Cannabis Safety Certification Requirements

PJRFSI Cannabis GMP Standard Version 2.0

PJRFSI Cannabis Safety Standard for Manufacturing. Issued 7/27/2020. Revised 12/1/2021. Rev 2.0

Note to All Readers - A Legal Statement

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Introduction

Perry Johnson Registrars Food Safety, Inc. (PJRFSI) is committed to providing value-added food safety certification to clients. Our entire team believes that rigor and consistency during audit activities leads to higher levels of customer and end-user satisfaction. PJRFSI is dedicated to uphold the highest standards of professionalism, technical competence and integrity throughout the life cycle of the audit process. We apply the principles of quality management, collaboration and organizational excellence in all of our office and field activities and comply with the requirements set forth by the international standards organizations, accreditation bodies and other affected parties. Through this dedication, we have created and maintain a work environment which provides opportunities and a culture of continual improvement, learning and development for clients, auditors, staff and stakeholders within the food chain.

PJRFSI Cannabis Safety Standard for Manufacturing is based on FDA 21 CFR Part 117 Subpart B GMP (Good Manufacturing Practice) principles. The standard covers the manufacture of cannabis products including marijuana-infused edible, inhalable and personal care products. The cannabis safety audit will include this standard's requirements. PJRFSI does not collect samples, perform product testing or analysis. PJRFSI Cannabis Safety Certification Program is a Cannabis Safety System Certification and does not guarantee the safety of all products at all times.

Good Manufacturing Practices (GMP) Requirements for Cannabis Manufacturing

1.0 Management System

1.1 Management Commitment

1.1.1 There is an approved product safety/GMP policy.
1.1.2 The product safety/GMP policy describes the company's commitment to meeting and producing safe product, customer expectations, regulatory requirements and continuous improvement of systems related to product safety.
1.1.3 There are product safety objects established to support the product safety/GMP policy.
1.1.4 Policy and product safety objectives are clearly communicated to staff.
1.1.5 Management commitment demonstrates adequate financial and staffing resources for implementation and maintenance of product safety, product quality, security programs and overall facility and equipment maintenance.
1.1.6 Roles and responsibilities are clearly defined for personnel responsible for food safety and quality. Said personnel are qualified to complete their tasks and duties, and an organizational chart and job descriptions are documented.
1.1.7 The facility ensures compliance with applicable regulations and has awareness of the regulations for its products in countries where they are exported. There is a documented procedure for identifying applicable regulations.
1.1.8 There is a process or method in place for tracking updated or new regulations.

1.2 Document Control and Record Keeping

1.2.1 There is an established document control program in place including a master list of all control documents, including all Policies, Procedures, SOP Work Instructions, SSOPs, and forms.
1.2.2 Changes to documents or introduction of new documents is managed and communicated to relevant parties.
1.2.3 The methods and responsibility for undertaking monitoring activities, verifying, maintaining and retaining records must be documented and implemented. All records must be legible and suitably authorized by those undertaking monitoring activities that demonstrate inspections, analyses and other essential activities.
1.2.4 Records must be readily accessible, retrievable, securely stored to prevent damage or deterioration and shall be retained in accordance with periods specified by a customer or regulations.

1.3 Customer / Consumer Complaint Management

1.3.1 A written procedure for handling customer and/or consumer complaints must be in place; the procedure must address responsibilities, response, root cause investigation and corrective actions where required. Records for said complaints must be maintained, and a system to identify trends should be implemented.

1.4 GMP / Facility Inspection Program

1.4.1 A documented inspection program defining frequency, responsibilities and corrective actions should be in place. Inspections should effectively cover facility conditions, GMPs and efficacy of Pre-Requisite programs. Records of inspection should be made available.

