
b) Describe how each batch of rework is inspected and analyzed before its release for use.
c) Ensure rework is processed, so it does not expire prior to the expiration date of the finished product.
d) Ensure rework is safe to use and processed "like-to-like."

2.2.3 Identification and Traceability

The site shall have documented procedures and practices for the identification and traceability of all raw materials, Work-in-Progress (WIP), finished products, and packaging materials throughout the entire process. The established procedures and practices shall:

a) Ensure all raw materials, Work-in-Progress (WIP), finished products, and packaging materials are clearly identified throughout the entire process.
b) Ensure finished products are traceable to the customer (one forward).
c) Ensure raw materials and packaging materials are traceable to the manufacturing supplier (one backward).
d) Ensure where rework is performed, traceability is maintained.

2.2.4 Recall Program

The site shall have documented procedures and practices for the recall of products. The established procedures and practices shall:

a) Include a list of key personnel (i.e., Recall Team) responsible for initiating, handling, and investigating a product recall with specific responsibilities identified.
b) Include an up-to-date list of key contacts that includes the above key personnel involved in the product recall, emergency services, customers, suppliers, regulatory agencies, and certification body.
c) Include a plan for communicating key information to customers, suppliers, regulatory agencies, certification body, and consumers.
d) Describe how the site plans to recover or dispose of affected products.
e) Include the testing of the recall procedure at least annually during a mock recall.

2.3 Internal Audits and Inspections

2.3.1 Internal Audits

The site shall have established practices for conducting internal audits to verify the effectiveness of the entire cannabis safety management system. The established practices shall:

a) Ensure an internal audit of the entire cannabis safety management system is completed at a minimum annually.
b) Ensure internal audits are recorded and identify any non-conformances and corrective actions taken.

2.3.2 Pre-Operational Inspections

The site shall have established practices for conducting pre-operational inspections to verify that production is ready to begin. The established practices shall:

a) Ensure employees are following cGMP policies and facilities and equipment meet sanitary and operational needs before production begins.
b) Ensure inspections are recorded and identify any non-conformances and corrections or corrective actions taken.

2.4 Supplier Approval Program

The site shall have documented procedures and practices for approving suppliers of raw materials and packaging materials. The established procedures and practices shall:

a) Include a current list of all approved suppliers.
b) Identify who is responsible for the approval and monitoring of suppliers.
c) Describe how the site selects, evaluates, approves, and monitors suppliers.
d) Include a provision for the use of non-approved temporary suppliers for emergencies and how the site verifies the safety of raw materials before use.
e) Include the annual review of all approved suppliers.

2.5 Cleaning and Sanitation

2.5.1 Cleaning and Sanitation Program

The site shall have a documented cleaning and sanitation program and practices that ensure the environment is sanitary for cannabis production. The established cleaning and sanitation program and practices shall:

a) Identify what is to be cleaned.
b) Describe the method for cleaning, including the cleaning chemicals and materials to be used.
c) Define the frequency of cleaning based on risk.
d) Identify who is responsible for cleaning.
e) Identify who is responsible for verification and what method is used to verify cleanliness.

2.5.2 Cleanliness of the Facility

The site shall ensure all facilities and equipment are maintained in a clean and hygienic condition, as to not pose a risk to product safety. Cleaning operations should not interfere with manufacturing operations and should not pose a potential risk to product safety.

2.6 Chemical Controls

The site shall have established practices for the control and storage of all chemicals. The established practices shall:

a) Include a chemical approval process and a list of approved chemicals used onsite.
b) Ensure all chemicals are stored properly so that they do not pose a risk to product safety.
c) Ensure all food-grade chemicals are stored separately from non-food-grade chemicals.
d) Ensure all chemicals are stored in their original container or clearly labeled secondary containers.
e) Ensure that Safety Data Sheets (SDS) are on file for each chemical used onsite.