1.5 Raw Material, Packaging Material, Processing Aids, and Finished Goods Specifications

1.5.1 A documented procedure for reviewing and approving specifications for raw materials, packaging materials, processing aids, and finished goods must be in place.
1.5.2 Specifications for raw materials, packaging materials, WIP, processing aids, cannabis labeling and finished goods must be on file.
1.5.3 Specifications must include: identity, purity, strength, microbial, and composition of finished batches.
1.5.4 Limits should be established for types of contamination that may adulterate or lead to adulteration.
1.5.5 Specifications and product labels must meet all applicable regulatory requirements.
1.5.6 All other ingredients must be approved USP quality or food codex quality.
1.5.7 Alternate methods and testing should be completed to establish shelf life for food products.

1.6 Allergen Management Program

1.6.1 A documented allergen control program should be implemented to include management of raw ingredients, WIP, processing aids, lubricants, rework and finished goods.
1.6.2 Ingredients containing allergens must be clearly identified as such and properly controlled, segregated in storage, production, or batching areas to prevent cross-contamination.
1.6.3 Controls should be identified to prevent allergen cross-contamination to include: scheduling, utensil/equipment segregation or sanitation requirements between allergen – non-allergen runs and etc.
1.6.4 Sanitation controls must be identified as part of the allergen control program to ensure removal of allergen residue is effective and has been validated. Records of validation should be maintained.
1.6.5 Labeling for allergen-containing products shall meet legal and customer requirements.
1.6.6 Allergen awareness/control training must be completed annually.

1.7 Control of Non-Conforming Materials

1.7.1 A documented procedure for management of non-conforming materials must be in place.
1.7.2 Adequately qualified authorized personnel must be designated to dispose of non-conforming materials.
1.7.3 Non-conforming materials must be adequately controlled and identified.

1.7.4 Employees must be adequately trained on non-conforming procedures.

1.8 Approved Supplier and Service Program

1.8.1 There must be a documented supplier approval process for materials and services in place. Criteria for the selection of suppliers must be adequate to ensure food/product safety.

1.8.2 Performance of approved suppliers must be effectively monitored, and records of performance monitoring kept.

1.9 Facility / Food Security / Video Surveillance

1.9.1 A written program describing assigned responsibility for facility/food security must be in place, including maintenance.

1.9.2 The company must carry out a vulnerability assessment to identify threats with respect of intentional contamination. Annual review of this assessment must be conducted.

1.9.3 A comprehensive food defense plan must be developed and implemented to manage the risks identified in the vulnerability assessment.

1.9.4 Screening of employees should be conducted, as well as training for employees in food defense awareness. Access to the facility must be controlled.

1.9.5 Details should be provided regarding video surveillance where cannabis or cannabis products are weighed, packed, stored, quarantined, loaded and unloaded for transportation, prepared, or moved within the premises.

1.9.6 On-site surveillance system storage devices should be located in secure rooms or areas of the premises in an access-controlled environment with appropriate controls in place.

1.9.7 Surveillance recordings must be kept for the length of time required by applicable regulations.

1.10 Product Release

1.10.1 Responsibilities and procedures must be implemented for product release, including qualification of personnel authorized to release finished product. All required testing must be completed and approved by QA.

1.11 Traceability

1.11.1 Products must be clearly identified and traced in the production system and in the supply chain.

1.12 Recall Plan

1.12.1 The documented recall plan must contain:

- Defined roles and responsibilities
- Contact lists for external notification (regulators, customers, public)
- Lot identification and verification information
- Product disposal procedures
- Effectiveness check procedures to be used during a recall

1.12.2 The recall plan must identify and document a recall coordinator and recall team, and describe in detail the duties and role of team members.
1.12.3 The recall plan must define the details of the following steps:

- Scope of recall
- Regulatory agency communication
- Recall initiation
- Customer notification
- Information and data compilation
- Document gathering
- Securing inventory of affected lots
- Product disposal documentation

1.12.4 Product disposal methods must be appropriately documented.
1.12.5 Procedure must include corrective actions related to recalls.
1.12.6 The facility must conduct a mock recall forward, backward, and including primary packaging materials at minimum annually. Efficacy of the mock recall(s) must be reviewed.
1.12.7 Any real (non-mock) product recalls in the past must have adequate records and evidence that recall management was adequate.