2.7 Pest Control

2.7.1 Pest Control Program

The site shall have documented procedures and practices for the control of pests. The established procedures and practices shall:

a) Clearly define the responsibilities of the site and/or contractors involved in the development, implementation, and maintenance of the pest control program.
b) Include a bait station map that identifies the type, location, and the number of the traps or bait stations used.
c) Ensure that traps, bait stations, insect light traps, and pheromone traps are located as to not pose a risk to product safety.
d) Include a list of regulatory compliant pesticides used with their Safety Data Sheets (SDS).
e) Define the frequency of the monitoring of pest traps or bait stations.
f) Describe how the site records and trends the sighting of pests and how the site effectively handles corrective actions and recommendations from pest control personnel.

2.7.2 Pest Control Personnel

The site shall ensure that all personnel, either staff or external contractors, involved with the application of pesticides do not pose a threat to product safety. Pest control personnel shall:

a) Be trained and qualified to conduct pest control activities and meet regulatory compliance.
b) Be licensed and approved by the relevant authorities.
c) Only use regulatory compliant pesticides.

d) Provide a documented report of findings and pesticides used during the inspection.

2.7.3 Pest Infestations

The site shall effectively prevent pest infestations inside the facility. The site shall not have any evidence of pests or pest excrement on raw materials (including packaging materials), Work-in-Progress (WIP), or finished goods.

2.8 Water and Air Quality

2.8.1 Water, Steam, and Ice Management

The site shall have established practices to ensure all water, steam, and ice used onsite is potable and in compliance with regulatory requirements. The established practices shall:

a) Ensure the volume, temperature, and pressure of water are adequate to meet operational and sanitation needs.
b) Include an, at minimum, annual microbiological and chemical analysis of the onsite water supply within the facility.
c) Ensure all water analyses are conducted by an accredited laboratory.
d) Include the use of backflow prevention devices installed on hoses, taps, and other similar water dispensing devices and at minimum annual testing of backflow prevention devices.
e) Ensure handwashing stations have a potable water supply and are at an appropriate temperature.

2.8.2 Air Quality and Ventilation

The site shall have established practices to ensure all air or other gases that come in contact with the product or product contact surfaces do not pose a risk to product safety. The established practices shall:

a) Ensure air and other gases that come in contact with product or product contact surfaces are filtered and monitored at an appropriate frequency.
b) Ensure ventilation is appropriately installed and maintained to effectively mitigate fumes, steam,, vapors, and odors from processing.

2.9 Waste

2.9.1 Standard Waste Disposal

The site shall have established practices to ensure all waste is removed regularly to prevent accumulation and the attraction of pests. The established practices shall:

a) Ensure waste containers are clearly identified.
b) Ensure waste containers are clean and maintained regularly.
c) Ensure waste is removed or emptied regularly.

2.9.2 Cannabis Waste Disposal

The site shall have established practices to ensure all cannabis waste is disposed of according to regulatory requirements and does not accumulate. The established practices shall:

a) Ensure cannabis waste containers are clearly identified according to regulatory requirements.
b) Ensure cannabis waste containers are clean and maintained regularly.
c) Ensure cannabis waste containers are kept sealed and restricted to authorized personnel.
d) Ensure cannabis waste is removed or emptied regularly and according to regulatory requirements.

2.10 Foreign Matter

2.10.1 Foreign Matter Detection

The site shall have documented procedures and practices to ensure foreign matter detection equipment, if present, effectively removes or detects foreign matter. The established procedures and practices shall:

a) Describe how the site plans to detect foreign matter.
b) Describe the methods used to monitor and verify foreign matter detection.
c) Include provisions for the inspection and investigation of foreign matter that is removed by detection devices.
d) Describe the methods used to calibrate foreign matter detecting equipment.

2.10.2 Foreign Matter Controls

The site shall have documented procedures and practices for the control of foreign matters. The established procedures and practices shall:

a) Exclude all wood, glass, brittle plastic, ceramics, or other similar materials from areas where open products are handled where possible.
b) Ensure there are no loose objects on equipment or overhead structures.
c) Ensure all pallets are clean and in good repair.
d) Include an inspection process to ensure the facility, equipment and tools remain in good repair as to not cause a potential foreign matter contamination.
e) Include provisions for the protection of the damage, breakage, or deterioration of wood, glass, brittle plastic, ceramic, or other similar objects that cannot be removed from the processing area and how the site monitors the objects.
f) Describe the methods for how the site controls the use of metal cutting instruments used in processing and packaging operations.

2.11 Storage and Distribution

2.11.1 Dry Storage

The site shall have established practices to ensure the safe storage of dry finished products, Work-in-Progress (WIP), ingredients, and other raw materials (i.e., packaging materials). The established practices shall:

a) Ensure dry storage areas are suitable for its purpose and constructed to protect the product from contamination.
b) Ensure raw materials, Work-in-Progress (WIP), and finished products are stored off the floor on racks or pallets.
c) Ensure packaging materials, ingredients, Work-in-Progress (WIP), and finished products are stored separately and not commingled.

2.11.2 Temperature and Atmosphere Controlled Storage

The site shall have established practices to ensure the safe storage of finished products, Work-in-Progress (WIP), and raw materials that require temperature or atmosphere controls. The established practices shall:

a) Ensure temperature and atmosphere-controlled storage areas are suitable for its purpose and constructed to protect the product from contamination.
b) Ensure raw materials, Work-in-Progress (WIP), and finished products are stored off the floor on racks or pallets.
c) Ensure raw materials, Work-in-Progress (WIP), and finished products are stored separately and not commingled.
d) Describe how the site monitors the temperature and/or humidity of storage areas.
e) Ensure condensation from cooling devices is controlled and not discharged onto raw materials, Work-in-Progress (WIP), or finished products.

2.11.3 Receiving

The site shall have documented procedures and practices to ensure raw materials are received in an acceptable condition. The established procedures and practices shall:

a) Include an inspection process before unloading.
b) Describe the methods used for unloading to ensure minimal exposure of the product to detrimental conditions.
c) Describe the methods used to ensure the prevention of cross-contamination and that the raw material maintains its integrity throughout the unloading process.
d) Describe the methods used to ensure the load was secured from tampering or external elements.

2.11.4 Shipping

The site shall have documented procedures and practices to ensure finished products are shipped safely. The established procedures and practices shall:

a) Include an inspection process before loading.
b) Describe the methods used for loading to ensure minimal exposure of the product to detrimental conditions.
c) Describe the methods used to ensure the prevention of cross-contamination and that the product maintains its integrity throughout the loading process.
d) Describe the methods used to ensure the load is secure from tampering or external elements.

2.12 Facility and Equipment Design

2.12.1 Location Design and Layout

The site shall be in a location suitable for the intended purpose and mitigate opportunities for cross-contamination between and during operations. The site shall ensure:

a) The site's construction is maintained and in good repair.
b) The site's grounds and surrounding area are maintained and free from debris, standing water, and excessive dust.
c) The site shall maintain all vegetation growth around the exterior of the facility to ensure there is no harborage of pests.
d) Roadways, loading, and unloading areas under the site's control are maintained and free from debris.

2.12.2 Internal Structures and Fittings

The site shall be suitable for the intended purpose and mitigate opportunities for cross-contamination between and during operations. The site shall ensure:

a) All floors, walls, doors, windows, ceilings, drains, and other building fixtures are constructed to not pose a risk to product safety, are designed to be easily cleanable, are maintained, and in good repair.
b) Light fixtures and skylights are constructed to not pose a risk to product safety, are of appropriate intensity, are maintained and in good repair.
c) Windows, light fixtures, and skylights that could pose a risk to product safety are shatterproof or protected against breakage.
d) Adequate ventilation and extraction to prevent condensation or excessive dust is provided.
e) All external openings are effectively sealed when closed and prevent dust and pests from entering the building.
f) Hand washing stations are located upon entering processing areas and in easily accessible locations throughout product handling areas.
g) Plumbing is designed to ensure adequate water supply throughout the site and ensure liquid waste is removed in a way that does not pose a risk to product safety.
h) Restrooms are easily accessible to all personnel and do not pose a risk to product safety.