1.13 Training

1.13.1 A documented training program must be developed, including identification of required training for employees.
1.13.2 Employees and management staff must be adequately trained on:

- GMP
- Food and/or product safety
- Facility/food security
- Quality testing
- Allergen management
- Product quality
- Hold procedure
- Traceability/labeling
- Personnel hygiene and product handling
- Sanitation SSOPs
- Work instructions/job-specific training
- Pest control awareness

1.13.3 A training matrix or schedule must be completed to ensure annual training for all employees and management.
1.13.4 Competency/effectiveness of training must be adequately measured.
1.13.5 Records of training must be maintained, and should include: Trainer name, topic of training, and date/signature of trainee.

2.0 GMP and Other Pre-Requisite Programs

2.1 Personnel

2.1.1 GMP and personnel hygiene shall be documented and monitored for compliance for all employees, temporary employees, visitors and contractors.

2.1.2 Personnel hygiene practices must be observed while working in direct contact with product, product-contact surfaces, and product-packaging materials. Practices while on duty must reach the extent necessary to protect against allergen cross-contact and against contamination of product.
2.1.3 A written dress code for all employees (including new and part-time), visitors, vendors, and contractors must be documented. Employees must wear clean clothing and shoes appropriate for their working conditions.
2.1.4 The facility must require the use of hair restraints and facial hair restraints. False fingernails, fingernail polish, jewelry (e.g. rings, exposed body piercings, bracelets, etc.), or watches are not to be worn.
2.1.5 Hands must be thoroughly washed (and sanitized if necessary to protect against contamination with undesirable microorganisms) in an adequate handwashing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.
2.1.6 Gloves, if used in product handling, must be properly maintained and kept intact, clean, and sanitary.
2.1.7 Eating, drinking, spitting, chewing or using tobacco products must only be permitted in designated areas.
2.1.8 Any person who, by medical examination or supervisory observation, is shown to have – or appears to have – an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of product, product-contact surfaces, or product-packaging materials becoming contaminated, must be excluded from any operations which may be expected to result in such contamination until the condition is corrected, unless conditions such as open lesions, boils, and infected wounds are adequately covered (e.g. by an impermeable cover). Personnel must be instructed to report such health conditions to their supervisors.

2.2 Plant and Grounds

2.2.1 Facility grounds must be kept in a condition that will protect against product contamination.
2.2.2 Maintenance must be performed of roads, yards, and parking lots so that they do not constitute a source of contamination or pest harborage. This must include adequate drainage.
2.2.3 Equipment must be properly stored, litter and waste removed, and weeds or grass within the immediate vicinity of the plant must be cut to avoid attracting or harboring pests.
2.2.4 Drainage systems must not contribute to contamination of product by seepage, back up/pooling or provide a breeding place for pests.
2.2.5 Systems for waste treatment and disposal must be operated in an adequate manner so as not to constitute a source of contamination in areas where food is exposed.

2.3 Plant construction and design/layout

2.3.1 The plant must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for product-production purposes.

2.3.2 Adequate space must be provided for such placement of equipment and storage of materials as is necessary for maintenance, sanitary operations, and the production of safe product.
2.3.3 The plant must be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and in good repair; drips or condensate from fixtures, ducts and pipes may not contaminate the product, product contact surfaces, or product-packaging materials; aisles or working spaces provided between equipment and walls must be unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating the product, product-contact surfaces, or product-packaging materials with clothing or personal contact.
2.3.4 Lighting in the plant must be adequate and appropriate for sanitation, inspection and processing tasks being performed.
2.3.5 Adequate ventilation or control equipment must be provided to minimize dust, odors and vapors (including steam and noxious fumes) in areas where they may cause allergen cross-contact or contaminate the product.
2.3.6 Walls, doors, and overhead doors must be adequately pest-proof.