2.12.3 Equipment

The site's equipment shall be suitable for its intended purpose and designed as to not pose a risk to product safety. The site shall ensure:

a) All equipment and cannabis contact surfaces are easily cleanable, maintained, and in good repair.
b) Equipment is stored in a manner that does not pose a risk to product safety.
c) All hoses are stored on racks and off the floor.

2.13 Maintenance and Calibration

2.13.1 Preventative Maintenance Program

The site shall have documented procedures and practices to ensure the building and equipment are maintained as to not pose a risk to product safety. The established procedures and practices shall:

a) Include a master preventative maintenance schedule.
b) Describe how the site documents unplanned maintenance.
c) Include a process for maintenance staff to alert the appropriate supervisor when repairs pose a threat to product safety.
d) Ensure that product safety is not jeopardized during maintenance.
e) Ensure that any product contamination hazards (tools, lubricants, debris, etc.) are completely removed from the area being maintenance before the commencement of operations.
f) Include a provision for how the site controls and monitors temporary repairs so as not to pose a risk to product safety and ensures that temporary repairs do not become permanent.

2.13.2 Calibration

The site shall have documented procedures and practices to ensure all equipment used to measure factors that affect product safety are calibrated appropriately. The established procedures and practices shall:

a) Identify all equipment being calibrated with the valid calibration due date.
b) Calibrate equipment against national or international standards and according to manufacturer's recommendations.

2.14 Good Hygiene Practices

2.14.1 Illness and Injuries

The site shall have documented procedures and practices to ensure employees are not vectors for the transmission of diseases. The established procedures and practices shall:

a) Inform all employees of the signs and symptoms of infectious diseases which would prevent them from working with products.
b) Include a system for all employees to report symptoms to senior management.
c) Ensure employees with exposed cuts, sores or lesions do not handle products.
d) Ensure minor exposed cuts are covered with bandages and disposable gloves.
e) Ensure areas where the spillage of bodily fluids (e.g., blood, vomit, etc.) occurs are adequately quarantined, cleaned, and sanitized, and released by authorized personnel.

2.14.2 Personal Hygiene

The site shall have documented procedures and practices to ensure that personnel hygiene practices do not pose a risk to product safety. The established procedures and practices shall:

a) Ensure smoking, chewing tobacco, eating, and drinking are only conducted in permitted areas away from product handling areas (drinking water is permitted in designated product handling areas as long as it does not pose a risk to product safety).
b) Ensure personnel does not wear false fingernails, fingernail polish, or false eyelashes.
c) Ensure personnel fingernails are kept short and clean.
d) Ensure personnel have clean hands and are effectively washing their hands at appropriate frequencies.
e) Ensure personnel are trained on proper handwashing techniques, and signage instructing personnel to wash their hands are located in close proximity to handwashing stations.

2.14.3 Personal Clothing, Jewelry, and Personnel Belongings

The site shall have documented procedures and practices to ensure that personnel clothing, jewelry, and personnel belongings do not pose a risk to product safety. The established procedures and practices shall:

a) Ensure that there are a sufficient number of protective clothing items for each employee.
b) Ensure protective clothing is suitable to prevent contamination of the product.
c) Ensure racks are provided at appropriate entrances and exits to ensure there is no contamination of clothing.
d) Ensure hair and beard nets are worn by all personnel involved with product handling.
e) Ensure that all protective clothing (unless disposable) is effectively cleaned, either by an approved contractor or in-house, at a frequency that minimizes risk to product safety.
f) Ensure that dirty and clean protective clothing is adequately separated and clean clothes are protected from contamination.
g) Ensure gloves are replaced at a frequency that does not pose a risk to product safety.
h) Ensure no jewelry, except for a plain wedding band or medical alert bracelet, shall be worn.

2.15 Security

2.15.1 Security Plan

The site shall have documented procedures and practices for the defense against acts of theft, bioterrorism, or intentional acts of adulteration. The established procedures and practices shall:

a) Include an initial threat assessment that identifies any potential threats and steps taken to mitigate these threats.
b) Describe what measures the site has in place to ensure only authorized personnel has access to sensitive areas.
c) Describe the methods in place to protect products from intentional adulteration throughout the entire process.
d) Ensure secured and locked access to all cannabis raw materials (i.e., flower), cannabis waste, Work-in-Progress (WIP), and final product.
e) Describe the methods to ensure the secured transportation of all finished products.
f) Include at a minimum annual review and testing of the Security Plan.

2.15.2 Visitors

The site shall have documented procedures and practices that ensure visitors do not pose a threat to product safety. The established procedures and practices shall:

a) Ensure visitors are not allowed to enter product handling areas if they are showing signs of illness.
b) Ensure visitors are informed of the site's specific current Good Manufacturing Practices (cGMPs).
c) Ensure visitors wear suitable clothing and footwear.
d) Ensure visitors remove all jewelry and other loose objects.
e) Ensure visitors practice good personnel hygiene and handwashing practices.

Appendix A: Audit Protocol

Scope of Audit

Audit Scope

The scope of a CSQ cGMP Audit is established during the application process with the site's Certification Body (CB) and confirmed during the audit by the auditor. The scope of the audit outlines where the site's responsibilities for the process begins and ends, as well as what products are being produced. Any changes relating to the location, or the products being produced shall be communicated with the site's CB prior to or when the change occurs. Some changes may require a remote scope extension audit or onsite audit to maintain the site's certificate.

Scope Extensions

Once a certificate has been granted, any significant changes to the site's products or processes shall be communicated to their Certification Body (CB). Examples of significant changes include, but are not limited to, the following:

- The addition of a new structure or building
- The introduction of new product types

The CB will review the significance of the changes to determine the impact on the validity of the current certificate. If the changes are deemed non-significant, then a change may be made to the certificate, if applicable. If the changes are deemed to be significant, then a remote scope extension audit or onsite audit may be required to maintain the site's certificate.

Audit Duration

The duration of a CSQ cGMP Audit will be quoted to the site during the application process with the site's Certification Body (CB). Please note that all audit times are an estimate and will fluctuate according to the size and scope of the location's operations. Considerations that can impact the audit duration include:

- Size of site
- Number of employees
- Number of product types/processes
- Scope of audit

Audit Frequency

A site's certificate expires one year and forty-five (45) days after the last day of their previous audit. A site must receive its annual audit before its certificate expires to maintain its certificate.

Applicable Products

Product categories and processes that are applicable to the cGMP audit include cannabis extraction, cannabis edibles and beverages, and cannabis dietary supplements.

The cultivation and packaging of raw cannabis flower either for wholesale or directly to retailer or consumer would need to be audited to the cGAP audit requirements.

Preparing for an Audit

Mock Audits

To prepare for your audit, a site may choose to get an optional mock audit before the scheduled audit to determine the readiness of the site.

Required Documentation

It is recommended that a site has at a minimum sixty (60) days of production records before receiving an audit. However, if the site is not able to provide sixty (60) days of production records due to regulatory or customer requirements, then a 6-month provisional certificate may be issued.

Selecting a Certification Body

Certification Bodies are licensed by CSQ to conduct both CSQ certification audits and verification audits, and issue CSQ certificates. All CSQ licensed Certification Bodies are required to be accredited to the international standard ISO/IEC 17065 and be subject to annual assessments of their certification activities by CSQ licensed Accreditation Bodies.

Any location that wishes to become registered with CSQ is always required to have an agreement in place with a licensed Certification Body which outlines the certification services provided. A current list of licensed Certification Bodies is available on the CSQ Website.

Registration

All sites must register their facility on the CSQ Database before the audit can commence. Accurate registration ensures that the site will be listed on the CSQ Database with the correct site information. The registration database can be accessed from the CSQ Website.