2.4 Equipment and Utensils

2.4.1 All plant equipment and utensils used in manufacturing, processing, packing, or holding food must be so designed and of such material and workmanship as to be adequately cleanable, and must be adequately maintained to protect against allergen cross-contact and contamination.
2.4.2 Equipment and utensils must be designed, constructed, and used appropriately to avoid the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.
2.4.3 Food-contact surfaces must be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds, sanitizing agents, and cleaning procedures.
2.4.4 Seams on product-contact surfaces must be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact.
2.4.5 Equipment and utensils not in use must be sanitarily stored and maintained to protect against allergen cross-contact and contamination.
2.4.6 Single-service articles (e.g. one-time use utensils, paper cups, paper towels, etc.) must be stored, handled and disposed of in a manner that protects against allergen cross-contact and against contamination of product, product-contact surfaces, or product packaging materials.

2.5 Sanitation

2.5.1 All processing, storage, warehouse, and employee welfare areas as well as processing and food handling equipment should be appropriately clean.
2.5.2 The facility should have documented standard cleaning procedures or Sanitation Standard Operating Procedures (SSOP's) that include what to clean, frequency, chemicals to be used, and dismantling instructions. The Master Sanitation Schedule (MSS) should include all facilities, buildings, and equipment, and should include cleaning and/or sanitation records.

2.5.3 Appropriate cleaning and sanitation chemicals should be used, with approval documents such as SDS and Technical Specification Sheets on file. All primary and secondary chemical dispensing containers must be labeled.
2.5.4 Cleaning equipment and tools should be maintained and stored in a way that does not contaminate foods or production equipment.
2.5.5 A documented verification or pre-operation inspections should be implemented and records kept on-file per the procedure.
2.5.6 Documentation should be in place of corrective actions in the instance of deviation identified during pre-op and re-inspection prior to production line release.

2.6 Microbial Control/Environment Monitoring

2.6.1 A risk-based environmental monitoring/microbial control program should be in place with roles and responsibilities documented.
2.6.2 The program should include a sampling plan or schedule, as well as pass/fail criteria for samples or swabs.
2.6.3 Environmental/microbial testing results should be monitored, and corrective actions implemented where unsatisfactory trends are observed in a timely manner.
2.6.4 Records should be maintained.
2.6.5 On-site laboratory facilities, if present, should not jeopardize product safety and/or contract labs should maintain appropriate accreditation to carry out the analyses performed and methods used.

2.7 Sanitary facilities and controls

2.7.1 Water supply must be adequate for the operations intended and must be derived from an adequate source. Any water that contacts the product, product-contact surfaces, or product-packaging materials must be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, must be provided in all areas where required for the processing of the product, for the cleaning of equipment, utensils, and food packaging materials, or for employee sanitary facilities.
2.7.2 Potability testing of municipal water supplies shall be conducted by a certified laboratory at minimum annually. Potability certificates available from municipal water suppliers are acceptable.
2.7.3 Plumbing must be of adequate size and design and adequately installed and maintained to: (1) carry adequate quantities of water to required locations throughout the plant, (2) properly convey sewage and liquid disposable waste from the plant, (3) avoid constituting a source of contamination to the product, water supplies, equipment, or utensils or creating an unsanitary condition, (4) provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor, (5) provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for product or product manufacturing.
2.7.4 Sewage must be disposed of into an adequate sewerage system or disposed of through other adequate means.
2.7.5 Each plant must provide employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and must not be a potential source of contamination of the product, product-contact surfaces, or product-packaging materials.