Audit Reporting

Scoring Guidelines

The overall audit score is based on the total number and level of non-conformances. The overall audit is allocated 100%, and deductions based on auditor findings are made as follows:

Minor = -1%

Major = -5%

Critical = -100%

Score	Certificate
70-100%	Certificate Issued
00-69%	No Certificate Issued

Non-Conformances and Corrective Actions

Minor – A minor non-conformity is a deficiency in the cannabis safety management system that may lead to a risk to product safety.

Major – A major non-conformity is a deficiency in the cannabis safety management system that carries a product safety risk or likely leads to risk to product safety.

Critical – A critical non-conformity is a clear deficiency that will potentially cause serious illness or death, or any falsification of cannabis safety records is found.

Corrective Actions

Although not required to attain a cGMP+ certificate, CSQ strongly recommends identifying the root cause of non-conformities and implementing corrective and preventative actions to drive continuous improvements in the site's cannabis safety management system.

Certificate

All sites that receive a 70% or higher on the audit will be granted a certificate of compliance.

Although certificates are issued to sites that receive 70% and above on an audit, retailer and/or customer requirements might require the site to maintain a higher percentage audit score. This is to be agreed upon by the site and the retailer, and/or the customer.

The certificate expires forty-five (45) days beyond the anniversary of the audit date.

Use of the CSQ Certification Mark

The CSQ cGMP Certification Mark is owned by Cannabis Safety & Quality (CSQ). All sites that achieve a certificate shall have the right to use the cGMP Certification Mark for the duration of the site's certificate. The site may use the cGMP Certification Mark on marketing material, product displays, brochures, flyers, advertisements, press releases, company websites, internal documents, etc. The cGMP Certification Mark may not be used on finished product labeling or packaging.

Recalls, Withdrawals, and Regulatory Warnings

In the event of a recall, voluntary withdrawal, or regulatory warning, the site shall notify their Certification Body within seventy-two (72) hours. Failure to report a recall, voluntary withdrawal, or regulatory warning may result in withdrawal of the site's certificate.

Appendix B: Audit Terms and Definitions

Adulteration – to make imperfect by adding extraneous, improper, or inferior ingredients.

Allergen – substances that cause an exaggerated immune response in some people and that may result in a runny nose, watery and/or itchy eyes, a rash, wheezing, serious illness or (occasionally) death.

Cannabinoids – are the chemical compounds unique to cannabis that act upon the human body's cannabinoid receptors, producing various effects including pain relief and other medically beneficial uses. Cannabis' most well-known cannabinoid is tetrahydrocannabinol (THC) due to the fact that it is the most abundant, and also because it produces the psychoactive effects (or the "high") that drives the plant's recreational use. However, there are several known cannabinoids all with varying effects.

Cannabis – a plant genus that produces three species of flowering plants: *Cannabis sativa*, *Cannabis indica*, and *Cannabis ruderalis*.

Calibration – the adjustment of an instrument for accuracy relative to an established standard.

Cannabidiol (CBD) – a type of cannabinoid found in cannabis and second only to THC when it comes to average volume in cannabis plants.

Certificate of Analysis (COA) – a document containing test results that are provided to the customer by the supplier to demonstrate that product meets the defined test.

Contamination – a condition that can affect a product that has been exposed to and faced introduction of foreign matter, including filth, a poisonous substance or pests, disease-causing microorganisms or parasites, or toxins.

Control Point – any step in the process at which a hazard can be controlled, reduced, or eliminated.

Critical Control Point – a point, step, or procedure in a process at which a control can be applied and is essential to prevent or eliminate a hazard or reduce such a hazard to an acceptable level.

Critical Limit – a maximum and/or minimum value, or combination of values, to which a biological, chemical, or physical parameter must be controlled to significantly minimize or prevent a hazard requiring a process preventive control or at a CCP.