2.7.6 Hand-washing facilities: Each plant must provide hand-washing facilities designed to ensure that an employee's hands are not a source of contamination of product, product-contact surfaces, or product-packaging materials, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature.
2.7.7 Rubbish and any offal must be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of product, product contact surfaces, product-packaging materials, water supplies, and ground surfaces.
2.7.8 The methods and responsibility for pest preventions shall be documented and effectively implemented. Inspections for pest activity shall be undertaken on a regular basis by trained personnel and the appropriate action taken if pests are present. Records of all pest control applications and corrective actions shall be maintained.
2.7.9 Pest Control Contractors must meet the following: a.) licensed and approved by the local relevant authority, b.) use only trained and qualified operators who comply with regulatory requirements, c.) use only approved chemicals and have labels and SDS on file, d.) provide a pest control management program including site maps of all devices, e.) provide a written report of their findings and the inspections and treatments applied.
2.7.10 All external windows, ventilation openings, doors and other openings shall be effectively sealed when closed and proofed against pests.

2.8 Maintenance Program/Equipment

2.8.1 Plant shall have a documented preventative maintenance program that covers all equipment and facilities. Records shall be on file.
2.8.2 Nonfood grade materials or otherwise inappropriate materials including, but not restricted to, wire, tape, string, plastic, or cardboard shall not be used for temporary repair in processing areas.
2.8.3 There shall be a procedure to ensure that cleaning and sanitation is done following maintenance as needed. This shall include a reconciliation of all tools and spare parts used during the maintenance work to ensure that the work site has been returned to conditions for safe processing.
2.8.4 Only food grade grease shall be used where exposure to food or food contact surfaces is a risk.
2.8.5 Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment must be treated in such a way that food is not contaminated with unlawful indirect food additives.

2.9 Raw Cannabis Flower Testing (If Purchased or No COA)

2.9.1 A procedure must be in place ensuring all cannabis suppliers have appropriate cannabis licenses per the authority having jurisdiction.
2.9.2 A procedure must be in place to ensure pre- and/or post-harvest testing as required by jurisdiction. Sampling size must be appropriate for the planted acreage. The third-party lab used for testing must be ISO 17025 accredited for THC testing, or else adhering to state or federal requirements for cannabis.
2.9.3 Cannabinoid testing must be able to determine potency/strength in order to determine marijuana legality.

2.10 Cannabis Concentrate/Finished Product Testing

2.10.1 A document sampling program must be fully implemented to ensure that the sampling is a statistical representation of the batch.
2.10.2 Sample size must be significant enough to conduct the testing and maintain a retention sample. The protocol must be developed to guarantee a high level of confidence that each container contains exactly what is on the label.
2.10.3 Cannabinoid testing must be able to determine the potency/strength to determine the legality of marijuana.
2.10.4 A documented purity and contaminants testing protocol must be implemented to meet the required testing, including heavy metals, pesticides, solvents, microbiology, mycotoxins, residual solvents, and any other substances as required by regulation.

2.11 Processes and controls – In-House Labs

2.11.1 Written laboratory practices and methods must be implemented. Testing methodology must be fit for the purpose. Good Laboratory Practices must be implemented.
2.11.2 Trained Quality personnel must review all testing results and approve them.
2.11.3 The facility must retain samples from each lot.
2.11.4 A calibration program for equipment or control devices that have an impact on product safety and/or compliance to quality regulatory requirements must be documented.
2.11.5 Control and monitoring devices essential to the control, monitoring or testing of regulatory parameters, food safety critical limits, pre-requisite program parameters and/or quality parameters must be calibrated by trained personnel according to a pre-determined schedule.
2.11.6 Records of calibration activities must be maintained and traced to a nationally recognized standard.
2.11.7 Corrective actions must be documented for products monitored/controlled with a device found out of calibration.

2.12 Calibration Program

2.12.1 A calibration program for equipment or control devices that have an impact on product safety and/or product compliance to quality and regulatory requirements must be documented.
2.12.2 Control and monitoring devices essential to the control, monitoring, or testing of regulatory parameters, food safety critical limits, pre-requisite program parameters and/or quality parameters shall be calibrated by trained personnel according to a pre-determined schedule.
2.12.3 Records of calibration activities shall be maintained and traced to a national recognized standard.
2.12.4 Corrective actions shall be documented for products monitored/controlled with a device found out of calibration.

2.13 Processes and controls – Third Party Labs

2.13.1 Appropriate scientific validity and fitness for purpose and measuring each established specification must be determined.
2.13.2 Facility must retain samples from each lot.
2.13.3 The laboratory must be ISO 17025 accredited.
2.13.4 Records of third-party testing must be on file and retained for the required retention period.

2.14 Quality Management System

2.14.1 Record of batch must be documented and maintained to contain:

- Grower information
- Raw material testing
- In processing and finished product testing results for purity, contaminants, cannabinoid quantifications
- Name of product
- Strength
- Concentration
- Weight or measure of each THC product for each batch size
- List of ingredients used and amounts
- The identity and measurement of THC levels in product that will be declared on the label
- Description of the packaging

2.14.2 Work instruction must be documented and implemented at each processing step requiring quality control to be monitored to ensure quality of the cannabis product and labeling accuracy.
2.14.3 Appropriate quality control operations must be employed to ensure that food is suitable for human consumption and that product-packaging materials are safe and suitable.

2.15 Edible Cannabis product production (n/a for Cannabis Concentrate/Oils)

2.15.1 Food that can support the rapid growth of undesirable microorganisms must be held at temperatures that will prevent the food from becoming adulterated during manufacturing, processing, packing, and holding.
2.15.2 Measures such as sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or controlling aw that are taken to destroy or prevent the growth of undesirable microorganisms must be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated.
2.15.3 Heat blanching, when required in the preparation of food capable of supporting microbial growth, must reach the appropriate temperature and holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Growth and contamination by thermophilic microorganisms in blanchers must be minimized by the use of adequate operating temperatures and by periodic cleaning and sanitizing as necessary.
2.15.4 Food, such as dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies principally on the control of water activity (aw) for preventing the growth of undesirable microorganisms must be processed to and maintained at a safe moisture level.

2.15.5 Food, such as acidic and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms must be monitored and maintained at a pH compliant with 21 § CFR 114.
2.15.6 When ice is used in contact with food, it must be made from water that is safe and of adequate sanitary quality in accordance with FDA cGMP § 117.37(a), and must be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.

2.16 Cosmetic Product(s) with active THC

2.16.1 There must be a product stability program in place.
2.16.2 The product stability program must include the conditions of use and storage through the expected use/shelf life of the product.
2.16.3 The concentration of active ingredient(s) must be demonstrated to meet the label declaration through the expected use/shelf life of the product.
2.16.4 The products may contain antimicrobial preservatives.
2.16.5 The efficacy of the preservative system must be demonstrated.
2.16.6 The effectiveness of the preservative system must be demonstrated through the expected conditions of use and storage through the expected shelf life of the product.

2.17 Foreign Material Controls

2.17.1 Adequate measures must be taken to protect against the inclusion of metal or other extraneous material in food.
2.17.2 There must be a program in place to manage glass and brittle plastic. A glass breakage procedure must be documented.
2.17.3 Sieves, filters, screens and magnets must be used where appropriate and properly managed and maintained.
2.17.4 Metal detection systems, where they have been determined by the facility's risk assessment to be required for food safety or quality control reasons must be properly managed and calibrated.
2.17.5 Blade and wood (where used) must be controlled and inspected.

2.18 Warehouse, Receiving and Distribution

2.18.1 There must be a written procedure for the inspection of delivery vehicles. This will also apply to receiving and shipping. Procedures must define when carriers are to be rejected.
2.18.2 There must be a written procedure for the inspection and receipt of ingredients, raw materials, and packaging.
2.18.3 Raw materials, ingredients, packaging and finished product must be stored separate, secure and protected in storage.
2.18.4 Storage temperatures must be controlled and monitored.
2.18.5 Storage and transportation of food must be under conditions that will protect against allergen cross-contact and against biological, chemical (including radiological), and physical contamination of the product, as well as against deterioration of the product and the container.
2.18.6 Refrigerated and/or frozen truck temperatures must be monitored prior to loading and unloading. Record of these temperatures must be kept.