Cross-Contamination – a situation that occurs when micro-organisms, allergens, chemicals, or other hazards that are carried by utensils, hands, towels or other items are transferred from one product, raw material, or surface to another.

Edibles – are food items that have been infused with cannabis extracts. They are commonly baked goods such as cookies and brownies, but options as varied as flavored drinks, candies, and other products exist as well.

Environmental Monitoring Program (EMP) – a program for the evaluation of the effectiveness of controls on preventing contamination from the manufacturing environment.

Foreign Matter – any substance or object that does not naturally or normally belong in a product.

Good Agricultural Practices (GAP) – are the basic environmental and operational conditions necessary to produce safe, wholesome agricultural products.

Good Handling Practices (GHP) – refers to the best practices for post-harvest handling of agricultural products to minimize contamination.

Good Manufacturing Practices (GMP) – outlines the conditions and practices the industry must follow for processing safe products under sanitary conditions, including personnel, plant and grounds, sanitary operations, sanitary facilities and controls, equipment and utensils, processes and controls, warehousing and distribution, and defect action levels considerations.

Hazard – a biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of a control.

Hazard Analysis Critical Control Point (HACCP) – a systematic approach that identifies, evaluates and controls hazards significant to product safety.

Mitigation Strategies – controls to remove, or reduce to an acceptable level, an identified risk, vulnerability, or threat.

Pathogen – a bacterium, virus, or other microorganism that can cause disease.

Pests – any animal or insect of public health importance, including, but not limited to birds, rodents, roaches, flies, and larvae that may carry pathogens that can contaminate products.

Pest Harborage – any condition or structural defect that provides a place for pests to live and reproduce.

Potable Water – water suitable for drinking, free from pollutants and harmful organisms, and conforms to local legal requirements.

Prerequisite Program (PRP) – all procedures used in the facility, which address operational conditions providing the foundation for the HACCP plan. Examples include Cleaning & Sanitation Programs, Good Manufacturing Practices Program, Pest Management Programs, etc.

Preventive Control – risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packaging, or holding of product would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe manufacturing, processing, packaging, or holding at the time of analysis.

Personal Protective Equipment (PPE) – PPE is protective clothing, helmets, goggles, or other garments or equipment designed to protect the wearer's body from injury or infection.

Quality – meeting of customers' specifications and expectations.

Quarantine – the holding of any raw material or product while awaiting confirmation of its suitability for intended use or sale.

Raw Material – commodities, parts or substances that are assembled or processed to form a final product

Rework – the process of re-manufacturing of semi-final and final products, to obtain a final product that complies with the customer requirements. It can also refer to material in a processed or semi processed state that is intended to be re-used in subsequent manufacturing steps.

Risk – the likelihood of an occurrence and the size of the consequences of an adverse event.

Risk Analysis – a process that includes risk assessment, risk management, and risk communication.

Risk Assessment – the process of identifying a hazard and characterizing the risk presented by that hazard in qualitative or quantitative terms.

Root Cause – the underlying cause(s) of a problem.

Specification – a detailed, exact statement of prescribed requirements for incoming materials or finished products.

Standard Operating Procedure (SOP) – a set of step-by-step instructions compiled by a site to help employees carry out operations.

Supplier – a person or organization that provides a product or service.

Tetrahydrocannabinol (THC) – the most well-known and most abundantly available cannabinoid in cannabis plants. THC is also the component in cannabis that is responsible for the psychoactive effects, or the "high." Also known as delta-9-tetracannabinol, it was first isolated in 1964 and is thought to serve as a natural defense for the plant against pests.

Threat Assessment – a risk assessment designed to examine a location's processes for potential product security.

Traceability – the identification of any suspect raw material of finished product and its initial shipment location.

Validation – confirmation of plausibility for a specific intended use or application through the provision of objective evidence that specified requirements have been fulfilled.

Verification – confirmation of truthfulness through the provision of objective evidence that specified requirements have been fulfilled.

Work-in-Progress (WIP) – partially manufactured products.


CSQ
Cannabis Safety and Quality